

# Documents Testing

## Documents Emails Submissions

Selected material has been published at the Chair's discretion: further information is in the Review Method. Published material represents the views of the authors/speakers, and not the views of the Review. The findings of the Review are contained in the report.



The Independent Covid Review  
Isle of Man

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## **Isle of Man COVID-19 Testing and Surveillance Strategy Working Group**

**Purpose:** The COVID-19 Testing and Surveillance Strategy Working Group is a task and finish group providing professional and technical appraisal of evidence relevant to COVID-19 testing and surveillance and assessment of options for implementation in the Isle of Man. The group will function for the duration required to support the response to COVID-19 on Island.

**Objectives:** The Working Group will

- Identify and review relevant published evidence from Public Health Agencies (including Public Health England, European Centre for Disease Control and the World Health Organisation) and peer reviewed professional journals
- Keep up to date with best practice in the UK through professional links with the North West Microbiology Network, laboratory scientist networks, Public Health England, Association of Directors of Public Health and the Chief Medical Officer
- Monitor test results from the current IoM testing and surveillance programmes and recommend changes to existing programmes and establishment of new programmes in line with the emerging evidence sourced as above

### **Role and responsibilities**

The Group will provide advice to the Isle of Man Government on strategic developments for COVID-19 testing and surveillance.

The Group is not a decision making body and does not have responsibility for the delivery of any testing or surveillance programmes agreed by Government. The Group does not hold a budget to cover any additional costs required for the development of existing or future testing and surveillance programmes.

### **Stakeholders:**

All Government Departments through COVID Gold Command

DHSC: through Senior Clinical and Public Health Advisory Group and DHSC Bronze/Silver/Executive Groups

### **Reporting:**

To CoMin for consideration of recommendations finalised with stakeholders

### **Membership:**

**Expertise required:** microbiology, laboratory scientist, Public Health Health Protection

**Members:** Dr Rizwan Khan (consultant Microbiologist), Steve Doyle (pathology manager), Dr Henrietta Ewart (Director of Public Health), Jacqui Dunn/Debra Ashmole (Health Protection Nurse)

Additional expertise will be included through co-option as required (for example, Consultant in Occupational Health to assess essential worker testing pathways)

**Frequency of meetings:** fortnightly or more often as required

## SARS-CoV-2 testing on the Isle of Man

### The next steps

The Pathology department is continuously exploring new methods for future diagnostic testing of SARS-CoV-2 with two technologies worthy of mention at this time:

Detection of Variants of Concern, (Viasure SARS-CoV-2 Variant Kits: Pro-Lab Diagnostics)

High Throughput Antigen Testing (Roche Elecsys Antigen Assay)

### Detection of Variants of Concern

VIASURE SARS-CoV-2 Variant PCR Detection Kit is a real-time RT-PCR test designed for the qualitative detection of RNA from genetic mutations in the S gene (E484K, K417N, K417T and N501Y) from positive SARS-CoV-2 clinical samples.

The presence of the E484K mutation in the S gene has been first detected in the following lineages: B.1.1.28.1 (Brazilian Variant), B.1.1.33 (Brazilian), B.1.351 (South African Variant), B.1.525 (Nigerian Variant), the presence of the K417T mutation in the S gene in the lineage B.1.1.28.1, the presence of the K417N mutation in the S gene in the lineage B.1.351 and the presence of the N501Y mutation in the S gene in the following lineages: B.1.1.28.1, B.1.1.7 (Kent Variant), B.1.351.

The test is a multiplex that can detect all four genetic mutations in real time, and by interpretation of the mutations present, the variant of concern can be presumptively identified, (final assignment to a lineage must be done by sequencing).

The kit is not CE marked at the moment, (undergoing validation work at PHE labs) and should be available sometime in late May at approximately £11 per test. Additionally, and due to the on-going verification process, there has been insufficient data to assess sensitivity / specificity.

The intention would be to re-test all positive swabs with the variant kit to inform increased isolation rules until confirmatory sequencing is carried out.

Viasure are already working on targets for the emerging Indian variant and future mutations will hopefully be targeted in the same way.

### Antigen Testing

Roche Cobas Elecsys SARS-CoV-2 Antigen is an immunoassay for the in vitro qualitative detection of the nucleocapsid antigen of SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples.

Unlike RT-PCR which amplifies and detects the viral RNA, antigens (viral proteins) are only expressed when the virus is actively replicating, thus making antigen tests clinically useful for identification of acute or early infection.

Current research suggests active replication of SARS-CoV-2 in the throat with high viral shedding in the first 5 days of infection, and infectious virus could be isolated from respiratory samples up to the first 7-9 days post symptom onset, indicating potential feasibility of antigen detection using throat swabs. This time period also coincides with the time when the highest viral load is generally observed in SARS-CoV-2-infected individuals. Therefore, the best performance of antigen tests is seen around symptom onset in symptomatic individuals and the initial phase of a SARS-CoV-2 infection.

In common with most antigen tests (including LFDs) sensitivity is much better at lower CT values (and thus higher viral loads). The Elecsys tests offers 94.5% sensitivity at a CT <30. Specificity is reported to be 99.9%.

As this test would be run in the main Clinical Chemistry department, work will be required on pre-analytical considerations around sample inactivation / workflow and staff resource. Further discussions will be taking place with Roche on Wednesday 28<sup>th</sup> April.

Indicative reagent costs are £4.15 per test and results are available within minutes.

### **Lateral Flow Devices (LFDs)**

Please refer to the previous paper by the testing group.

We are in discussion with DHSC colleagues in the UK to see if we can obtain an allocation of these. Cost, numbers and supplier are unknown at the point although Innova are the main manufacturer used in England. Indicative prices are in the £8-£10 range but it remains to be seen if we can secure centrally FoC.

Currently, there are 19 LFDs that have passed phase 3c validation by the DHSC:

<https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/outcome-of-the-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices>

**Emergency Advisory Group  
Advice Note**

**Lateral Flow tests and PCR tests  
29 July 2021**

**Introduction**

The Council of Ministers requested that the EAG consider the merits or otherwise of Lateral Flow antigen testing for Covid under certain circumstances through the use of Lateral Flow Tests (LFTs) compared to the use of Polymerase Chain Reaction (PCR) tests in all situations. The paper requesting this advice is attached at Annex 1.

The EAG notes that given the current numbers of Covid cases in the community, the use of PCR tests in all cases is no longer practical or achievable given the capacity of on-Island testing.

The EAG further notes that the Council of Ministers has already introduced the use of LFTs for the day 6 release test on the border entry pathway.

**Advice**

1. The EAG draws the Council of Ministers' attention to the fact that LFTs are not undertaken in laboratory conditions and while there are risks related to false positives, there are also greater risks in relation to false negatives.
2. The EAG therefore advises that clear and easy to follow guidance for users is vital in ensuring the best use of LFTs in testing for Covid-19.
3. For the reasons described above, the EAG would also not support the use of an LFT testing regime that is less than daily for seven days if identified as a close contact.
4. The EAG urges CoMIN to increase publicity of the online reporting feature for LFTs and to promote its use widely in an effort to increase the data available to it for decision making purposes. Linked to this, the EAG advises CoMIN to start including the breakdown of LFT versus PCR tests in respect of positive cases reported on the Government's Covid dashboard.
5. The EAG advises CoMIN that it must increase the supply of LFTs significantly. The EAG believes the current supply model is not sustainable and urges CoMIN to consider a more frictionless distribution model to allow people to obtain LFTs more easily. This could include through the postal service or in workplaces, for example.
6. Linked to the above, the EAG notes the concern raised by many businesses on the issues caused by isolation of their staff, particularly in smaller businesses. The EAG believes clearer guidance is needed for small or medium enterprises in when staff can work and when they cannot, and how businesses can use LFTs to protect their staff, customers and revenues. The EAG would advise CoMIN to require the Department for Enterprise to provide such targeted guidance as soon as possible, working in conjunction with the Chamber of Commerce.
7. In respect of businesses or services which are critical to the Isle of Man's daily operation, the EAG notes that the UK has taken steps to identify alternative pathways to isolation for certain key workers. The EAG's advice is that CoMIN should undertake a prioritisation

exercise to identify key businesses which are critical to the Island's national infrastructure. This would then enable CoMIN to set policies where such businesses (or public sector services) are given priority access to LFTs or return to work pathways.

8. Finally, the EAG advises that the Council of Ministers should ensure it has a robust, clear and well communicated plan for the return of children to school in September which includes the use of LFTs to give confidence to students, teachers and parents in respect of controlling the spread of Covid-19 in educational settings.

Whilst we hope that the above is self-explanatory, the EAG is happy to engage in discussion or further clarification, if required.

### **Emergency Advisory Group July 2021**

#### **About the Emergency Advisory Group**

The Emergency Advisory Group is a committee, appointed by the Council of Ministers, consisting of a range of people from across the community with a broad range of skills and expertise. Its primary role is to consider matters referred to it by CoMIN and provide independent advice and analysis. All its members are unpaid volunteers.

The current membership is:

Hon Graham Cregeen, MHK	Minister for Justice and Home Affairs (Vice Chair)
Rob Mercer, MLC	Tynwald representative
Mrs Jacqueline Bridson	
Mr Steven Christian	
Mr Peter Davidson	
Professor Peter Edge	
Dr Rachel Glover	
Ms Julie Hotchkiss	
Mr John Spellman	Chair
Mr Jonathan Wild	

**Council of Ministers Paper No. 2020/234**

**Paper for Council of Ministers  
Routine Business**

<b>Department/Board/Office</b>	<b>DHSC</b>
<b>Chief Officer</b>	<b>Kathryn Magson</b>
<b>Responsible Officers</b>	<b>Kathryn Magson</b>
<b>Cut ups to be sent to</b>	<b>Kathryn Magson, Will Greenhow, Dr Henrietta Ewart, Steve Doyle and Dr Rizwan Khan</b>
<b>Date of Council Meeting</b>	<b>28<sup>th</sup> May 2020</b>

<b>Title</b>	<b>Antibody Rollout Testing Plan</b>
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<b>Collective Responsibility: (Mandatory field, please choose an option)</b>	Which of the 3 Government Strategic Objectives does this proposal comply with?	Which of the Council of Ministers Sub-Committees has considered this proposal?	The proposal relates only to the Department's core or statutory responsibilities
<b>Matter of National Importance</b>	Inclusive, Caring Society	Not applicable	Core

Has appropriate internal and/or public consultation taken place?	Not applicable
Are there any resource/personnel implications?	Yes
Has Treasury concurrence been obtained where necessary?	Not applicable
Is the Department acting within its legal powers or has legal advice been obtained? (If yes confirm and provide evidence within the paper)	Yes
Are there any inter-Departmental implications?	No
If yes, which other Departments are involved?	CABO
What is the intention of this paper?	Seek Approval
<b>Primary Legislation:</b> Has Council Legislation Subcommittee approved the inclusion of the proposed Bill on the Legislative Programme. If Yes please give decision date:	No
<b>Major Policy Proposal/Primary Legislation:</b> Have you completed an Impact Assessment? If yes please attach a copy as an Appendix to the paper.	No
Have you taken appropriate Corporate Communications Service advice?	Yes
Does this initiative/announcement have a communications plan?	Yes
<b>Purpose of the Paper: To provide a roll out plan for antibody testing for the first 5,000 tests.</b>	

**Collective Responsibility:**

This is a matter of National Importance as part of the response to the COVID-19 pandemic.



## **1. Background**

The Isle of Man response to the COVID-19 pandemic includes a comprehensive range of testing methodologies and strategies including real time PCR and rapid PCR that indicates whether an individual is currently infected with the virus. The strategies around these tests are continually evolving and include clinically indicated testing, surveillance testing (all patients admitted to Noble's), enhanced testing for essential workers, discharge / transfer testing and increased screening for residential care homes.

Whilst these tests can give us a real time diagnostic snapshot of a patient who currently has COVID-19, we now need to expand our protocol to examine how many people on the Isle of Man have previously had the disease through the means of antibody testing. We now have a validated antibody test which has been procured for use on Island. The test requires a venous blood sample. At present, it is not known whether the presence of detectable antibodies to COVID-19 confers immunity to further infection and, even if it does, how long that immunity would last. This means that having an antibody test will tell the individual that they had the infection in the past and mounted an immune response to it. It will not give them any information that could be used to support future decisions around, for example, work or travel. Specifically, a positive antibody response is in no way an 'immunity passport'. It is important that people understand this as part of the process of consenting to have blood taken for antibody testing.

Measuring antibody levels across the population is a valuable epidemiological tool to tell us how far COVID-19 has spread on Island. It will give us information about asymptomatic cases to set alongside the evidence of symptomatic infections we have from the PCR testing programmes. This document sets out a proposal for offering antibody testing as an additional test when people are already attending for a blood test or for blood donation. The groups set out below should give an appropriate mix of age, gender, place of residence and health status to be representative of our population. We propose to use the first 5,000 tests on order (which have a shelf life through to late July) to undertake preliminary testing as described. This will be based on a single test on individuals in the groups below. The results will then be reviewed and options generated for the next phase of testing which will consider whether wider testing is required and also whether serial testing to monitor change in antibody status over time would be appropriate.

### **Antibody Tests**

Unlike PCR testing, which looks for the genetic material of the SARS-CoV-2 virus itself, antibody tests are designed to detect antibodies produced by the body in response to the pathogen.

The host immune system reacts to infection by producing antibodies from a few days to 2 weeks after the onset of symptoms. IgM is one of the first antibodies to be produced and is seen as the vanguard immunoglobulin allowing for binding of multiple antigens and rapid clearing of the infection. It is short lived and non-specific. IgG appears later in infection and is typically longer lasting and much more specific. With

many infections, IgG will afford some protection against re-infection with the same Pathogen but this varies in effectiveness and duration.

**It must be emphasised that there is no evidence that IgG detection will assure any immunity against COVID-19.**

Antibody tests have been available for many weeks in the form of lateral flow kits (finger prick type tests). These have all proven to have low sensitivity / specificity and although purchased in their millions by many jurisdictions, their use is questionable.

The Isle of Man testing strategy has always considered antibody testing, but we have resisted using lateral flow types of kit until other, verified solutions became available.

On the 15<sup>th</sup> May, Public Health England validated for use antibody tests produced by Roche and Abbott. The IOM had to move quickly as all tests are scheduled to be on allocation only (rationed) by NHS England and we managed to procure 10,000 tests from Abbott (analyser already used within Pathology). We have purchased in two batches, the first have an expiry on the 24th July, the second 5,000 will be despatched at a future date and will have a later expiry. The serology tests to be offered at Noble's targets the longer-lasting, highly specific IgG antibodies and not the shorter acting, less specific IgM isotype.

Funding has been provided by Henry Bloom Noble's Trust for 10,000 tests.

## 2. Strategy

### Estimated levels

To determine sample size to give a specified accuracy of result we need an idea of the likely prevalence of positive tests. Limited studies have already taken place in other countries using the less accurate lateral flow tests which have given prevalence results ranging from 2%-20%. New York State, one of the worst hit areas globally, have tested and found an overall prevalence of 12.3% in the state and 19.9% in the city. Their fatality rate has been about 4 times the IOM, and it is therefore reasonable to assume prevalence on the Isle of Man of 3% or possibly less, given our fatalities are mostly in one cluster. Our proven positive rate is only 0.4% of the population and this, combined with the assumption that we may have identified only a proportion of cases due to asymptomatic carriage, mildly symptomatic patients not reporting to 111, false negatives due to timing of swabs, and swabbing inaccuracies fits with an estimate of likely IgG prevalence here in the low single figures.

### Sample sizing

Based on a predicted 3% positivity rate, confidence intervals with various sample sizes are:

- 95% CI 0% - 6% sample size 149
- 95% CI 2% - 4% sample size 1212
- 95% CI 2.5% - 3.5% sample size 467

### 3. Roll out plan

Ideally, a formal population study would be designed and implemented. However, this will take time to model and approve with significant extra resources required. Recruitment of a test population reflecting the geographical and demographic of the population would be needed. Volunteer identification, contacting, allocation, consent, research ethics, sample collection, informatics and result reporting would all take time and resource. This is not something that we could achieve without significant delay.

Due to the time and resource constraints at the moment it is proposed by the working group with support from the CPHLT that the first 5,000 tests are used in a cross sectional point prevalence study whereby antibody tests are, in the main, piggy backed onto existing tests, whilst we endeavour to design a more robust study in the near future using the other scheduled 5,000 kits. This will employ a combination of sampling strategies in order to reduce statistical bias.

A review of the first phase will be undertaken in order to call off the second 5,000 tests and the plan presented to COMin.

#### **Groups suggested for testing: (volumes at 50% to reflect consent requirements)**

1. All hospital attendees through the ED department that are already having blood tests (500)
2. Blood test referrals (GP and hospital outpatients including paediatrics – 2500)
3. Contacts of confirmed cases (close contacts/high risk contacts - 500)
4. Confirmed positives ( 40 days post confirmation - 300)
5. Blood donors - 100
6. A sample of negatively tested 111 callers - since the prevalence in this group is likely to be higher than the general population a smaller sample is likely to give tighter confidence intervals than generally; 400 would be a reasonable test target (about 10% of the negatives)
7. Healthcare workers (including Primary Care and Communities - 600)
8. Antenatal patients undergoing routine blood tests – 100

#### ***Recommendation : To approve the rollout of antibody testing line with the groups listed above.***

Most of these are readily achievable with others requiring minimal administrative and logistical support. These groups could be combined and analysed to give useful data about the general prevalence of COVID-19 on the Isle of Man.

Patient consent would need to be obtained but this can be simply achieved at point of test through an informational leaflet.

Patients will be advised of the outcome of their result.

Although the tests have arrived on the Island, the calibrators are still in transit which are needed in order to begin. Subject to receipt of all the required consumables we could start testing in the early part of next week.

## **6.0 Recommendations**

**Council is invited to approve the roll out of antibody testing with the groups listed above in line with the Clinical and Public Health Advisory Group approach, supported by bronze and silver command structure within DHSC.**

Kathryn E Magson  
Interim Chief Executive  
27th May 2020

# Preliminary results on COVID-19 antibody testing on the Isle of Man

This report should be viewed as preliminary and subject to revision once additional data checking and analysis have been conducted. It is important to note that the testing completed on the Isle of Man was not part of an epidemiological study and the initial testing strategy of 5,000 tests has not been yet been completed. This report does not provide any conclusions and is a statement of the current results so far.

After completion of the initial testing strategy we recommend that a formal population study should be designed and implemented which will require time to model and significant resource implications. Recruitment of a test population reflecting the geographical and demographic of the population would be needed. Volunteer identification, contacting, allocation, consent, research ethics, sample collection, informatics and result reporting would all take time and resource.

## Background

In early 2020 it was announced that a novel beta-coronavirus designated 'severe acute respiratory syndrome coronavirus 2' (SARS-CoV-2) had been responsible for a cluster of pneumonia cases of previously unknown aetiology in the Chinese city of Wuhan<sup>1</sup>. Although this virus was initially named '2019 novel coronavirus' (2019-nCoV), it is the SARS-CoV-2 nomenclature that has been adopted by the World Health Organization (WHO), with the resultant syndrome being referred to as COVID-19.

This virus quickly spread across the world, prompting WHO to declare a pandemic status on 11th March 2020. Clinical features include fever, cough or chest tightness, myalgia, fatigue and dyspnoea, with a variety of abnormalities on chest radiographs similar to that seen with other types of viral pneumonias.

At the commencement of testing for this virus on the Isle of Man, the analysis gold standard of genetic detection via Real Time Polymerase Chain Reaction (PCR) was adopted, with samples sent away to the Public Health England (PHE) reference laboratory in Manchester for analysis. Currently, in-house genetic detection of the virus is being utilised.

At this time, it is not known whether the presence of detectable antibodies to COVID-19 confers immunity to further infection and if it does, how long that immunity would last. This means that having an antibody test will tell the individual that they had the infection in the past and have mounted an immune response to it. It will not give them any information that could be used to support future decisions around, for example, work or travel. Specifically, a positive antibody response is in no way an 'immunity passport'.

## Details of Test

On the 15th May, Public Health England validated for use a chemiluminescent microparticle assay tests produced by Abbott Laboratories (Architect i200SR) to detect IgG antibodies against the nucleocapsid protein of the SARs-CoV-2 virus. This assay has a reported sensitivity of 93.9% (21 days post symptom onset) and specificity of 99.7%. (For further details on testing please see appendix 1)

As of the 10th July 2020, 3,892 antibody tests had been completed. These consisted of the following categories (33 individuals were classified in more than one group):

Group	Number tested	Av Age	Antibody Pos	Antibody Neg	% Pos	95% Confidence Limit
HCWs	2,171	47	57	2,114	2.6%	2.0%-3.3%
GP Patients/ Donors	965	58	20	945	2.1%	1.3%-3.9%
Known PCR positive	210	48	156	54	74.3%	69%-80%
Known PCR negative	427	46	17	410	4.0%	2.3%-5.9%
Close contacts	152	41	22	130	14.5%	9.2%-20.0%

# Results

## **Patients previously tested positive by rt-pcr for COVID-19**

210 known positive patients were tested up to the 10th July and 156 (74%) demonstrated IgG antibodies to SARS-CoV-2. The average time between the PCR swab and the antibody test was 69 days which possibly indicates that some patients may have had an antibody response earlier in their recovery which might have waned. There is evidence that individuals that only develop modest nAb titres post infection, the levels become undetectable after ~50 days. However, looking closely at the raw data from the analysers, it is considered more likely that a proportion of patients do not elicit an IgG response which is in line with results from similar studies carried out in other jurisdictions.

## **Patients previously tested negative by rt-pcr for COVID-19**

427 patients were tested and 17 (4%) demonstrated IgG antibodies to SARS-CoV-2. It could be that these were false negatives due to technical error, inadequate swabbing or that the timings of samples did not coincide with patient viral shedding.

## **Individuals at low risk for COVID-19**

Samples were tested from GP patients undergoing other blood tests (n=752), patients at Nobles undergoing other blood tests (n =58) and consenting blood donors (n=155). Of these 965 individuals, 20 (2.1%) demonstrated IgG antibodies to SARS-CoV-2.

The average age was 54yrs with 390 males and 575 females.

## **Healthcare and essential workers**

Samples were collected from 2,171 Government employees of which 2,123 identified as Healthcare workers with 57 (2.6%) demonstrating IgG antibodies to SARS-CoV-2. Of these employees, 2,133 had no previous testing during the outbreak resulting in 31 positive tests (1.5%) whereas 9 had swabbed negative for COVID-19 (antibodies demonstrated in 6) and 29 had swabbed positive for COVID-19 (antibodies demonstrated in 19). Of these 38 employees that were previously tested with positive PCR, positive antibodies or both, 18 were from one care home on the Island.

It is clear that healthcare workers per se have not been exposed to the Coronavirus to any greater extent than the general population which could be reflective of good hand hygiene and PPE use during the pandemic.

## **Close contacts**

Samples were collected from 152 individuals identified by the Public Health Track and Tracing team as close contacts of a known COVID-19 patient or self-identified as a family member of a COVID-19 patient. Of these, 22 (14.5%) demonstrated IgG antibodies to SARS-CoV-2. Of these contacts, 138 had no previous testing during the outbreak resulting in 13 positive antibody tests (9.4%). 14 had previously been swabbed with a primary clinical indicator of being a close contact with 10 of these being diagnosed with COVID-19 during the outbreak.

18 samples were received with no clinical details.

## Summary Status

The average age of individuals tested was 48 years (range = 10-96) with 2691 females and 1201 males. This is likely to be due to the large number of health care workers tested at this stage which also explains the low average age.

In conclusion, and after removing the previously known positives (PCR), the underlying rate on the Isle of Man seems to be about 2.1%.

Factoring in the PCR positives as a percentage of the total population we estimate that population prevalence rate of SARS-CoV-2 antibodies on the Isle of Man is:

2.5% ± 0.5% (95% confidence interval)

The estimated prevalence rate implies that the total number of cases of SARS-CoV-2 that have occurred on the Isle of Man is between 1,680 and 2,520 to date (population estimated at 84,000).

It is acknowledged that these figures, being derived from multiple patient and worker groups, are statistically biased to some extent but it also holds that they will give some insight to the estimated spread of COVID-19 on the IOM.



## Appendix 1

The patient sample, SARS-CoV-2 antigen-coated paramagnetic microparticles and assay diluent are combined and incubated. IgG antibodies present in the patient sample bind to the antigen coated microparticles. The mixture is washed. Anti-human IgG acridinium-labelled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

- The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of IgG antibodies to SARS-CoV-2 in the sample and the RLU detected by the system optics.
- This relationship is reflected in the calculated Index (S/C). The presence or absence of IgG antibodies to SARS-CoV-2 in the sample is determined by comparing the chemiluminescent RLU in the reaction to the calibrator RLU.

The ARCHITECT i System calculates the calibrator mean chemiluminescent signal from 3 calibrator replicates and stores the result. Results are reported by dividing the sample result by the stored calibrator result. The default result unit for the SARS-CoV-2 IgG assay is Index (S/C). The cut off is 1.4 Index (S/C).

The manufacturer limitations of the assay are:

Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E, have not been evaluated with this assay. In a population of patients with non-COVID-19 respiratory illnesses, no cross-reactivity has been observed.

Not to be used to screen units of blood for SARS-CoV-2 infection.

Immunocompromised patients who have COVID-19 may have a delayed antibody response and produce levels of antibody which may not be detected as positive by the assay.

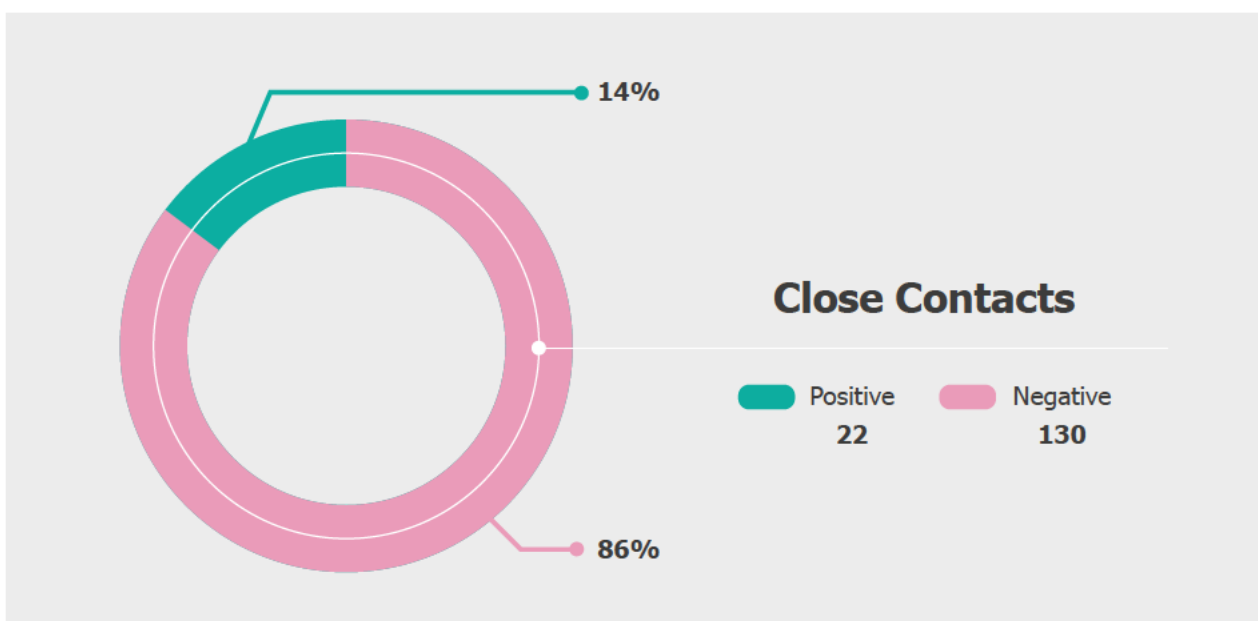
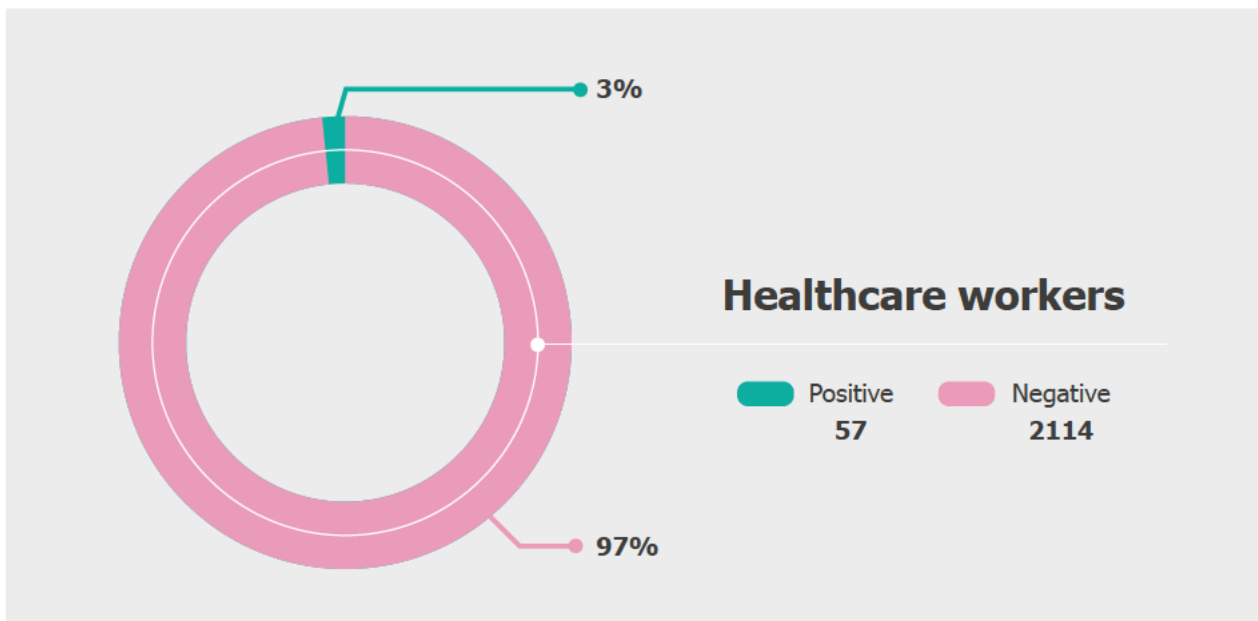
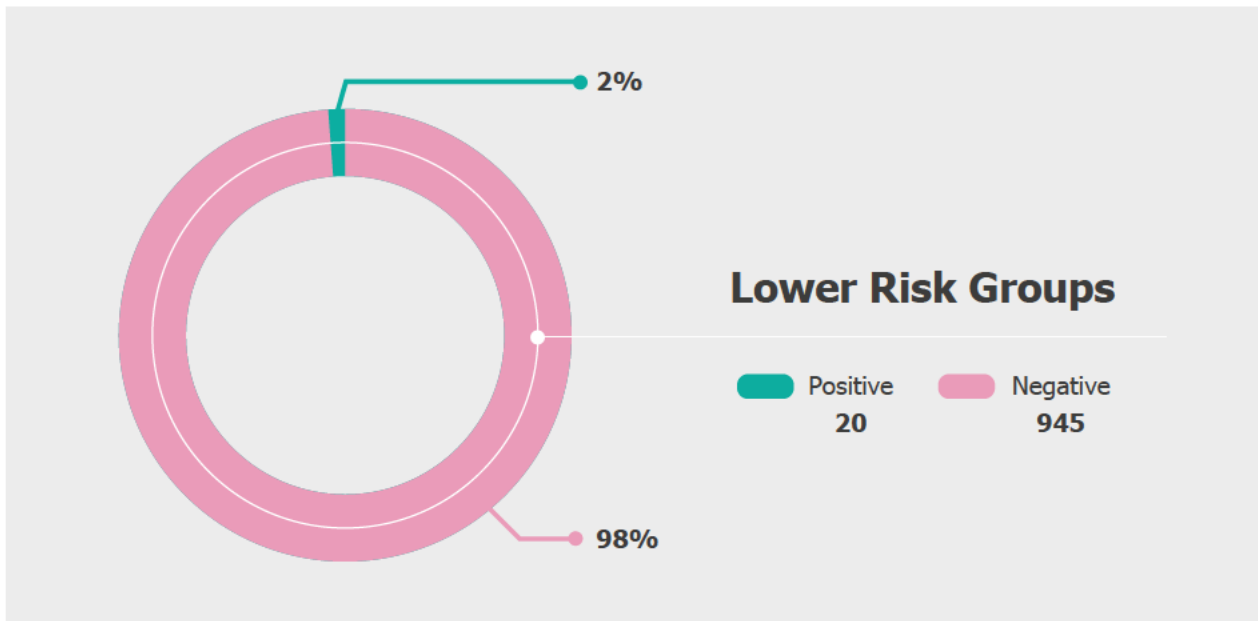
Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits such as SARS-CoV-2 IgG that employ mouse monoclonal antibodies.

Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed.

Rheumatoid factor (RF) in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays.

To estimate the negative percentage agreement (NPA), 100 serum specimens from subjects assumed to be negative for SARS-CoV-2 were tested. These samples were anonymised and stored samples from blood donors collected prior to August 2019 (pre-COVID-19 outbreak). All samples tested negative for IgG SARS-COV-2 antibodies and therefore reflects the manufacturer's claims around specificity.

## Appendix 2



could be reserved for PHE testing, while more abundant buccal-style swabs could be used for on-Island testing.

### Changes which need to be made immediately

- **Dual swabbing to be implemented by close of play Tuesday 24<sup>th</sup> March to allow on-Island testing to proceed in parallel to PHE testing.** The validation carried out so far strongly suggests that on-Island testing can use dry cotton swabs rather than swabs with viral transport media. The dual swabbing is required to further validate this and there is no time to waste on operational implementation.

### Current challenges

- Speed of deliveries of reagents to the Island. There is little we can do to mitigate this apart from ordering as soon as decisions are made.

### Tasks and timelines

Tasks to be completed	
In the next 48 hours	<ul style="list-style-type: none"> <li>• Chris Helm to contact PHE and request details of their assay (primers, probes, concentrations, cycling conditions).</li> <li>• Arrival of the initial VIASURE Covid kit and ABI manufacturer's validation plate</li> <li>• Validation of the 7500 real-time PCR machine with the manufacturer's validation plate</li> </ul>
In the next 3-5 days	<ul style="list-style-type: none"> <li>• Rachel Glover to set up an initial protocol document for RNA isolation and real-time PCR assays</li> <li>• Freezer storage of second (cotton) swabs from patients.</li> <li>• Rachel Glover to order PHE assay primers and probes</li> <li>• <u>The first viral genome from a positive patient?</u></li> </ul>
In the next fortnight	<ul style="list-style-type: none"> <li>• Begin testing in parallel with all samples sent to PHE</li> <li>• Rapid "interim" results service for critical cases</li> <li>• Comparative analysis of PHE and on-Island tests</li> <li>• Preparation for wider roll-out and increase in number of tests to the thousands per week</li> </ul>

## Appendix I: Detailed challenges and solutions

**Challenge:** PHE testing requires a swab with viral transport media to preserve the swab for travel to Manchester. While we can remove a small amount of this media for dual testing, early testing on-Island has shown the volume may be too small to provide robust molecular results.

**Solution:** A dual swabbing approach should be implemented as soon as possible. The first swab should be the viral transport media swab currently in use. The second swab – taken at the same time - should be a normal cotton swab (plastic stick) which will be used exclusively for on-Island SARS-Cov-2 testing only.

**Details:** Early validation experiments for RNA isolation on-Island have shown that the 100ul viral transport media which we could remove from swabs being sent to PHE may not be adequate for robust detection of SARS-Cov-2. Further validation will occur once the VIASURE SARS-Cov-2 kit and RNaseP human control kit arrive but there is no time to waste in implementing a dual swabbing approach.

**Challenge:** The VIASURE SARS-Cov-2 kit preferred by the DHSC due to its CE marking does not include a human RNA isolation control, which could lead to false negative results.

**Solution:** Inclusion of a human RNA isolation control test step prior to SARS-Cov-2 testing. Transfer to using one of the international testing protocols (preferably PHE) as testing proceeds to further increase efficiency and reduce costs.

**Details:** The lack of a human RNA extraction control may result in false negative results due to RNA isolation failure being interpreted as a negative result. A false negative result is the worst case scenario for such a small community and must be avoided. When RNA is isolated from a swab it will contain both human and (potentially) viral RNA. By including a human RNA test alongside the viral test it makes sure that the RNA isolation was successful. The results can then be interpreted correctly and sampling/testing repeated as required to ensure accuracy. In the absence of a multiplex human/viral test running a human RNA isolation control prior to SARS-Cov-2 testing with the VIASURE kit will negate this in the short term. Validation of a multiplex human/viral test should be considered a priority and preferably we should contact PHE for a copy of their protocol. We should include a human RNA isolation control as false negative results would be unacceptable in such a small community. The ABI RNaseP assay can be run prior to Covid testing in the interim until a multiplex assay is sourced. While a CE mark is beneficial for assuring routine biomedical testing, the current SARS-Cov-2 is not a routine situation and the molecular tests being carried out by other countries (including the UK) are not CE marked. The reality is that all DNA tests developed for SARS-Cov-2 were designed and validated within the last 12 weeks. All of the DNA tests currently being used by major countries are listed on the WHO laboratory technical guidance<sup>1</sup>.

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<sup>1</sup> <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>

**Challenge:** Lack of staff trained in molecular biology theory and techniques

**Solution:** Once a protocol is finalised at least 8 DHSC staff will need to be trained in the theory, reagents and equipment used to carry out testing.

**Details:** Reliance on a small number of staff would be a significant risk to testing turnaround given the potential for staff illness, holidays and shift patterns. Should the amount of testing increase rapidly an alternative shift system may need to be operated to ensure turnaround times.

**Challenge:** Real-time PCR capacity is capped at up to 96 tests per four hours.

**Solution:** Additional real-time PCR capability will be ready at Taxa Genomics Limited by the end of March. This would double capacity.

**Details:** Once prepared and ready to be tested the ABI 7500 real-time PCR machine takes around 2-2.5hrs to complete the thermocycling on a reverse-transcriptase real-time PCR. This means that a theoretical maximum of the DHSC machine in a 24 hour period is 9 runs (~800 samples per day). If additional tests were prepared fully at the DHSC category 2 laboratory and transported for running on the machine at Taxa Genomics, capacity could be doubled to ~1600 tests per day. The Taxa Genomics real-time PCR machine is due to be operationally ready by the end of March.

# Isle of Man Response to the COVID-19 Pandemic: Proposals for Testing and Surveillance Strategy

For consideration by the Clinical and Public Health Leadership Team (CPHLT) on 27 April 2020

CPHLT is asked to consider the recommendations below and amend/approve for progression to DHSC Bronze.

## Summary

This paper has been drafted for consideration through the DHSC Pandemic Response Command structure by the COVID-19 Testing and Surveillance Strategy Working Group. It will be presented to the Clinical and Public Health Leadership Team on 27 April 2020.

The paper sets out the objectives of COVID-19 testing and surveillance as part of the overall response to the COVID-19 pandemic. It summarises testing and surveillance programmes that are currently being delivered on Island, programmes that are already in the planning and implementation phase, programmes that could be considered for planning and implementation based on current evidence and programmes for which the Testing and Surveillance Strategy Working Group considers there is currently inadequate evidence and/or planning is at too early a stage to plan delivery on Island at present. The Working Group will keep these proposals under review, as well as continue to horizon scan for further developments, and will bring these through the DHSC Command structure for consideration for inclusion in the testing and surveillance strategy as the evidence matures.

## Summary of recommendations

### Programmes in place that should continue:

1. **Clinical testing** – continue current approach of testing all individuals presenting with symptoms meeting the current clinical case definition for COVID-19
2. **Surveillance testing** – continue current approach of sentinel surveillance testing of all non-COVID-19 patients admitted to hospital.

### Programmes currently in the planning and implementation phase that should continue:

1. **Enhanced testing for health and care and other key workers (symptomatic, first test negative)** – to enable rapid return to work if a symptomatic worker, or a symptomatic member of their household, has two negative test results.
2. **Enhanced testing for health and care and other key workers (COVID-19 positive)** – two negative tests to confirm appropriateness for return to work after 14 days self-isolation for workers confirmed COVID-19 positive.

### New programmes that should be considered now

1. **Enhanced testing in residential care settings** – screening tests for all residents and staff following confirmation of a confirmed positive index case.

- 2. Discharge planning prior to transfer to residential care** – confirmation of recovery through two negative tests in COVID-19 positive patients prior to discharge from hospital to a residential care setting. Programme would also include confirmation of recovery as above for patients with mild symptoms who have been self-isolating at home prior to transfer to residential care.
- 3. Pre-admission and pre-transfer testing for asymptomatic people prior to admission to residential care from the community or transfer between residential facilities** – a single negative test would be required before admission or transfer.

#### **Enhanced testing where further evidence is required before local progression**

- 1. Routine screening/testing for health and care workers and other key workers**
- 2. Extended community surveillance** – e.g. ‘one-off, snap shot’ assessment of current levels and distribution of infection (cf Iceland model) or serial testing of a population cohort (cf planned UK programme).
- 3. Routine testing after death (for all decedents, testing is already done as part of post-mortem/autopsy examination)**

#### **Further programmes on the horizon**

- 1. Antibody testing to confirm ‘who has been infected’ via a community sampling programme** – no antibody test has yet been validated as fit for purpose.
- 2. IoM participation in the Public Health England/UK Overseas Territories/Crown Dependencies Proposal for Serum Storage for Serology and Genomics** – this is at the developmental stage. The Working Group have confirmed interest in participation to PHE.

## **Background**

The Isle of Man response to the COVID-19 pandemic is built on a comprehensive range of community measures to reduce transmission of the virus, work to strengthen capacity and resilience of health and care services, information for and engagement with the public and comprehensive testing and contact tracing strategies.

There is currently no effective treatment or vaccination available for COVID-19. While there continue to be infected individuals and a susceptible population on Island, transmission will continue to occur. The stringent physical distancing measures that have been put in place have suppressed transmission but at a cost to society, both economically and socially. As we move to a review of the current stringent measures, it is essential that we have in place enhanced population and hospital-based testing and surveillance systems to inform and monitor escalation/de-escalation strategies and assess the epidemiological consequences.

This paper sets out the key elements of a comprehensive testing and surveillance strategy for the Island to support de-escalation of restrictive measures, understand the intensity and spread of the virus in the population, identify cases rapidly to enable appropriate health care and control spread (through self-isolation) and to identify and break wider chains of transmission (in combination with the Contact Tracing Service).

The objectives of clinical testing and surveillance testing are set out below:

## Clinical Testing

Timely and accurate laboratory testing of specimens from possible cases is essential to support appropriate clinical response and decisions on contact tracing and infection control strategies.

## Surveillance Testing

Surveillance testing should occur in both hospital and community. It complements clinical testing by identifying people who have COVID-19 but who either have no symptoms or only mild subclinical symptoms which they would not report. The objectives are to:

- Monitor the intensity and geographical spread of the virus in the population
- Identify risk groups for severe disease
- Measure the impact on the population and health and care services
- Measure the impact of the mitigation measures and identify triggers for escalation/de-escalation measures (as part of ongoing 'suppression and release', or 'hammer and dance' strategy).

The paper sets out the clinical and surveillance testing that is currently delivered on Island, the enhancements that are currently in the planning and implementation phase, further developments that could be supported on the basis of current evidence and, finally, developments that are in an early stage of consideration or planning. Recommendations for each from the COVID-19 Testing and Surveillance Strategy Working Group are provided for discussion and decision through the DHSC COVID-19 command chain.

## What are we currently doing?

### 1. Clinical testing

We are testing all individuals who present with clinical symptoms indicating possible COVID-19. This includes people with mild symptoms in the community and those with more severe acute respiratory infection presenting to the Emergency Department or requiring admission to hospital. This provides us with a good overview of the intensity and spread of virus in individuals with symptoms. It does not provide any information on levels of asymptomatic infection in the community.

**Recommendation:** continue policy of testing all those who meet clinical criteria for COVID-19, including mild cases in the community.

### 2. Community surveillance/asymptomatic testing

We are testing all patients admitted to hospital for reasons unrelated to COVID-19. This includes all age groups and all reasons for admission (children, pregnant women, people with fractures or other acute conditions). This provides sentinel surveillance of the extent of asymptomatic COVID-19 in the wider community.

**Recommendation:** continue sentinel surveillance through testing all hospital admissions. This policy was only recently introduced and to date (23 April 2020) all tests have been negative. Test results should be kept under regular review through the Testing Strategy Working Group. Change in positives detected will trigger reconsideration of need for wider community surveillance.



## Enhanced testing currently in the planning and implementation phase

### Enhanced testing for healthcare and other key workers

This includes a testing pathway for symptomatic healthcare/key workers including:

1. For those whose initial COVID-19 test is negative, a repeat test to confirm negative status and allow early return to work
2. For those who are confirmed as positive for COVID-19, further testing after 14 days to confirm that they are negative and safe to return to front line work

Enhanced testing for healthcare/key workers self-isolating with a household member who is symptomatic but has a negative COVID-19 test: repeat test at 24 hours on symptomatic case – if negative, HCW/KW can return to work (end self-isolation)

**Current Position:** pathways have been approved and are being implemented for DHSC health and care staff. Further work is in progress to extend to key workers across other government departments/contractors.

**Recommendation:** progress as already agreed.

## What further testing could we develop?

### Enhanced testing that should be developed now

#### High risk groups

#### 1. Enhanced testing in residential care settings

**Proposal:** test all residents and staff (symptomatic and asymptomatic) following identification of a confirmed COVID-19 index case.

**Rationale:** asymptomatic carriage of virus is increasingly recognised. Patients in residential care settings (for example frail elderly people, people with learning disability) may have atypical symptoms which would not be identified through standard clinical case definition. The higher risks of transmission in residential care settings and the risk of severe disease in residents with frailty and/or other health conditions, justify pre-emptive action to identify others carrying the virus and enable swift action to break the transmission chain.

**Recommendation:** It is understood that approach above is already being followed operationally. This needs to be reflected in a written policy.

#### 2. Discharge planning

Testing confirmed COVID-19 positive patients prior to discharge from hospital to a residential facility or prior to admission to a residential facility from 'self-isolation at home' (mild cases). Testing needs to support (and not replace) rigorous infection prevention and control measures as standard in all facilities.

**Proposal:** confirm recovery through two negative tests of individuals with confirmed COVID-19 prior to admission to a residential facility from hospital or the community.

**Rationale:** to reduce risk of transmission to high risk individuals in residential settings.

**Recommendation:** That the above proposal be accepted and reflected in written policy.

### 3. Pre-admission and pre-transfer testing

Testing of people with no symptoms of COVID-19 prior to admission to a residential care facility (including transfers between residential facilities and admissions from the community)

**Proposal:** a single negative test is required before any admission to a residential care facility direct from the community or via transfer from another facility (in which there are no confirmed cases of COVID-19).

**Rationale:** Although there is a low risk that admissions from the community (where most of those requiring admission will already have been self-isolating/shielding as part of a vulnerable group) or residential settings with no confirmed COVID-19 cases, the risks of transmission within the receiving care home make pre-admission testing an appropriate precautionary response. Pre-admission testing does not replace need for rigorous infection prevention and control measures and monitoring of all residents (including new admissions) for developing symptoms.

**Recommendation:** That the above proposal be accepted and reflected in written policy.

## Enhanced testing requiring further evidence before progression to implementation

### Screening for Healthcare/Key Workers

**Routine testing/screening of asymptomatic healthcare/key workers** to detect asymptomatic carriage and exclude from work to prevent transmission. Evidence base to support this is not mature and there are unanswered questions regarding appropriate intervals for repeat testing, risk/frequency of 'interval cases' and implications for transmission, decision points in pathway/algorithm, etc. University College London is currently considering implementing screening with a one or two week interval.

**Recommendation:** There is insufficient evidence, and too many uncertainties, to recommend introduction of routine screening for asymptomatic health and care workers. Key questions include frequency of testing, and the exclusion period and retest strategy for those testing positive. The position should be kept under review and be revisited as outcomes from screening pilots elsewhere become available.

### Extending Community Surveillance

Methods for surveillance typically include sentinel virological testing in primary care and hospitals and all-cause excess mortality monitoring.

As noted above, testing of all hospital admissions is already underway. Sentinel testing through sampling of individuals presenting with non-COVID-19 symptoms at designated general practices is not currently feasible with the restrictions on face to face consultations.

Other options for discussion include testing in some other non-COVID-19 context, eg ED attenders or other groups – e.g. blood donors.

Population surveillance based on Iceland approach (<https://www.nejm.org/doi/full/10.1056/NEJMoa2006100>): could use open invitation or invitations

to individuals identified through a sampling frame. Other suggestions include offering testing to work places, schools, at pop-up drive throughs (eg Shoprite car parks in Ramsey, Peel, Port Erin, Tesco's in Douglas etc) or exploring 'self-swab' kits through the post.

The Iceland study was based on one-off testing to give a snap-shot of 'who has COVID-19 now (at the time of testing)'. In the UK, a study is planned based on regular testing of a cohort of 20,000 households for current infection based on PCR testing (home test kits), with blood tests for serology on around 2,000 adults. To date (23 April 2020), the only information on this is from the press release. Further information and details of the protocol are awaited.

**Recommendation:** pending decision on whether to move to wider community surveillance including sequential/repeat testing of a defined cohort until further information on UK protocol is available and we can consider priority in light of local results from the 'hospital surveillance' programme.

**Routine testing on all decedents** – to enhance identification of deaths with and of COVID-19. This would need to include arrangements for testing on decedents in the community (eg would require testing at place of death or funeral home). Note that testing as part of post-mortem (autopsy) examinations is already in place (with Coroner's permission) in line with guidance from the Royal College of Pathologists.

**Recommendation:** not currently supported as a priority due to limited additional information it would provide.

## **Proposals currently at an early stage and under review by the Testing Strategy Working Group**

**Antibody testing** – to answer the question 'who has been affected' – no validated test kits are yet available. The Testing Strategy Group liaise regularly with PHE/CMO and other sources (e.g. NW Microbiology network) to ensure that when validated test kits are available a proposal for their roll out here will be considered as soon as possible. Note that a validated high throughput blood test is expected to be available shortly.

**PHE protocol for serum storage and genomics serology** – this is a proposal for blood sampling/storage for serology and genomic analysis being overseen and co-ordinated by PHE. UK Overseas Territories and Crown Dependencies are being offered the opportunity to participate. The Testing Strategy Group has confirmed to PHE that the Isle of Man is interested in participation. Further details are awaited.

### **COVID-19 Testing and Surveillance Strategy Working Group:**

Dr Rizwan Khan  
Steve Doyle  
Dr Henrietta Ewart  
Jacqui Dunn  
Debra Ashmole

25 April 2020

**Council of Ministers Paper No. 20/181**

**Paper for Council of Ministers  
Routine Business**

<b>Department/Board/Office</b>	<b>Cabinet Office and Department of Health and Social Care</b>
<b>Chief Officer</b>	<b>Will Greenhow/Kathryn Magson</b>
<b>Responsible Officer</b>	<b>Dr Henrietta Ewart</b>
<b>Cut ups to be sent to</b>	<b>Kathryn Magson/Henrietta Ewart</b>
<b>Date of Council Meeting</b>	<b>2 May 2020</b>

<b>Title</b>	COVID-19 Testing and Surveillance Strategy
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<b>Collective Responsibility: (Mandatory field, please choose an option)</b>	Which of the 3 Government Strategic Objectives does this proposal comply with?	Which of the Council of Ministers Sub-Committees has considered this proposal?	The proposal relates only to the Department's core or statutory responsibilities
<b>Matter of National Importance</b>	Inclusive, Caring Society	Not applicable	Not Applicable

Has appropriate internal and/or public consultation taken place?	Internal
Are there any resource/personnel implications?	Yes
Has Treasury concurrence been obtained where necessary?	No
Is the Department acting within its legal powers or has legal advice been obtained? (If yes confirm and provide evidence within the paper)	Yes
Are there any inter-Departmental implications?	Yes
If yes, which other Departments are involved?	All
What is the intention of this paper?	Seek Approval
<b>Primary Legislation:</b> Has Council Legislation Subcommittee approved the inclusion of the proposed Bill on the Legislative Programme. If Yes please give decision date:	No
<b>Major Policy Proposal/Primary Legislation:</b> Have you completed an Impact Assessment? If yes please attach a copy as an Appendix to the paper.	No
Have you taken appropriate Corporate Communications Service advice?	Yes
Does this initiative/announcement have a communications plan?	Yes
<b>Purpose of the Paper:</b>  To update Council on the proposed approach to COVID-19 testing and surveillance and request Council's support.	

## **Collective Responsibility:**

The matter is one of collective responsibility. The challenges posed by COVID-19 require a clear and joined up response.

## **Summary**

This paper has been taken through the DHSC Pandemic Response Command structure by the COVID-19 Testing and Surveillance Strategy Working Group<sup>1</sup>. It was agreed by the Clinical and Public Health Leadership Team on 27 April 2020.

The paper sets out the objectives of COVID-19 testing and surveillance as part of the overall response to the COVID-19 pandemic. It summarises testing and surveillance programmes that are currently being delivered on Island, programmes that are already in the planning and implementation phase, programmes that could be considered for planning and implementation based on current evidence and programmes for which the Testing and Surveillance Strategy Working Group considers there is currently inadequate evidence and/or planning is at too early a stage to plan delivery on Island at present. The Working Group will keep these proposals under review, as well as continue to horizon scan for further developments, and will bring these through the DHSC Command structure for consideration for inclusion in the testing and surveillance strategy as the evidence matures.

## **Summary of recommendations**

### **Programmes in place that should continue:**

- 1. Clinical testing** – continue current approach of testing all individuals presenting with symptoms meeting the current clinical case definition for COVID-19
- 2. Surveillance testing** – continue current approach of sentinel surveillance testing of all non-COVID-19 patients admitted to hospital.

### **Programmes currently in the planning and implementation phase that should continue:**

- 1. Enhanced testing for health and care and other key workers (symptomatic, first test negative)** – to enable rapid return to work if a symptomatic worker, or a symptomatic member of their household, has two negative test results.
- 2. Enhanced testing for health and care and other key workers (COVID-19 positive)** – two negative tests to confirm appropriateness for return to work after 14 days self-isolation for workers confirmed COVID-19 positive.

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<sup>1</sup> Membership of the Working Group is listed at the end of this paper

### **New programmes that should be considered now**

- 1. Enhanced testing in residential care settings** – screening tests for all residents and staff following confirmation of a single confirmed positive index case.<sup>2</sup>
- 2. Discharge planning prior to transfer to residential care** – confirmation of recovery through two negative tests in COVID-19 positive patients prior to discharge from hospital to a residential care setting. Programme would also include confirmation of recovery as above for patients with mild symptoms who have been self-isolating at home prior to transfer to residential care.
- 3. Pre-admission and pre-transfer testing for asymptomatic people prior to admission to residential care from the community or transfer between residential facilities** – a single negative test would be required before admission or transfer.

### **Enhanced testing where further evidence is required before local progression**

- 1. Routine screening/testing for health and care workers and other key workers**
- 2. Extended community surveillance** – e.g. ‘one-off, snap shot’ assessment of current levels and distribution of infection (cf Iceland model) or serial testing of a population cohort (cf planned UK programme).
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### **Further programmes on the horizon**

- 1. Antibody testing to confirm ‘who has been infected’ via a community sampling programme** – no antibody test has yet been validated as fit for purpose.
- 2. IoM participation in the Public Health England/UK Overseas Territories/Crown Dependencies Proposal for Serum Storage for Serology and Genomics** – this is at the developmental stage. The Working Group have confirmed interest in participation to PHE.

All testing should be undertaken with appropriate quality control for both swab taking and laboratory processing.

## **Background**

The Isle of Man response to the COVID-19 pandemic is built on a comprehensive range of community measures to reduce transmission of the virus, work to strengthen capacity and resilience of health and care services, information for and engagement with the public and comprehensive testing, surveillance and contact tracing strategies.

There is currently no effective treatment or vaccination available for COVID-19. While there continue to be infected individuals and a susceptible population on Island, transmission will continue to occur. The stringent physical distancing measures that have been put in place

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<sup>2</sup> Testing of all residents and staff has taken place as part of the management of a recent outbreak in a residential care home. It is now recommended that this becomes routine policy in all future cases of COVID-19 in residential facilities.

have suppressed transmission but at a cost to society, both economically and socially. As we move to a review of the current stringent measures, it is essential that we have in place enhanced population and hospital-based testing and surveillance systems to inform and monitor escalation/de-escalation strategies and assess the epidemiological consequences. This paper sets out the key elements of a comprehensive testing and surveillance strategy for the Island to support de-escalation of restrictive measures, understand the intensity and spread of the virus in the population, identify cases rapidly to enable appropriate health care and control spread (through self-isolation) and to identify and break wider chains of transmission (in combination with the Contact Tracing Service).

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## **What are we currently doing?**

### **1. Clinical testing**

We are testing all individuals who present with clinical symptoms indicating possible COVID-19. This includes people with mild symptoms in the community and those with more severe acute respiratory infection presenting to the Emergency Department or requiring admission to hospital. This provides us with a good overview of the intensity and spread of virus in individuals with symptoms. It does not provide any information on levels of asymptomatic infection in the community.

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## 2. Community surveillance/asymptomatic testing

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**Recommendation:** continue sentinel surveillance through testing all hospital admissions. This policy was only recently introduced and to date (23 April 2020) all tests have been negative. Test results should be kept under regular review through the Testing Strategy Working Group. Change in positives detected will trigger reconsideration of need for wider community surveillance.

## Enhanced testing currently in the planning and implementation phase

### Enhanced testing for healthcare and other key workers

This includes a testing pathway for symptomatic healthcare/key workers including:

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Enhanced testing for healthcare/key workers self-isolating with a household member who is symptomatic but has a negative COVID-19 test: repeat test at 24 hours on symptomatic case – if negative, HCW/KW can return to work (end self-isolation)

**Current Position:** pathways have been approved and are being implemented for DHSC health and care staff. Further work is in progress to extend to key workers across other government departments/contractors.

**Recommendation:** progress as already agreed.

## What further testing could we develop?

### Enhanced testing that should be developed now

#### High risk groups

##### 1. Enhanced testing in residential care settings

**Proposal:** test all residents and staff (symptomatic and asymptomatic) following identification of a confirmed COVID-19 index case.

**Rationale:** asymptomatic carriage of virus is increasingly recognised. Patients in residential care settings (for example frail elderly people, people with learning disability) may have atypical symptoms which would not be identified through standard clinical case definition. The higher risks of transmission in residential care settings and the risk of severe disease in residents with frailty and/or other health conditions, justify pre-emptive action to identify others carrying the virus and enable swift action to break the transmission chain.

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## 2. Discharge planning

Testing confirmed COVID-19 positive patients prior to discharge from hospital to a residential facility or prior to admission to a residential facility from 'self-isolation at home' (mild cases). Testing needs to support (and not replace) rigorous infection prevention and control measures as standard in all facilities.

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**Recommendation:** There is insufficient evidence, and too many uncertainties, to recommend introduction of routine screening for asymptomatic health and care workers. Key questions include frequency of testing, and the exclusion period and retest strategy for those testing positive. The position should be kept under review and be revisited as outcomes from screening pilots elsewhere become available.

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As noted above, testing of all hospital admissions is already underway. Sentinel testing through sampling of individuals presenting with non-COVID-19 symptoms at designated general practices is not currently feasible with the restrictions on face to face consultations. Other options for discussion include testing in some other non-COVID-19 context, eg ED attenders or other groups – e.g. blood donors.

Population surveillance based on Iceland approach

(<https://www.nejm.org/doi/full/10.1056/NEJMoa2006100>): could use open invitation or invitations to individuals identified through a sampling frame. Other suggestions include offering testing to work places, schools, at pop-up drive throughs (eg Shoprite car parks in Ramsey, Peel, Port Erin, Tesco's in Douglas etc) or exploring 'self-swab' kits through the post.

The Iceland study was based on one-off testing to give a snap-shot of 'who has COVID-19 now (at the time of testing)'. In the UK, a study is planned based on regular testing of a cohort of 20,000 households for current infection based on PCR testing (home test kits), with blood tests for serology on around 2,000 adults. To date (23 April 2020), the only information on this is from the press release. Further information and details of the protocol are awaited.

**Recommendation:** pending decision on whether to move to wider community surveillance including sequential/repeat testing of a defined cohort until further information on UK protocol is available and we can consider priority in light of local results from the 'hospital surveillance' programme.

**Routine testing on all decedents** – to enhance identification of deaths with and of COVID-19. This would need to include arrangements for testing on decedents in the community (eg would require testing at place of death or funeral home). Note that testing as part of post-mortem (autopsy) examinations is already in place (with Coroner's permission) in line with guidance from the Royal College of Pathologists.

**Recommendation:** not currently supported as a priority due to limited additional information it would provide.

## Proposals currently at an early stage and under review by the Testing Strategy Working Group

**Antibody testing** – to answer the question 'who has been affected' – no validated test kits are yet available. The Testing Strategy Group liaise regularly with PHE/CMO and other sources (e.g. NW Microbiology network) to ensure that when validated test kits are available a proposal for their roll out here will be considered as soon as possible. Note that a validated high throughput blood test is expected to be available shortly.

**PHE protocol for serum storage and genomics serology** – this is a proposal for blood sampling/storage for serology and genomic analysis being overseen and co-ordinated by PHE. UK Overseas Territories and Crown Dependencies are being offered the opportunity to participate. The Testing Strategy Group has confirmed to PHE that the Isle of Man is interested in participation. Further details are awaited.

**COVID-19 Testing and Surveillance Strategy Working Group:**

Dr Rizwan Khan, Consultant Microbiologist, DHSC

Steve Doyle, Pathology Manager, DHSC

Dr Henrietta Ewart, Director of Public Health, Public Health Directorate

Jacqui Dunn, Senior Health Protection Nurse, Public Health Directorate

Debra Ashmole, Health Protection Nurse, Public Health Directorate

Kathryn Magson

Interim Chief Executive

DHSC

1<sup>st</sup> May 2020

**Council of Ministers Paper No. 2021/202**

**Paper for Council of Ministers  
Routine Business**

<b>Department</b>	<b>Cabinet Office</b>
<b>Chief Officer</b>	<b>Will Greenhow</b>
<b>Responsible Departmental Officer</b>	<b>Mark Lewin</b>
<b>Cut ups to be sent to</b>	<b>Henrietta Ewart, Kathryn Magson, Kevin Willson, Sam McCauley</b>
<b>Date of Council Meeting</b>	<b>Monday 26 April 2021</b>

<b>Collective Responsibility: (Mandatory field, please choose an option)</b>	Which of the 3 Government Strategic Objectives does this proposal comply with?	Which of the Council of Ministers Sub-Committees has considered this proposal?	The proposal relates only to the Department's core or statutory responsibilities
<b>Matter of National Importance</b>	Not Applicable	Not applicable	Core

Has appropriate internal and/or public consultation taken place?	Internal
Are there any resource/personnel implications?	Yes
Has Treasury concurrence been obtained where necessary?	Not applicable
Is the Department acting within its legal powers or has legal advice been obtained? (If yes confirm and provide evidence within the paper)	Yes
Are there any inter-Departmental implications?	Yes
If yes, which other Departments are involved?	All
What is the intention of this paper?	Seek Direction
Have you taken appropriate Corporate Communications Service advice?	Yes
Does this initiative/announcement have a communications plan?	Yes
<b>Purpose of the Paper:</b> To consider and agree final aspects of the planned move to Borders Level 3.	

**Collective Responsibility:**

The matter is one of collective responsibility. The challenges posed by COVID-19 require a clear and joined up response.

**1. Agreed position**

- 1.1 On 23/04/21 through Council paper 2021/200 Council agreed the following decisions:
- Expansion of existing compassionate route to include family and partners
  - Amendment to the Regulations to include all Property Owners
  - Amendment to the Regulations to reduce contractual requirement for employed positions from 6 months to 3 months
  - Requirement to declare previous international travel for a 14 day period
  - Applicant only declaration on eligibility with penalties for false declarations
  - To introduce a 7 day pathway option for all travellers and a maximum isolation period of 10 days

- To introduce an ability for a traveller to join a shared household where the traveller follows a 7 day pathway
- To allow Exercise after first negative test rather than Day 7

1.2 There is significant level of permutation on the remaining aspects which Council wished to bring back for discussion which this paper now covers including:

- Testing Charges
- Restrictions on other household members when traveller joins household
- Restrictions on traveller after day 7 negative test
- Additional options for regular IOM resident UK key workers

**2 Context**

2.1 The Exit Framework considered a reduction in border restrictions from 1<sup>st</sup> May 2021 and the UK position continues to support a reduction in the mitigations on the border in line with the thresholds set, however every change carries a level of additional risk, and the discussion and paper from Warwick University is helpful in understanding the residual risk of introducing community transmission in the short / medium term.

2.2 Whilst there is undoubtedly continued comparisons to other jurisdictions around border processes, border restrictions have to be considered in the context of any domestic restrictions in place. This is to mitigate against the risk of a traveller seeding a level of community transmission and contact tracing’s ability to trace, test and isolate relevant contacts.

2.3 This is demonstrated with the difference in approach between Jersey and Guernsey as they approach their own border adjustments at a similar time but from a different basis of domestic restrictions:

	<b>Jersey – 23/04/21</b>	<b>Guernsey – 30/04/21</b>
Border Position	<ul style="list-style-type: none"> <li>• <b>Low level</b> of UK Border Restrictions</li> <li>• Reintroduction of Traffic Light system</li> <li>• England, Wales, Scotland, Isle of Man, Guernsey – all Green</li> <li>• Test on arrival, Isolate 12 Hours</li> <li>• Negative test = no residual restrictions</li> <li>• Follow on surveillance test D5, D10</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Medium Level</b> of Border Restrictions</li> <li>• Reintroduction of Category System</li> <li>• UK likely to be in Category 3</li> <li>• 7 Days Isolation and 7 Days “passive follow on”</li> </ul>
Domestic Cases	<ul style="list-style-type: none"> <li>• <b>Low level</b> of community spread</li> <li>• 2 Active cases, 26 Contacts</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Zero Level</b> of community spread</li> <li>• Reintroduction of Category System</li> </ul>
Domestic Mitigations	<ul style="list-style-type: none"> <li>• <b>Medium Level</b> of domestic Mitigations</li> <li>• Pubs limited to table service</li> <li>• Contact Tracing records required</li> <li>• Nightclubs / Saunas closed</li> <li>• Masks required indoors</li> <li>• Events / Gatherings limited to 20</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Minimum Level</b> of domestic Mitigations</li> <li>• Masks required indoors</li> <li>• No other restrictions</li> </ul>

2.4 Consequently Jersey have a more open border position, but still retain a stronger domestic mitigation position whereas Guernsey are moving to an adjusted border position that is still relatively strong, as it has limited domestic mitigations when the traveller joins society other than face coverings in indoor public spaces being required.

2.5 In an Isle of Man context, under Level Zero, there are effectively no domestic mitigations as recognised by WHO with a reliance heavily upon personal choice. The risk of a traveller seeding community spread that subsequently requires a level of further mitigations (lockdown)

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is therefore higher and any changes to the Border Mitigations needs to consider this.

2.6 As to the outstanding points to consider, in the context of Jersey / Guernsey these are:

	<b>Jersey – 23/04/21</b>	<b>Guernsey – 30/04/21</b>
Testing Charges	<ul style="list-style-type: none"> <li>• <b>Free</b> of charge</li> </ul>	<ul style="list-style-type: none"> <li>• <b>£25</b> per test</li> </ul>
Shared Isolation	<ul style="list-style-type: none"> <li>• <b>Allowed</b></li> <li>• Rest of household - <b>Unrestricted</b></li> <li>• Travellers advised to remain separate in house during 12 hour isolation period</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Allowed</b></li> <li>• Rest of household - <b>Restricted</b></li> <li>• 7 Day isolation period</li> <li>• Whole household has to register details and have an exit test - currently Day 13 and expected to be on Day 7</li> </ul>
Residual Restrictions	<ul style="list-style-type: none"> <li>• <b>Unrestricted</b></li> <li>• Traveller free to resume normal life</li> <li>• Asked to be vigilant for symptoms</li> <li>• Day 5, Day 10 Surveillance Test required</li> <li>• Contact Tracing continue to monitor</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Low Level of Restrictions</b></li> <li>• Traveller and household prevented from attending high risk health settings without authorisation</li> </ul>

2.7 As stated above, Jersey’s position is more relaxed on the traveller, but it is in the context of the higher level of domestic restrictions that are still in place.

**3 Testing Charges**

3.1 Council requested further information on charges for Level 3. It is currently envisaged that for Level 1 (unrestricted) it will be impractical to have testing for all domestic travellers on arrival due to the sheer numbers involved and the impact on travellers and this was signalled in the Exit Framework V2.

3.2 Consequently any decision on charging is likely to be for a limited period up to end of June. A level of pre-departure testing may be required, especially for international travel which will depend on the final UK position.

3.3 Currently the charging regime is £150 for 3 tests. If retained at £50 per test, this will already reduce to £100 per traveller based on a reduced 2 test approach for the 7 day pathway which Council has now agreed.

3.4 Recent income recovered from testing is recorded in Axapta as follows:

January 2021	£48.5k
February 2021	£62.5k
March 2021	£78.8k

3.5 It has not been possible to accurately identify the level of costs for the whole end to end service in the time available.

3.6 Clearly a lower cost, or free of charge, testing regime is more likely to find favour with travellers and more likely to encourage them to go on a reduced testing pathway. The counter argument to this is that it could increase the number of travellers and those taking a reduced pathway so by consequence is increasing by perhaps a marginal level, the overall level of risk.

3.7 The level of forward potential cost implications will be dependent upon the number of travellers which is unknown. A reasonable assumption could be that, with the reintroduction of a 7 day pathway and opening up to family, partners and property owners, travel could increase once again from around 250 per week to around 1,000 per week in line with summer 2020 numbers.

3.8 Consequently the options represented are:

- **Option 1 – Full cost Recovery** – retain at £50 per test for D0,D6 tests
- **Option 2 – Partial subsidy** – only recover estimated consumables and pathology costs - £30 per test for D0,D6 tests
- **Option 3 – Full subsidy** – no cost recovery

	Costs	Assumed Number of Travellers to end June	Assumed Potential Cost recovery to end of June
Option 1 – Full cost recovery	£50 per test	10,000	£1M
Option 2 – Partial subsidy	£30 per test	10,000	£0.3m
Option 3 – Full subsidy	£-	10,000	£-

3.9 In determining the policy for the proposed testing approach, Council may wish to be mindful of the precedent that this decision will set. Whilst this paper quite rightly provides cost projections until the end of June, there is a risk that it could be required for a longer period and indeed could be required to be reinstated over the winter months.

3.10 Therefore in the longer term the full cost of this policy determination could be much higher.

3.11 There is no revenue funding for this cost and so the loss of income should Council determine that there should be no or a partial cost recovery will need to come from the reserves.

3.12 There is adequate provision available in the reserves, although the coronavirus contingency will require further topping up at some point and a paper will be provided to Council on this shortly. The cost of responding to the pandemic is increasing and is substantial.

3.13 **Recommendation 1 – Council to determine the proposed charging regime for tests:**

3.14 **Option 1** – Full Recovery at £50 per test

3.15 **Option 2** – Partial Subsidy at £30 per test

3.16 **Option 3** – Full subsidy with free of charge tests

#### **4 Shared Isolation Options**

4.1 Council has already determined that the ability for a traveller to join an existing household should be brought back in, as an option for travellers opting for the 7-day pathway, as part of Level 3.

4.2 In the context of the above considerations on the balance between border restrictions and domestic restrictions, the consideration on shared isolation for travellers should be considered in the overall context of the Island currently having no domestic restrictions other than personal choice.

4.3 As shown above, Guernsey has a higher level of border restrictions with no domestic restrictions, other than face coverings being required for indoor public settings and consequently insists on full isolation for the whole shared household, as well as an exit test for the whole household.

4.4 Jersey conversely has a lower level of border restrictions with a higher level of domestic restrictions and therefore allows a traveller to isolate in a property with another household for the 12 hours until a negative result (and longer if a positive result) with the rest of the household under no restrictions unless the traveller returns a positive result.

4.5 The range of options for Council is as below and advice from the DHSC clinical and Public Health perspective will be brought to the meeting.

	<b>Restrictions on Traveller</b>	<b>Testing for Traveller</b>	<b>Restrictions on Household</b>	<b>Testing for Household</b>
Option 1 - <b>High</b> Mitigations	7 Days isolation Exercise after D0 negative	D0, D6	7 Days isolation	No testing
Option 2 - <b>Medium</b> Mitigations	7 Days isolation Exercise after D0 negative	D0, D6	1 Day precautionary isolation until traveller receives D0 negative result	No testing
Option 3 - <b>Low</b> Mitigations	7 Days isolation Exercise after D0 negative	D0, D6	No isolation other than restriction on visiting high risk health and care settings for 7 days	No testing

**4.6 Recommendation 2 – Council to determine the Shared Household Isolation option:**

- 4.6.1 **Option 1** – High Mitigations - Whole Household to isolate until D7 negative result
- 4.6.2 **Option 2** – Medium Mitigations – Whole Household to isolate until D1 negative result
- 4.6.3 **Option 3** – Low Mitigations – Whole household has no restrictions other than high risk health and care settings unless with a positive result.

4.7 Council also asked for consideration be given to the circumstance upon which a traveller leaves the Island early, and therefore no D7 test is available, which could leave the rest of the household exposed to developing the virus without ever knowing.

4.8 In practical terms, this risk exist today under the current compassionate route, and there is clearly a level of risk with any form of shared isolation, even with a test on Day 7 should the traveller be infectious from day 1 onwards.

4.9 Options to deal with this additional risk of an early departure are limited and the risk level will depend to a large extent on which option Council determines above.

4.10 The application form could have expected departure date added, but many travellers will not know this or will need a way of changing it, and there is currently no ability to monitor and check this. Jersey have a requirement that the traveller cannot leave the Island unless having completed the isolation period or had a negative test within last 72 hours, although this isolation period is reducing to 12 hours from Monday 26<sup>th</sup> April.

4.11 Alternatively the traveller could declare that “should they leave the Island before the 7 day period expires, they must notify TNS” which would flag a risk. Ideally the traveller would also commit to an early departure test but in emergency situations this may not be possible.

4.12 If it becomes clear, for example through a notification or through monitoring identifying the traveller has left, there is currently no ability in law to mandate that the rest of the household (who are not known individually to TNS) to come forward for testing.

4.13 In the absence of the whole household formally declaring and committing to the rules (the position in Guernsey but not currently available in the Isle of Man for a range of reasons including GDPR advice), the only residual practical mitigation that could be applied is to offer voluntary testing to the whole household upon identification of an early departure.



4.14 Given this risk has existed right since the start of the pandemic and is only an additional risk for a limited period (up to the end of June), it is recommended the most appropriate option is to require the traveller to notify TNS of an early departure outside the 7 day pathway, and to encourage the rest of the household to come forward for voluntary testing.

**4.15 Recommendation 3 – that Council requires travellers to commit to notifying TNS of an early departure outside the 7 day pathway, and offer voluntary testing to the remaining household as a surveillance test.**

**5 Residual Restrictions on Travellers after 7 Days**

- 5.1 Council has already determined that the residual pathway for the traveller should be reduced from 14 days to 10 days in line with the overall reduction in isolation period from 14 days to 10 days.
- 5.2 In the context of the low level of domestic mitigations in place on the Island, the level of residual restrictions could have a higher level of risk of community seeding that would otherwise be the case.
- 5.3 Jersey have no restrictions after 12 hours but a higher level of domestic mitigations including limits on gatherings / events, table service at bars and contact tracing in restaurants. Guernsey has no domestic mitigations other than face coverings indoors and therefore only restricts the traveller from entering high risk health settings (Hospital / GP / Care Home).
- 5.4 In 2020, when the Island introduced its 7 day pathway, it maintained a relatively high level of restrictions such as precluding traveller from visiting restaurants, pubs, and working in public facing settings.
- 5.5 It is also relevant to note that the overall residual position has been adjusted from an additional 7 days to only 3 (D8,9,10) from the position in 2020.
- 5.6 Consequently the range of options for Council are set out below and should be considered in the overall context of risk. Advice from the DHSC clinical and Public Health perspective will be brought to the meeting.

Option 1 – High Mitigations	Traveller limited from public settings, restaurants , bars and from gatherings and educational settings etc.	Mirrors 2020 position, but for D8-10 only
Option 2 – Medium Mitigations	Traveller restricted from access to health and care settings	Mirrors Guernsey position, but for D8-10 only
Option 3 – Low Mitigations – Not recommended	Traveller has no restrictions other than being vigilant for symptoms	Mirrors Jersey position, although they have society wide restrictions – e.g. events, nightclubs

**5.7 Recommendation 4 – that Council determines the option for the residual 7 – 10 day pathway as follows:**

- 5.7.1 **Option 1 – High Mitigations** – Traveller limited from public settings mirroring 2020 position
- 5.7.2 **Option 2 – Medium Mitigations** – traveller restricted only from health and care settings
- 5.7.3 **Option 3 – Low Mitigations** – No restrictions (not recommended)

**6 Key Worker Additional Considerations**

- 6.1 Council requested further options be developed for IOM based regular travellers who are working off Island as UK key workers. For example airline pilots , oil and gas workers etc.
- 6.2 It should be noted that in addition to UK key workers there are Isle of Man business leaders who equally are increasingly requesting more flexibility on travel and isolation as the UK opens up, and as such any change to a small cohort of regular travellers may need to be also considered to a wider pool of travellers.
- 6.3 The position today and that from 1<sup>st</sup> May for these workers could be significantly changed:

	Today	1st May
Maximum isolation	14 Days	10 Days with option to reduce with 7-day pathway
Exercise	After day 6 negative test	After day 0 negative test
Shared Household Isolation	Allowed under exception process, subject to whole household also isolating	Allowed
Restrictions on Household	Not applicable as have to isolate separately	Depends on decisions above

- 6.4 Consequently the challenges faced by a frequent traveller today, will be markedly improved by the introduction of the 7 day pathway, with the following 3 days being less restricted depending Recommendation 4.
- 6.5 The impact on their family could also be profound if they are able to re-join the household in all circumstances and depending on Decision 2 if restrictions on the household are reduced.
- 6.6 Although some of these workers operate in low level risk environments (for example oil and gas and airline workers all have regular testing), they carry the same residual risk as any inbound traveller as their route of travel through the UK carries new risk.
- 6.7 The Steam Packet pathway recognises that the mitigations applied to the worker when on board the vessel are intended to restrict contact with passengers and with UK based crew to reduce infection risk.
- 6.8 In addition modified self-isolation only applies to Manx-resident crew who do not leave the vessel in the UK and consequently, subject to the mitigations on board being applied, should pose a lower level of risk than any other form of traveller.
- 6.9 In light of Council’s request for further options officers have looked at any options to provide even more flexibility for the traveller, and are included below.
- 6.10 A possible way to reduce this additional risk could be through an additional test(s) at 72 hour intervals to try and capture any developing infection. The 72 hour window is a reasonable one that is applied in a number of other jurisdiction travel settings.
- 6.11 Consequently if the worker is able to demonstrate a pre-departure PCR test within 72 hours of travel (most of whom should be able to comply), they could be allowed to enter isolation

assuming this as the entry test.

- 6.12 Building on this, the option is then to allow them to be tested on D3, and upon a negative result be released other than high risk health and care settings. Although further restrictions on public settings (bars, events) could be considered, they have not been shown as an option, as they are unlikely to be palatable and would be difficult to enforce.
- 6.13 Alternatively, accepting an even higher level of risk, an additional 1 day pathway is shown, where the pre-departure test is combined with a test on / after arrival (D0), and after results the traveller is able to be released other than high risk and care health settings.
- 6.14 This clearly carries considerable additional risk as outlined above and both these options would require an exemption process to be developed.
- 6.15 It should be noted that such an additional exemption process would further complicate an already complex regulatory, and operational, landscape at a time when significant changes are being introduced which will further limit available resources.
- 6.16 The range of options for Council is as below and advice from the DHSC clinical and Public Health perspective will be brought to the meeting.

Options	Principles	Commentary
Today	<ul style="list-style-type: none"> <li>14 Days full isolation</li> <li>Separate accommodation</li> <li>Exercise from D7</li> </ul>	
<p><b>Option 1</b> – Standard reduced 7 day pathway.</p> <p>Risk as for all travellers</p>	<ul style="list-style-type: none"> <li>7 Day pathway</li> <li>Exercise from D1 results</li> <li>Shared isolation available</li> </ul>	<p>Replicates process for all travellers recognising the risk and reduces complexity for additional exemptions.</p> <p>This is the option that was recommended in paper 2021/200</p>
<p><b>Option 2</b> – Exceptional 4 day pathway.</p> <p>Higher level of risk than other travellers.</p>	<ul style="list-style-type: none"> <li>Require a pre-departure PCR test in previous 72 hours</li> <li>3 days of isolation required upon arrival</li> <li>Shared isolation available</li> <li>Test D3, D7 (surveillance)</li> <li>Unrestricted after results on D4</li> </ul>	<p>Requires a D0 and D3 Negative test, thereafter restricted from high risk health and care settings until D7</p>
<p><b>Option 2</b> – Exceptional 1 day pathway.</p> <p>Highest level of risk compared to all travellers.</p>	<ul style="list-style-type: none"> <li>Requires a pre-departure PCR test in previous 72 hours</li> <li>1 Day of isolation required</li> <li>Shared isolation available</li> <li>Test D3, D7 (Surveillance)</li> <li>Unrestricted after results on D1</li> </ul>	<p>Requires a D0 Negative test, thereafter able to go out</p> <p>Would be a bespoke process to be considered on a case by case basis. Restricted from high risk health settings.</p>

**6.17 Recommendation 5 – that Council determines the option for case by case key workers who have a need to travel to the UK for their employment as a key worker.**

- 6.18 **Option 1** – Standard Reduced Pathway - 7 day pathway with exercise and shared isolation available
- 6.19 **Option 2**- Exceptional 4 day pathway – Isolation for first 3 days then restricted from high risk health settings only. Testing D3, Surveillance test on D7
- 6.20 **Option 3** – Exceptional 1 day pathway – Isolation for only 1 day then restricted from high risk health settings. Surveillance tests on D3, D7

## **7 Summary & Recommendations**

- 7.1 As set out in this paper, any changes to the border position carries an increased level of risk and has to be considered against the domestic mitigations that might help mitigate this risk. For the Island there are no domestic restrictions other than personal choice and therefore any easing of border restrictions carries a higher risk of seeding than would otherwise be the case.
- 7.2 The Warwick information suggests that an uncontrolled outbreak over the next two months would be extremely difficult, if not impossible to mitigate against on the current Level Zero without further significant restrictions being brought back in.
- 7.3 As such, whilst the formal clinical and public health advisory group has not met and discussed this paper, the view from Public Health would be to make any changes in a gradual and cautious manner such as:
- 7.3.1 Recommendation 2 – Option 1 – Whole household isolate for 7 days
- 7.3.2 Recommendation 4 – Option 1 – High Mitigations – traveller excluded from high risk public settings for day 8,9,10 including pubs, schools and healthcare settings.
- 7.3.3 Recommendation 5 – Option 1 – UK Key worker follows same 7 day pathway as all travellers
- 7.4 The full set of recommendations are set out once again for ease of reference below.
- 7.5 **Recommendation 1** – Council to determine the proposed charging regime for tests:
- 7.6 **Option 1** – Full Recovery at £50 per test
- 7.7 **Option 2** – Partial Subsidy at £30 per test
- 7.8 **Option 3** – Full subsidy with free of charge tests
- 7.9 **Recommendation 2** – Council to determine the Shared Household Isolation option:
- 7.9.1 **Option 1** – High Mitigations - Whole Household to isolate until D7 negative result
- 7.9.2 **Option 2** – Medium Mitigations – Whole Household to isolate until D1 negative result
- 7.9.3 **Option 3** – Low Mitigations – Whole household has no restrictions other than high risk health and care settings unless with a positive result.
- Recommendation 3** – that Council requires travellers to commit to notifying TNS of an early departure outside the 7 day pathway, and offer voluntary testing to the remaining household as a surveillance test.
- 7.10 Recommendation 4** – that Council determines the option for the residual 7 – 10 day pathway as follows:
- 7.10.1 **Option 1 – High Mitigations** – Traveller limited from public settings mirroring 2020 position
- 7.10.2 **Option 2 – Medium Mitigations** – traveller restricted only from health and care settings
- 7.10.3 **Option 3 – Low Mitigations** – No restrictions (not recommended)
- 7.11 **Recommendation 5** – that Council determines the option for case by case key workers who have a need to travel to the UK for their employment as a key worker.
- 7.12 **Option 1** – Standard Reduced Pathway - 7 day pathway with exercise and shared isolation available
- 7.13 **Option 2**- Exceptional 4 day pathway – Isolation for first 3 days then restricted from high risk health settings only. Testing D3, Surveillance test on D7
- 7.14 **Option 3** – Exceptional 1 day pathway – Isolation for only 1 day then restricted from high risk health settings. Surveillance tests on D3, D7

## **PAC Enquiry re Genomic Sequencing**

### **1. What is the purpose of genomic sequencing**

As Covid-19 replicates within a host, mistakes get made. Most of these small genetic mutations make no difference to the behaviour of the virus. They can, however, be tracked by scientists through virus genome sequencing which enables an understanding of patterns of spread over time and place.

The minor mutations lead to subtly different lineages. This can be seen in the RNA sequence, and used to determine the phylogenetics: the coronavirus family tree, as it splits and diversifies. Very roughly, a mutation occurs every 20 “transmission events” or about once every two weeks.

This leads to the emergence of different ‘variants’ of the virus, the surveillance of which is useful in understanding patterns of spread by country or globally. Although most variants make no difference to transmission, severity of illness, accuracy of diagnostic methods or effectiveness of existing vaccines, occasionally variants arise which do. Variants are identified through genomic surveillance and noted as ‘variants of interest’ or ‘variants under investigation’ while further work is undertaken by Public Health agencies to determine whether the variants are linked to significant changes in virus behaviour.

Levels of genomic surveillance differ between countries. The UK has a very strong system, through the UK Genomics Consortium (COG-UK), which was established early on in the pandemic last year. Their early work demonstrated how the epidemic in the UK was driven in mid-March by the high level of active infections arriving from European destinations which were already experiencing large epidemics. However, globally sequencing remains patchy, with higher levels in higher income countries and very low to no sequencing in others.

### **2. What has been the journey with genomic sequencing in the Isle of Man from the beginning of the pandemic to now**

We have had links to the Liverpool Genomics Centre laboratory (part of COG-UK) since the start of the pandemic. Positive samples from our first wave were submitted for analysis during the summer of 2020. The results confirmed that our outbreak resulted from imported cases of European variants via the UK. This confirmed what we already knew through contact tracing.

During the period June to November 2020, when we were only seeing sporadic imported cases with no onwards transmission, we did not send the positive samples for sequencing. From mid-November, when concerns about the Kent variant emerged, all positive samples have been submitted for sequencing. In the current outbreak, due to the numbers involved, samples are only being sent if there is no direct link between the patient and known positive cases.

### **3. To what extent the turnaround time for results affects the use of information**

Sequencing results do not impact on the immediate health protection/public health response to cases or clusters of COVID-19. Rapid turnaround (24 hours or shorter) is not required for outbreak management. When multiple variants were responsible for COVID-19 infection across the UK, there was interest (from COG-UK and public health agencies) in the possibility of using sequencing to identify specific clusters/outbreaks (eg linked to a work place, other setting or geographical area) within the overall pattern of infection, on the basis that this could enable the local public health authority to undertake targeted work to control these. However, now that nearly all cases of COVID-

19 in the UK are Kent variant, the ability to pick up this kind of 'signal' from the background noise has effectively been lost and use of sequencing for this purpose is not being progressed.

There is a trial underway, at University College Hospital London, looking at whether rapid (24 to 48 hour turnaround) sequencing may be useful in identifying and containing nosocomial (hospital) spread of COVID-19.

#### **4. How sequencing will help determine the response in the Island in the short term, in relation to the current lockdown; and also to the longer term exit plan**

Cases of COVID-19 on Island all ultimately derive from imported cases/travel related events. As the vast majority of inbound travellers are coming from the UK, infections will reflect the variants seen there. Therefore, at the present time, we would expect imported cases here to be Kent variant and this will then be reflected in any ongoing transmission.

If we were still seeing a variety of variants coming across the border, sequencing would be useful in confirming whether all putative cases within a cluster/transmission chain were in fact related to the same imported case, or due to different chains from more than one event. In reality, these links can usually be identified through standard epidemiological approaches (linking between persons, times and places), with sequencing as confirmation. Now that the majority of cases reaching the Island will be Kent variant, the sequencing is not able to distinguish between one 'Kent cluster' and another.

When a new variant with potential for enhanced transmission/severity/vaccine resistance is identified, sequencing to identify incursion onto the island is informative. This is a continuation of the current situation, where we have been able to identify (via sequencing) that cases of Kent variant and South Africa variant have reached the Island through travel. As with the UK response to the South African and Brazil variants, knowledge of the emergence of 'variants of concern' will inform ongoing border policy.

Ongoing surveillance, at national and global level is, of course, essential in order to monitor the emergence of new variants the behaviour of which may be cause for concern. This is particularly important in terms of understanding whether new variants can evade existing vaccines and in order to drive the development of 'updated' vaccines to respond to this.

Genomic surveillance systems do not need to include sequencing every positive case's genome. However, all health systems should have capacity to sequence sufficient to detect and track mutations and their effects on transmission, illness severity, diagnostic accuracy and vaccine effectiveness. This requires not only laboratory sequencing capacity but also capacity to contextualise the findings with clinical data and to formulate appropriate and effective public health policy.

The Isle of Man Public Health and laboratory teams continue to participate in COG-UK, Public Health England, and other public health and laboratory networks and to liaise with neighbouring jurisdictions to ensure we are aware of developments in this field and seek appropriate expert advice to contextualise its implications for the Isle of Man.

**Paper prepared for PAC by:**  
**Dr Henrietta Ewart, Director of Public Health, Cabinet Office**  
**Dr Rizwan Khan, Consultant Microbiologist, DHSC**  
**Steve Doyle, Pathology Manager, DHSC**

**18 March 2021**

## COVID-19 Testing Strategy Group

### Notes of the meeting held on 13<sup>th</sup> July 2021 via Teams.

**Present:** Steve Doyle, Henrietta Ewart, Jacqui Dunn

**Apologies:** Rizwan Khan

1. **Review of recommendations from Silver Public Health and Clinical Group meeting held on 12 July 2021.** The following recommendations from PH and CG were reviewed:
  - a) Positive cases: move from a day 9 exit test to standard 10 full days' isolation with release on completion provided individual is asymptomatic. An LFD for home use could be offered with strong recommendation that the person should use it at end of SI and contact 111 for PCR if positive.
  - b) Close (high risk) contacts – household and non-household. No routine self-isolation. Provide 7 days' LFDs for daily use and report negative results to an online form. Provide guidance on avoiding high risk settings and use of face coverings. If symptoms develop, self-isolate and call 111 to arrange PCR.
  - c) Exempt children under 11 from testing.
  - d) Health and Social Care should consider policies for managing staff in the work place and possible introduction of NPIs to reduce risk of nosocomial spread.

**The Group supported the recommendations** above based on the need to agree a sustainable approach to managing spread within a mitigation, rather than an elimination, strategy. It was noted that the PHE contact testing pilot results have not yet been published and, therefore, we do not have real world data on the impact of LFDs in containing spread from close contacts.

2. **Using home LFDs as initial screen for symptomatic patients.** The group had been asked to consider this in response to the high numbers of symptomatic people contacting 111 for PCR. There was a current backlog of around 150 calls waiting for 111 response. Since 28 June, 900 callers had been booked for swabbing from which 26 positive cases were identified – a positivity rate of around 3%. This was putting excessive pressure on 111/swabbing/lab, disproportionate to the pick up rate.

**The group supported a move to advising individuals with symptoms of possible COVID-19 to access LFDs for home use.** Individuals should stay at home as far as possible while they have symptoms. If they have a positive LFD, they should contact 111 to arrange PCR. If their initial LFD is negative, they should continue to remain at home while they have symptoms and repeat LFD after 48 hours. Whilst there is no direct evidence to compare use of LFDs vs self-isolation and PCR in this context, the recommendation is a pragmatic response to current demand (and positivity rate) based on the known operating characteristics of LFDs.

3. **Possible changes to the routine workplace screening for IoM Steam Packet staff not covered by the '2 + 2' vaccination exemption.** There are 47 IoM based crew, currently

receiving weekly PCR; 47 CTA based crew currently receiving PCR on test and release; and 22 crew based outside the CTA also receiving PCR on a 7 day pathway.

**The Group supported moving to LFD for workplace screening for all three groups**, with monitoring to be developed by TNS. SPC staff should be reminded that if they develop symptoms, they should isolate and call 111 to arrange PCR.

**4. Review of exemption from testing for people with previous confirmed positive PCR.**

People who have a confirmed positive PCR (and are 14 days post sample/test) are exempted from contact tracing/testing/isolation and routine screening (borders or workplace) for 90 days from sample date. A recent WHO update extends this exemption period to 180 days based on latest evidence for duration of immunity. **The Group supported moving to 180 days exemption post positive PCR, in line with WHO.** Individuals within this category who develop symptoms within the 180 days should access appropriate testing.



**Minutes of the Meeting of the Council of Ministers  
Held on Monday 26 April 2021 at 09:30am  
in the Council Chamber & via MS Teams**

Present: Hon R H Quayle MHK, Chief Minister  
Hon L D Skelly MHK, Minister for Enterprise  
Hon A L Cannan MHK, Minister for the Treasury  
Hon D J Ashford MBE MHK, Minister for Health and Social Care

Present via MS Teams: Hon A J Allinson MHK, Minister for Education, Sport and Culture  
Hon T S Baker MHK, Minister for Infrastructure  
Hon G G Boot MHK, Minister for Environment, Food and Agriculture  
Hon G D Cregeen MHK, Minister for Justice and Home Affairs  
Hon R K Harmer MHK, Minister for Policy and Reform

In attendance: Mr W J Greenhow, Chief Secretary  
Mr J L M Quinn QC, Her Majesty's Attorney General  
Mr C Randall, Chief Financial Officer, Treasury  
Miss G Nicholls, Executive Office, Cabinet Office (Sec)  
Dr H Ewart, Director of Public Health, Cabinet Office  
Mr K Willson, Senior Manager, Covid Response Team, Cabinet Office  
Mr M Lewin, Chief Executive, Department for Enterprise  
Ms S McCauley, Covid Response Team, Cabinet Office  
Mr S Stanley, Executive Director, Strategic Projects, Cabinet Office  
Ms J Taylor, Strategic Projects, Cabinet Office

In attendance via MS Teams: Ms K Magson, Chief Officer, Department of Health and Social Care  
Mr J Davies, Interim Head of Government Communications, Cabinet Office  
Mr P Boxer, Executive Director External Relations, Cabinet Office  
Miss K Parkinson, Executive Assistant, Cabinet Office  
Mr G Kinrade, Chief Executive, Education, Sport and Culture

Apologies:

**519/2021 Declarations of Interest or Conflict**

**Action**

No declarations of interest or conflict were noted.

**520/2021 Coronavirus Update**

Mr Willson [COVID-111 Manager] provided a verbal update:

- One case of the weekend had been a returning traveller, who had presented with mild symptoms, following entry to the Island from [REDACTED] via Heathrow
- The other positive case during the previous 24 hours was a community case, based in Douglas
- A number of concerns in relation contact tracing information as the person had recently been discharged from Noble's and had caring teams visiting the place of residence
- Contact tracing and investigation of transmission chains was ongoing

- The Chief Officer of the Department of Health and Social Care (“CO-DHSC”) [Ms K Magson] advised that the patient had been re-admitted to Noble’s [Ward 1] for COVID-19 treatment
- The two cases the previous week [retained firefighters] had been recently vaccinated as had the positive travelled case [via Canada]

The Director of Public Health [Dr H Ewart] (“DPH”) advised that there was a monitoring brief ongoing in relation to the local outbreak and that the positivity rate of tests remained at less than 1%.

The DPH advised that in relation to genomic sequencing of the two cases from the previous week in order to ascertain links to previous cluster, one case was nearing the end of the infectious period and therefore there was insufficient viral particles to be assayed, and in relation to the other case, the Liverpool lab had not yet returned a result.

Mr Willson advised that infection controls at the vaccination hubs and other healthcare settings were being reviewed to understand if any links would be established.

The CO-DHSC advised that Noble’s Hospital bed capacity was at limit; there was one positive case being treated in Ward 1 [as explained above] and one positive case being treated in ITU [a previous patient transfer].

The CO-DHSC noted the recent increase in booking cancellations for vaccination, particularly in light of the significant reduction in future supply. The CO-DHSC stated that the public messaging was that all adults who had yet to receive a vaccination appointment were urged to come forward to have a vaccine prior to 10 May 2021, after which focus would shift to the delivery of the 2<sup>nd</sup> doses, and that it was likely that no further first doses would be provided until August 2021.

**Action: The Chief Minister requested that a public message be drawn up in relation to the impact or otherwise of the vaccine on fertility, and that continued emphasis was required in empowering the younger adults to engage in the programme.**

## **521/2021 Borders Level 3 Implementation – Outstanding Decisions**

Paper: 2021/202

File ref:

Collective Responsibility Criterion identified by the Cabinet Office: The challenges posed by the Coronavirus [SARS-CoV-2] pandemic [COVID-19] requires a clear and joined up response

Council considered a paper submitted by the Cabinet Office seeking agreement in respect of the remaining recommendations in relation to the implementation of Border Framework Level 3 from Saturday 1 May [minute 517/2021 refers].

The Chief Minister welcomed the Chief Officer of the Department for Enterprise ("CO-DFE") [Mr M Lewin] and requested discussion be facilitated on remaining recommendations.

The CO-DFE provided an overview of the paper and noted that a number of Ministers had made comments, in relation to monitoring isolation of travellers, data protection where information was to be shared, and penalties for breaches, and received responses on such since the circulation by email [25 April 2021 6:03pm by Mr M Lewin].

Council considered and discussed following recommendations:

**Recommendation 1** – Council, noting that Ministers for Infrastructure, Education, Sport and Culture and the Treasury supported Option 1 [Full cost recovery at £50 per test], and that the Minister for Policy and Reform supported Option 3 [Full subsidy with free of charge tests], determined to **support Option 2** [Partial Subsidy at £30 per test, a total for the 7 Day Pathway [Day 0 / Day 6 testing] of £60].

**Recommendation 2** – Council noted that it was only the traveller that would be tested unless a positive result; and that a traveller could choose to isolate away from a household in separate accommodation.

Following discussion, and noting that the Ministers for Environment, Food and Agriculture, Treasury and Enterprise supported Option 2 [Medium Mitigations: Whole Household to isolate until D1 negative result] and Minister for Justice and Home Affairs supported Option 3 [Low Mitigations: Whole household has no restrictions other than high risk health and care settings unless with a positive result] Council determined to **support Option 1** [High Mitigations: Whole Household to isolate until D7 negative result].

**Recommendation 3** – Following discussion, noting that system was in place and in use in relation to monitoring isolation, Council **agreed** that travellers must commit to notifying the Travel Notification Service of an early departure outside the 7 day pathway, and that voluntary surveillance testing be offered to the remaining household.

**Recommendation 4** – Council discussed the restrictions that would remain for the traveller between the 7<sup>th</sup> day and the 10<sup>th</sup> day, noting that such could be that the traveller was limited from public settings, from gatherings, restaurants, bars, as well as healthcare and educational settings, and further noted that the preferred option from the Clinical and Public Health Group was Option 1.

Council, noting that the Ministers for Justice and Home Affairs and the Treasury supported option 2 [Medium Mitigations: traveller restricted only from health and care settings], determined to **support Option 1** [High Mitigations: Traveller limited from public settings mirroring 2020 position].

**Recommendation 5** – Council discussed the options for case by case consideration of workers who need to travel to the UK for their employment as a key worker. Council noted that there continued to be provision within Public Health Protection Regulations for those essential to the facilitation and operation of critical infrastructure such as ports and airports, shipping and aircraft, Merchant Navy, energy generation, Armed Forces, medical professionals, police and fire service and the Judiciary. Council further noted such provisions did not extend to Formula 1 teams or Financial Services sector. **Action: Council requested that the list of workers be circulated.**

The Minister for Justice and Home Affairs advised that clarity was required in relation to any potential changes to patient transfer pathways; the Chief Officer of the Department of Health and Social Care (“the Department”) (“CO-DHSC”) [Ms K Magson] noted that there were no considerations to modify such at this time.

Council, noting that the Minister for Infrastructure supported option 1 [Standard Reduced Pathway: 7 day pathway with exercise and shared isolation available], and the Treasury Minister supported option 3 [Exceptional 1 day pathway – Isolation for only 1 day then restricted from high risk health settings; Surveillance tests on D3, D7], determined to **support Option 2** [Exceptional 4 day pathway: Isolation for first 3 days then restricted from high risk health settings only, with testing D3 and surveillance test on D7].

Council further **agreed** that for the residual period between day 4 and 7, following a negative test, the worker will be restricted from public settings, aligned to the same restrictions as the 7 day pathway.

## **522/2021 Lateral Flow Devices – Presentation**

Paper: 2021/206

File ref:

Chief Officer of the Department of Health and Social Care (“the Department”) (“CO-DHSC”) [Ms K Magson] provided a presentation in relation to lateral flow devices to provide further requested information and guidance [minute 473/2021 refers].

The CO-DHSC advised that the Clinical and Public Health Group consider that Lateral Flow Devices may be useful in reducing the spread of COVID 19 against a background of significant levels of infection; however there were no real world peer reviewed studies in relation to any evidence to support such an approach.

Council noted the use of lateral flow device testing in England was generating data against a backdrop of significant reduction in positive cases, and therefore statistically such could be skewed.

Council noted the ECDC guidance provided in relation to lateral flow testing in populations with significant vaccine uptake.

The CO-DHSC advised of the various diagnostic tests available and the potentials for the future, and the continued dialogue with manufacturers Roche and Viasure in relation to such.

Council noted the pilot principles and venues [UCM, VillaGaiety, NSC, Fire Service and Police Service (using UK protocols) couple of private sector companies who wish to participate as identified via the Department for Enterprise], and that such did not include a secondary school setting, due to educational examinations for years 11 and 13 and the considerable amount of work that would be required to set up and administer such a testing regime within a school.

Council considered the nature of the trial/pilot, noting that it would not have a scientific statistical basis, and the challenges of reliable testing mechanisms, being that self testing was open to error and that there at present there was no legal basis to require follow-up PCR testing or isolation should a positive result be identified.

Council noted that the overall aim to provide public reassurance of such a pilot could become counterintuitive, and that should surveillance testing been required during an outbreak, the capacity and efficacy of PCR testing was sufficient.

**Action: Council requested a paper in due course to develop out products trials [both Roche and Viasure], at the indicated venues, noting that such were laboratory based tests, not lateral flow devices.**

**DHSC**

Council, noting the content of the presentation, **agreed** that a lateral flow testing pilot was not indicated at this time.

**523/2021 Any Other Urgent Business**

**a) Public Health Act 1990 secondary legislation**

Council noted that amendments to the secondary legislation and direction notices under the Public Health Act 1990 would take place in order to bring into effect the decisions recently made; and that such effect would be from 00:01 Tuesday 27 April 2021.

Mr Willson advised that the system was in place for applications for entry to the Island from 00:01 Saturday 1 May 2021.

**The meeting closed at 10:55am.**

Signed.....

Dated.....

**MINUTES**  
**PUBLIC HEALTH AND CLINICAL JOINT SILVER GROUP**  
**Monday 26<sup>th</sup> April 2021**  
**3:30pm to 4:30pm**  
**MS Teams**

**Present:** Kathryn Magson (KEM) Chief Executive Officer, DHSC  
Steve Doyle (SD) Pathology Manager  
Cath Quilliam (CQ) Director of Nursing  
Dr Rizwan Khan (RK) Consultant Microbiologist  
Dr Sreeman Andole (SA) Medical Director, Manx Care  
Kevin Willson (KW) 111

**Apologies:** Dr Rosalind Ranson (doyRR) Medical Director, DHSC  
Dr Henrietta Ewart (HE) Director of Public Health  
Will Greenhow (WG) Chief Secretary  
Teresa Cope Chief Executive Officer, Manx Care

**Minutes:** Nicola Grose (NG) PA to CEO

Item	Discussion	
1.	<p><b>Minutes of the last meeting – 19/04/2021</b></p> <p>Not discussed.</p>	
2.	<p><b>Warwick modelling – For Information</b></p> <p>CoMin have changed from elimination strategy to a mitigation strategy.</p> <p><u>Warwick Model</u> – It was commented that masks and social distancing are a good measure for mitigation. Minister doesn't agree that this is possible to use as a mitigation strategy as economically the IOM cannot cope with this i.e. pubs, restaurants etc. Need to protect the health &amp; social care system but equally also the economy. Minister notes that the public opinion supports this position.</p> <p>SD thinks perhaps Warwick don't understand the Island setting. SD said that our main mitigation is the speed of our Contract Tracing and how we can react quickly.</p> <p>CQ would advise masks and / or social distancing professionally even if there is no appetite from the public for it.</p> <p>SA asked what other Islands are doing. SA thought that they were still wearing masks in public places. SA would like to keep masks and social distancing. KEM suggested we strongly advised wearing masks at CoMin. Government strategy is now living with covid long term. Hard ask now to introduce masks as this is not the behavioural norm.</p> <p>Warwick saying that outbreaks will continue to happen but they will be slow in pace. Hand, face and space is probably the new normal - behavioural change needed</p>	

	<p>RK wrote in Teams chat: <i>IW's initial model was very optimistic and Warwick is suggesting whatever we do towards mitigation outbreaks remain inevitable The big difference is that these outbreaks will likely be slower in pace hence manageable with more treatment options available to us and most of the population having been vaccinated.</i></p> <p><i>Caveats like highly transmissible variants and efficacy of vaccine remain and this is where CoMIN has to decide how much risk they're prepared to take.</i></p> <p><i>It is not all doom and gloom though – we have excellent contact tracing system, testing capacity, vaccination programme so some behavioural changes - 'Hands, Face &amp; Space' and good vigilance at borders will surely help keep things under control</i></p> <p><i>Probably time to get out of a nervous mindset into a pragmatic mindset for over all good of the people of Isle of Man.</i></p> <p>Professional advice is masks and social distancing but final decision is political recognising balance of the economy.</p>	
<p><b>3.</b></p>	<p><b>SI pathways for households</b></p> <p>One pathway for hospital and one pathway for community.</p> <p>KEM advised that a paper has been produced over the weekend. It was noted that we were due to meet this afternoon and CI and PH group views would be provided to CoMin after. Cost of test will reduce to £30 which mirrors Guernsey. Will come in on the 1<sup>st</sup> May. This morning was agreed at CoMin allow households to self-isolate together from 1<sup>st</sup> May. Between day 7-10; differing options based on risk considered:</p> <ul style="list-style-type: none"> <li>• Option 1 - Test on day 7, on day 8-10 traveller could exercise after 1<sup>st</sup> negative test but would be restricted to go into pubs etc. Can go essential shopping.</li> <li>• Option 2 - Test on day 7, on day 8-10 traveller would be restricted – in H&amp;C settings only.</li> <li>• Option 3 - test on day 7, on day 8-10 traveller would have no restrictions at all</li> </ul> <p>Option 1 was approved by CoMin.</p> <p>SA said that we brought the 14 days to 10 days to allow more freedom. No science between day 7 and 10. Might as well take it from 7 days. RK advised that PHE is 10 day self-isolation. KEM argument for 8-10 is that most of the super-spreader transmission takes place in public spaces or households. RK day 0 (day traveller lands on IOM) and day 1 (day of test). Day 1 and day 6 are the days the traveller is tested.</p> <p>To mitigate the risk between 7-10 you are not allowed to go into public spaces.</p> <p>If positive they will have to have a negative test on day 9 and then isolate for 21 day isolation if positive.</p>	

<p><b>4.</b></p>	<p><b>Key Worker pathway Options</b></p> <p>Regular travellers; oil and gas workers, steam packet, airline pilots, others in perpetual self-isolation.</p> <ul style="list-style-type: none"> <li>• Option 1 – Follow 7 day pathway, exercise from day 1</li> <li>• Option 2 – Pre-departure 72 hours before, isolate for 3 days, surveillance testing day 3 and 7 and unrestricted from day 4. Not allowed in high risk settings.</li> <li>• Option 3 – Pre-departure test, isolate for 1 day then unrestricted</li> </ul> <p>The above is for a distinct group of people. CoMin opted for option 2.</p> <p>SD noted that CoMIN are making decisions but not based on science. Understand why it's being done but not supportive. KEM noted this is a political and economic decision, and in this case related to those in perpetual self-isolation.</p> <p>RK noted that 3 days is a formality - why not just do 1 day. SD noted that no consistency with high risk contact and key workers.</p> <p>CQ doesn't think that we can support this as it's not consistent with 10 days advice.</p> <p>SA would like to take key worker pathways for Health to Clinical Advisory Group to review.</p> <p>Agreed in summary of the changes this morning discussed at COMin – that there couldn't be professional, scientific and clinical advice to support the changes, with 10 days (following ECDC) our standard. However, the group recognised that COMin were trying to find a balance between economy and societal needs and that risks increase along the 0-10 days pathway, accepting that it will be a political call on what level of risk they want to take. All accepted difficult call, no rule book to follow and clearly we would need to see what happened.</p> <p>RK asked if these changes were permanent – KEM advised no, will be subject to review and expected further changes as the exit plan is rolled out stage by stage.</p>	
<p><b>5.</b></p>	<p><b>LDFs and PCR surveillance pilot</b></p> <p>KEM presented this morning. Agreed not to go ahead with an LDF pilot.</p> <p>CoMIN would like us to consider how we do PCR surveillance. KEM asked the testing group to look at this. Do this in the settings where people are not vaccinated i.e. secondary schools. SD suggested TMA, capacity is about 500 per day. Increase allocation from 1<sup>st</sup> May. Raise at Testing Group for further discussion around a random sampling pilot.</p>	
<p><b>6.</b></p>	<p><b>Any Other Business</b></p> <p>None.</p>	



**Minutes of the Meeting of the Council of Ministers  
Held on Thursday 29 April at 9.30am in the Council Chamber & via MS Teams**

- Present: Hon R H Quayle MHK, Chief Minister  
Hon L D Skelly MHK, Minister for Enterprise  
Hon A L Cannan MHK, Minister for the Treasury  
Hon D J Ashford MBE MHK, Minister for Health and Social Care  
Hon T S Baker MHK, Minister for Infrastructure  
Hon G D Cregeen MHK, Minister for Justice and Home Affairs  
Hon R K Harmer MHK, Minister for Policy and Reform
- Present via MS Teams Hon A J Allinson MHK, Minister for Education, Sport and Culture  
Hon G G Boot MHK, Minister for Environment, Food and Agriculture
- In attendance: Mr W J Greenhow, Chief Secretary  
Mr J L M Quinn QC, Her Majesty's Attorney General  
Mr C Randall, Chief Financial Officer, Treasury  
Mr G Nicholls , Executive Office, Cabinet Office (Sec)
- In attendance via MS Teams Miss K Parkinson, Executive Assistant, Cabinet Office  
Teams:  
Apologies:

**524/2021 Declarations of Interest or Conflict**

**Action**

No declarations of interest or conflict were noted.

The following Officers were in attendance from 9:30am [minute references: 525/2021 – 530/2021]

In person:

Dr H Ewart, Director of Public Health, Cabinet Office  
Mr K Willson, Senior Manager, Covid Response Team, Cabinet Office  
Mr M Lewin, Chief Executive, Department for Enterprise  
Mr S Stanley, Executive Director, Strategic Projects, Cabinet Office  
Ms J Taylor, Strategic Projects, Cabinet Office

Via MS Teams:

Ms K Magson, Chief Officer, Department of Health and Social Care  
Mr J Davies, Interim Head of Government Communications, Cabinet Office  
Mr P Boxer, Executive Director External Relations, Cabinet Office  
Ms A Taylor, Head of Passports, Immigration & Nationality, Cabinet Office

**525/2021 Minutes of the recent meetings**

Having been previously circulated the minutes of the recent meetings of Council held on the below dates were agreed:

- 22 April 2021
- 23 April 2021
- 26 April 2021

## 526/2021 Matters arising from the Minutes

### a) Lateral flow devices/New Laboratory Based Tests

Minute ref: 522/2021  
File ref:

The Minister for Education, Sport and Culture advised that the dialogue continued with the Public Health Directorate [Cabinet Office] and the Department of Health and Social Care in respect of organising a trial of testing products such as Roche and Viasure in an educational setting, and that a paper would be submitted in due course [13 May 2021].

**Action: The Department of Education, Sport and Culture, to prepare a paper for submission [Council meeting 13 May 2021] in relation to a trial of testing in an educational setting.**

### b) Rolling Actions [including those related to COVID-19]

Council noted the collated Rolling Actions and amended such.

## 527/2021 COVID-19 (Coronavirus) Verbal Update

Mr Willson [COVID-111 Manager] advised that there were no further positive cases, and that containment had been achieved in relation to the recent single unlinked case [Douglas]. He further advised that exit testing in relation to the primary school high risk contacts would be completed by the weekend [1 May 2021].

The Director of Public Health [Dr H Ewart] ("DPH") advised that the recent outbreak curve could be noted as significantly different to that modelled as part of the research by Warwick University, as such was deterministic rather than stochastic. The DPH concurred that the outbreak appeared contained. The DPH further noted that the February outbreak had resulted from multiple community seeding instances.

Council noted that the messaging continued to need to focus on the World Health Organisation 3 Cs [Close Contact, Crowded Places, Confined Spaces] and the change shift to "stay at home if unwell and get a test".

The Minister for Justice and Home Affairs advised that the Isle of Man Fire and Rescue Service crew members who had tested positive had received unwanted and unwarranted negative public feedback.

The Chief Officer of the Department of Health and Social Care ("the Department") ("CO-DHSC") [Ms K Magson] provided a verbal update:

- Noble's along with other health and care provision was busy, with all services being resumed and PPE level 2 being implemented;

- Visiting across all settings was being reinstated;
- Staffing resources were improving;
- Planning was underway to address the “learning to live with COVID-19” strategy within health and care settings;
- Vaccination programme continued with the aim to have completed first doses for all adults who have registered by 10 May, at which point focus would shift to providing second doses;
- There were approximately 1,000 individuals waiting having requested that they wished to receive a Pfizer BioNTech;
- A reciprocal agreement in relation to provision of vaccines to University students had been implemented, allowing for one dose locally and one dose in the UK, so long as the student registered with a GP as a temporary resident;
- Consideration was being made to a clinic during 3<sup>rd</sup> week of June for students, approximately 500 individuals were likely to book, and a catch-up programme would not necessarily be possible as it was unlikely that any further deliveries of vaccines would arrive before the end of July;
- Notably take-up of the vaccination in the younger adult age groups was reduced;
- Guidance in relation to specific type of vaccine in respect of age groups was clear from the UK Joint Committee on Vaccination and Immunisation (JCVI);
- It was noted that the Moderna vaccine had MHRA licence and was therefore not considered an emergency product, which had implications in relation to indemnity, a drawdown could be made on 300 doses; however this was not required at present.

The Treasury Minister requested clarification as to whether vaccination passporting was being considered and whether the use of a UK App would assist, such as the NHS App.

CO-DHSC advised that dialogue was ongoing with NHS Digital in relation to a local version with all functionality, and that improvements to record keeping was an important part of the Health and Care Transformation Programme, in order for wider digital solutions to be implemented in health and care in the future.

CO-DFE advised that a work-stream was underway exploring and formalising programmes in relation to the use of digital technology for contact tracing, vaccination and passporting.

**Action: Council requested the Terms of Reference, structure and programme for the work-stream be circulated for information.**

**Action: Council requested a paper in due course in relation to the roll-out of a digital solution such as the NHS App.**

## 528/2021 Border Level 3 Clarifications

Paper:  
File ref:

Collective Responsibility Criterion identified by the Cabinet Office:  
The matter is one of collective responsibility. The challenges posed by COVID-19 require a clear and joined up response.

Council considered a paper submitted by the Cabinet Office seeking agreement of a number of complex elements as a result of the implementation of the Level 3 Borders Framework with effect from 1 May 2021.

Council considered and discussed following recommendations, noting that "in the short term" meant during the next 4-6 weeks:

**Recommendation 1** – Council **supported** that there be no change to the default isolation period: "That the default isolation period across a range of circumstances without a testing pathway, remains 21 days in the short term".

**Recommendation 2** – Council **supported** that, in the short term, the whole household shared isolation option and 7 day pathway be available to only those travellers who have been in the UK, Jersey or Guernsey for the previous 14 days prior to travel, noting the detailed information in respect of the situation in relation to the island of Ireland.

### **Recommendation 3**

Council noted the concerns of the Minister of Justice and Home Affairs in relation to the monitoring of travellers and the checking of isolation adherence, and the advice of Mr Willson that an understanding of the separation between managing border security and managing the risk of importation of the virus was required, and the advice of Her Majesty's Attorney General that there remained powers of enforcement within the Public Health Protection Regulations.

Following discussion, Council **supported** that, in the short term, the testing pathway for travellers coming from outside the UK, Jersey or Guernsey, remained unchanged at 14 days (Day 1, Day 7 and Day 13), with the non-testing default pathway remaining 21 days as per Recommendation 1.

**Recommendation 4** – Council **noted** that under recommendation 2 above, in the short term, whilst family, partners and property owners would be able to apply to enter the Island from anywhere in the world, travel restrictions in the home country and entry restrictions into England would remain the priority; therefore in some instances this would preclude travel to the Island other than for essential reasons (e.g. a funeral).

### Recommendation 5

Council discussed the Island's close ties with the island of Ireland, the 14 day notification infection rates of COVID-19 which showed as 114 per 100,000 and that residents of Ireland were not allowed by their law to travel out of the country.

Council noted that there was an increasing need for a clear traffic light system for countries outside of the UK, Jersey and Guernsey.

Council **supported** that for eligibility to the 7 day pathway and shared isolation options, Ireland was **not** an eligible area and any traveller who had resided in Ireland within the last 14 days prior to travel would be treated as any other country outside the UK, Jersey and Guernsey and would therefore follow the appropriate pathways.

### 529/2021 Clinical and Public Health Group Outputs

Paper: 2021/210  
File ref:

Collective Responsibility Criterion identified by the Cabinet Office:  
The matter is one of collective responsibility. The challenges posed by COVID-19 require a clear and joined up response.

Council, considering the importance of the advice provided, **noted** a paper submitted by the Cabinet Office supplying an update on the considerations of the Clinical and Public Health Advisory Group following the [Council] decisions taken in relation to the Mitigation Strategy and Exit Framework.

### 530/2021 Isle of Man Borders

Paper: 2021/196  
File ref:

Collective Responsibility Criterion identified by the Cabinet Office:  
Matter of National Importance: The security and integrity of the Common Travel Area is vital for National Security and Economic stability of the Island.

Council **noted** a paper submitted by the Cabinet Office providing information on progress against the policy to create a shared borders agency; that the team would be formed over a transitional period; and that the relevant cross-Government partners would develop a short term approach to such formal co-operation including mechanisms for intelligence and information sharing as was necessary.

Council noted the concerns of the Minister for Justice and Home Affairs including those of the Isle of Man Chief Constable in relation to monitoring, adherence to isolation checking and data sharing and

warranted officer time and capacity, and that such would be discussed with the Chief Secretary [outside of the meeting].

The Minister for Education, Sport and Culture requested clarification as to when the Border Agency had been envisaged to be launched, prior to the programme being accelerated due to the pandemic. Ms A Taylor [Head of Passports, Immigration & Nationality ("PIN")] advised that consideration had been made to the implementation of such by 2022.

Council noted that legislation would be required under immigration and public health regulation. Her Majesty's Attorney General advised that officers could be warranted if required.

Dr H Ewart, Mr K Willson, Mr M Lewin, Mr S Stanley, Ms J Taylor, Ms K Magson, Mr J Davies, Mr P Boxer, and Mrs A Taylor left the meeting.

Mr M Edwards, Government Communications Executive, Cabinet Office joined the meeting via MS Teams.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

## Edge, Paul

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**From:** Doyle, Steve  
**Sent:** 22 March 2020 20:58  
**To:** Ranson, Rosalind; Magson, Kathryn; Murray, Angela  
**Subject:** Fwd: On-Island Covid testing update  
**Attachments:** Isle of Man Covid Testing update 1.docx

In strictest confidence

Dear all,

You may be aware that we employed Dr Glover a Couple of weeks ago to look at potential local solutions for Covid testing on the IOM.

The below and attached are the current state of play.

It's promising but very early days at the moment so I would ask that you don't circulate widely. Obviously, I've told Rachel that all of our resources are available whilst she and Chris science the hell out of this. It's by no means confirmed, but would be incredibly advantageous if we could make this work. Double swabbing would be the first step.

I'm sure Rizwan can fill you in when you speak next.

Regards

Steve

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----- Forwarded message -----

From: "Rachel Glover" <[REDACTED]>  
Date: Sun, Mar 22, 2020 at 7:42 PM +0000  
Subject: On-Island Covid testing update  
To: "Doyle, Steve" <[REDACTED]> "Shields, Rebbeca"  
<[REDACTED]> "Helm, Chris" <[REDACTED]> "Khan, Rizwan"  
<[REDACTED]>

**Caution: This email is from an external sender. Please take care before opening any attachments or following any links.**

Evening everyone,

I've attached an update document for what has been achieved so far towards on-Island testing. It's pitched as a high-level overview but also includes a more detailed appendix of challenges and solutions. Feel free to circulate upwards if you feel it will help things along. I'm planning on sending out a high-level update every 1-2 days to keep everyone in the loop as things progress.

If we have positive material it is possible to obtain a viral genome in a few hours with the Oxford Nanopore MinION (we have two at Taxa and the reagents ready). On the academic side of things it would be fascinating to compare the strains with those being sequenced world-wide (see <https://www.nextstrain.org/ncov>). It may also inform epidemiology as to whether multiple strains are circulating on-Island and whether the sources are single or multiple. Just a thought and might make an interesting paper once all this calms down.

Kind regards,

Rachel

**Dr. Rachel Glover**

Chief Scientific Officer

---



M: [REDACTED] -

[www.taxagenomics.com](http://www.taxagenomics.com)

Unit 11A-12A Village Walk, Onchan, Isle of Man, IM3  
4EB





From: **Doyle, Steve** 19/05/2021 09:42  
To: **Khan, Rizwan**

**RE: Updated Risk Mitgation Pathway**

I was blanked at bronze despite putting my hand up.

Cath Q made it clear that the pathway was decided between the four of you and she didn't want it debating so I'll keep my nose out in future.

From: Khan, Rizwan  
Sent: 19 May 2021 09:12  
To: Doyle, Steve  
Subject: Re: Updated Risk Mitgation Pathway

Wasn't sure if 7 day SI was still in place! Anyway will amend after what's agreed at bronze

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From: Doyle, Steve Sent: Wednesday, May 19, 2021 9:06:42 AM  
To: Khan, Rizwan  
Subject: RE: Updated Risk Mitgation Pathway

Hi mate,

You still have pathway 2 people on self-isolation??

From: Khan, Rizwan  
Sent: 18 May 2021 23:59  
To: Doyle, Steve  
Subject: Updated Risk Mitgation Pathway

I have done another draft with essentially two pathways – 1 for day visitors and 2 for all other HCWs  
3A worked for elimination strategy so staying away from it  
I have kept EWs as a separate entity as their PPE requirements will be different depending on where they work  
I'll send it to CQ and SA so you all can discuss it in Bronze tomorrow  
Regards  
R

From: **Doyle, Steve** 05/05/2023 11:15  
To: **Rachael Geddes (ICRIoM)**

**FW: Discrepant Testing Figures**

From: Ashford, David (MHK)  
Sent: 08 March 2021 22:58  
To: Doyle, Steve  
Subject: Re: Discrepant Testing Figures

Dear Steve,

That would as always be much appreciated, as there does seem to be this confusion around the verification via GTS and then Cabinet Office. I believe a live dashboard is being created that will feed directly from the lab figures as is ridiculous in this day and age that there can be differences between what you guys process on the ground and what then ultimately comes out of Cabinet Office which is then provided to me.

Hon. David Ashford MHK  
Minister for Health & Social Care  
MHK for Douglas North  
Legislative Buildings  
Finch Road  
Douglas  
Isle of Man  
IM1 3PW  
British Isles  
Mobile | [REDACTED] tel: [REDACTED] >  
[REDACTED] [www.tynwald.org.im](http://www.tynwald.org.im) | [www.davidashford.im](http://www.davidashford.im)

The House of Keys, a branch of Tynwald, the oldest continuous parliament in the world. The House of Keys is the elected branch of the Manx Parliament. The Isle of Man is an independent nation with its own laws, legislation and police force. It also has its own unique, very special and world renowned culture, language, history, heritage, wildlife and countryside.

On 8 Mar 2021, at 22:11, Doyle, Steve wrote:

Dear David,

I hope you are well.

There seems to be continuing confusion around the number of positive tests reported per day.

My team will not leave the department until EVERY test is processed for any particular day; I then personally report these figures each morning which gives tests performed and positive numbers for the previous day. This is accurate, timely, and not open to interpretation. It is

never a 'snapshot' but a comprehensive report on the previous day's testing.

For clarity, swabs tend to start arriving around lunchtime, we then work into the evening to ensure all are reported.

I wonder why these figures, after leaving my office each morning, are changed and misinterpreted. This makes the lab look inefficient and the Government ill advised. I'm now of the mind that these numbers are being confirmed and 'verified' by someone in CabO. There is absolutely no need for this and it leads to miscommunication resulting in us all looking rather silly.

Like many things nowadays in Government, there seems to be levels of admin between the horse's mouth (me) and the communicator (you). We really need to rid ourselves of this.

I'm happy to send the real figures each day directly to you and save half a dozen people a job.

Keep up the good work

Steve

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Isle of Man. Giving you freedom to flourish



# The Independent Isle of Man Covid Review

## Submission to the Independent Review (Invited)

Are you submitting as an individual, or on behalf of an organisation, or group?

Individual

First Name\*

Stephen

Surname\*

Doyle

Please provide your email address if you are content for the Review Team to contact you further about your submission.\*

[REDACTED]

Are you content for your name and the contents of your submission to be published as part of the Chair's report if she wishes to do so?\*

Yes

Which of the following topics does your submission mainly relate to (Please select one only)?\*

Testing

To assist your choice please click [here](#) to refer to a detailed list on our website.

Choose other topic

What would you like to tell the Chair about the Government's handling of the Covid pandemic?

(Limit of 5,000 characters).

I've attached a narrative report

Please attach any supporting documentation using the button below (please note that there is a maximum aggregate file size of 25MB):

Upload

Testing Timeline .docx

73.19KB

Covid Narrative.docx

28.8KB

Testing Numbers.xlsx

9.49KB

# Covid-19 Narrative - Stephen Doyle

## Covid Testing on the Isle of Man

At the beginning of the pandemic, the Pathology Department at Noble's Hospital, in common with most hospital based diagnostic laboratories, did not have access to commercial reagents to test for the virus. Additionally, to identify and measure the RNA associated with SARS-CoV-2, Real Time PCR needed to be employed necessitating the use of a piece of equipment called a thermocycler which are typically only found at large molecular laboratories, Universities and Public Health England labs.

At this time, all areas in the UK (including us) were sending their Covid-19 testing to PHE Colindale, the only validated SARS-CoV-2 testing centre in the UK. As the UK got more organised, regional testing hubs were set up across the UK including one in Manchester to which we then sent samples to.

We did have other PCR technologies on island including a BioFire FilmArray (used for other respiratory infections) and we were in the process of purchasing another platform called Cepheid GeneXpert for influenza testing. We also used another technique called Transcription Mediated Amplification (TMA) on a machine called a Hologic Panther which we used to diagnose chlamydia and other STIs. We presumed (correctly) that at some stage in the near future, suppliers would release reagent packages for all these platforms enabling local testing for Covid-19.

We were actively looking at other alternatives when a local scientist, Dr Rachel Glover contacted the Path Lab in March 2020 offering to work with us to come up with another solution for rapid testing. Like us, Rachel didn't have access to the right equipment but we agreed to work together to see what we could achieve.

By a stroke of amazing good fortune, one of our senior Biomedical Scientists was in the Government Analysts' Lab in Douglas a few days later and came across a thermocycler of exactly the same specifications of that used in Colindale. We later found out that it had been purchased many years previously for a project on fish viruses but never used.

There were still obstacles to overcome including reagent supplies, calibrations, purchase of enough specialised throat swabs, robotic pipetting etc. but Rachel and the team in Microbiology pulled out all the stops and we were testing on the Isle of Man by April 20<sup>th</sup>. This was a major achievement and I believe we were one of the first jurisdictions to come up with a local solution. I personally attended virtual meetings with islands all over the world and although all had plans around testing, none had materialised yet.

Over the next few months, techniques were refined and perfected, a replacement robotic pipetting system (we had borrowed one from Rachel's company – Taxa Genomics) was ordered along with another thermocycler. Sample numbers were manageable as the island

had been able to quickly bring the first wave to a close by locking down and our last confirmed case was in May 2020.

Between May and September, we managed to get an allocation of cassettes for our Cepheid analysers mentioned previously and also carried out a Covid Antibody study to assess how many of our population had been exposed to Covid-19. We also started sending positive samples to the Covid-19 Genomic UK consortium (COG-UK) to have them genomically analysed to ascertain the variants circulating on the IOM.

During this time, IOM Government were assessing strategies for re-opening of the borders and the required testing requirements once this happened (don't forget, the pandemic was continuing in the rest of the world).

Rachel Glover maintained a couple of social media accounts (Twitter and Facebook) and posted regularly about testing and the pandemic in general and she would sometimes be a little critical of the IOM Government and decisions made. She was employed on the 'bank' at the time and although there are conventions for employee usage of internet forums etc. Rachel was in a position where she could walk away at any time so it was a delicate situation to manage. The relationship between her and the lab staff was still very good but I was getting concerns raised to me from senior managers. I attempted to address these with Rachel but to no avail. At this time, she felt that she should be consulted on policy decisions and advocated a 'Scientific and Technical Cell' be formed to advise the Government.

Our first positive case since May was reported on the 7<sup>th</sup> September 2020 and the relationship between DHSC, Government and Rachel deteriorated quickly following tweets she had made about political decision making. At this time, we thought it prudent to start looking at further alternative methods of testing in case the collaboration with Rachel came under threat. Things escalated in late October following further communications between the Health Minister and Rachel and a presentation she had given to Tynwald about testing and epidemiology. She had already spoken to me the week before about changing her status from employee to external contractor but on the 27<sup>th</sup> October, she resigned stating that this had nothing to do with the lab, but was about politics.

I met with Rachel and the head of Microbiology on the 28<sup>th</sup> October in what was a convivial meeting where Rachel confirmed reagents that she had been preparing for the testing system would still be available but a formal supply agreement would need to be put in place.

On the 30<sup>th</sup> October, the Health Minister read out a letter at his regular press briefing purportedly from a member of the lab team expressing frustration at the kudos given to Rachel when it was in fact a team effort. Rachel was understandably annoyed by this and I protested strongly at the time to the Minister at the unwise decision to read this out. It undermined our whole working relationship as she thought it had been penned by me. When asked for evidence of the letter, the Health Minister declared that it had been shredded. Social media exploded at this time (it must be pointed out that social media in small jurisdictions takes on more importance and focus than in the UK for instance).

We were carrying on with testing at the time. Rebecca Shields, Head of Microbiology had undergone some training in reading PCR runs and we had sourced alternative reagent supplies. However, as we were more familiar with the reagent supplied by Rachel's company, we were keen to keep this relationship and so worked on a Heads of Agreement document to validate the contract.

[REDACTED]

At the end of December, new border regulations came into effect on the island which coincided with a massive wave of new infections. We were confident that the department could continue testing without Rachel, but this was the acid test as we were inundated with samples over the Christmas period and for the following months. Unfortunately, Rachel's social media posts shifted from the political arena to direct criticism of the laboratory and the methods of testing employed (she didn't actually have information on what we were using). This created a lot of adverse pressure for the team in Pathology where people were often working 14 hour days.

We were sending positive samples to Liverpool University as part of the COG-UK genomics project to be sequenced to determine what variants were circulating. Rachel then started tweeting that she could sequence the samples quicker and more in depth and that the DHSC should send them to her. Again, this created enormous pressure on the team with questions being asked in Tynwald. It culminated with various MHKs and individuals contacting Liverpool themselves asking about their abilities and the legalities of the testing. Some even asked for views on the competence of Noble's Pathology staff. Professor Alistair Darby, lead

for the genomics hub, expressed to our consultant Microbiologist that they were thinking of ceasing testing for the Isle of Man at this time. Additionally, Pathology started receiving numerous Freedom of Information Requests on a daily basis around our own methods. This appeared orchestrated and distracted us from providing what was an incredibly busy testing service.

In March, the Public Accounts Committee (a standing committee of Tynwald) announced that it was holding an investigation into the use of genomic testing on the Isle of Man. Rachel Glover was the first to give evidence but rather than limit itself to genomics, the committee gave free reign to criticise many aspects of testing and Government handling of the pandemic. I was extremely angry at another attack on my team by the very politicians who should be offering their thanks and support. I asked to appear before the committee to refute many of the things said but was denied this and evidence instead was given by the then CEO of the DHSC who had never actually met Rachel.

In June 2021, the Government focus had changed to some degree and asked us if we could source Lateral Flow Devices (antigenic) which were much more accurate at this time than previously. There is a separate paper about this in the bundle.

Borders opened again at the end of June and once again, Pathology was inundated with samples for PCR (up to 800 a day). At this time we were running another additional RT-PCR test specifically focused on identification of Variants of Concern meaning that the island could be given a result and the specific Covid-19 variant on the same day that the swab was taken. Indeed, we have always been proud of the fact that our turnaround time for results has never been above 6 hours which is favourably comparable to anywhere.

A waste water project started off in March 2022 (outlined in separate section)

## **Genomic testing / Sequencing**

As a virus replicates, mistakes can be made leading to genetic mutations which can be identified through sequencing. Most of these mutations make no difference to the behaviour of the virus but can sometimes lead to different variants as we saw with Covid-19 (Alpha, Beta, Delta etc.)

These variants were identified through international genomic surveillance and during the pandemic, certain lineages were denoted as 'Variants of Interest' or 'Variants of Concern'.

UK surveillance was organised through the COVID-19 Genomic UK (COG-UK) Consortium early in the pandemic and the Isle of Man approached them in June 2020 in order to submit our positive cases from our first wave for analysis. The local hub was at Liverpool University and led by Prof Alistair Darby. At this time, most of our positive isolates were in Manchester (where we sent all samples before testing locally). We continued submitting samples through COG-UK throughout the pandemic with a turnaround time of about 5 days.



Sequencing did not impact the front line health response to the pandemic and was not required for outbreak management as all IOM infections were derived from travel related cases and so mirrored the variants seen in the UK. When multiple variants are circulating, there had been interest in the possibility of using sequencing to identify specific clusters to help health agencies to target transmission but in reality, these links can usually be identified by established track and trace techniques. Furthermore, if we look back starting from wave 1, there was a huge diversity in the lineages that we had in UK and the world generally. By the time it was wave 2, Alpha was beginning to appear and it swept away other variants certainly in the UK. Heading into wave 3, Delta was the dominant variant in UK and across the world, and now Omicron has replaced regional variants and very little of anything else is there causing infection barring occasional cases.

Genomics is a powerful tool, and as well as looking at high level data, it allows you to dig down into a more granular level and identify small genetic changes even within a variant. By doing this, it becomes theoretically possible to look at transmission closer and say that person A may have passed on the virus to person B and even try to identify patient zero when an outbreak occurs. However, we have to be careful with this type of investigation. Genomic information cannot be used to conclusively prove direct transmission because other sources of exposure cannot be ruled out and this remains true even if two genomic analysis are identical. We also need to consider ethical considerations and to not point fingers.

There was one individual on the island at the time that advocated immediate and real time sequencing of cases and her supporters (including many MHKs) were vocal that this was essential for outbreak management. Notwithstanding multiple concerns around ethics, governance, quality control and interpretation (the aforementioned lab was located above a chip shop) the testing team remained unconvinced of the utility of this. Additionally, keeping samples on island for local sequencing would jeopardise our partnership with the international community and ability to share information with COG-UK. The individual at the forefront of this suggestion was also in a legal argument with the DHSC at the time and was giving evidence to the Public Accounts Committee which made any collaboration difficult.

By June 2021, we were using a RT-PCR reflex genotyping assay locally at Noble's. The genotyping or reflex assay comprised a panel of nucleotide probes that can detect the presence of specific mutation sequences in a PCR positive sample, giving an indication of the presence of Variants of Concern. This reduced the time of VOC identification to 6-12 hours after initial PCR result. Genotyping was not considered a substitute for Whole Genome Sequencing (WGS), but was an additional step, and the two technical approaches were performed in parallel so that variant identification by genotyping assay may be confirmed subsequently via sequencing. All of our samples that were sent for sequencing were confirmed as being correctly identified on island.

The pressure to perform sequencing locally was a needless distraction when the lab had been working tirelessly for the previous year or so when the staff should have been given support and protection from the government and not political intervention.

## Lateral Flow Devices

Note – Antigen testing devices (not Antibody)

Antigenic Lateral Flow Device (LFD) testing is a fast and simple way for people to self-test for Covid-19. They are able to detect people with high viral loads who, if asymptomatic and therefore not self-isolating, pose a high risk of infecting others.

When levels of virus are at their highest and people are most likely to pass on the disease, lateral flow tests can detect the vast majority of cases. Lateral flow is useful for finding out if a person is infectious now, and able to transmit the virus to others.

The testing group on the Isle of Man prepared a paper in May 2021 on the utility of LFDs in response to Council of Ministers (CoMin) expressing a desire to use them (initially in schools). We had previously been opposed to their use on the IOM due to questions around sensitivity / specificity but were now agnostic to their use.

On the 9<sup>th</sup> June, following a CoMin meeting, the lab was asked to source 28,000 LFDs. The project involved voluntary testing of secondary school children and staff over five weeks to provide additional intelligence on asymptomatic cases in the highest potential transmission groups. We had previously been in touch with various suppliers and with NHSE to see if we could source directly from them (Innova test), but the compliances to become part of their pillar 2 testing protocols were too onerous. Most privately purchased LFDs had their own limitations and we decided in the end to go with FlowFlex (Hughes Healthcare) after approaching various other suppliers on the PHE approved list.

After financial exemptions were applied for, these were ordered on the 15<sup>th</sup> June.

The uptake on these tests were quite low in schools to begin with but increased as an outbreak became apparent with about 15,000 LFDs being distributed by mid-July. 340 children reported positive tests during this time with 93% of these being confirmed by PCR.

On the 13<sup>th</sup> July, an emergency CoMin meeting decided to extend the use of LFDs to other groups and we were asked to put an urgent order in for more stock. Unfortunately, the announcement for free LFDs was made on the 14<sup>th</sup> July and our held stock at that time was used up in short order. Another order for 100,000 was then asked for with people being able to pick them up at various locations around the island. By the end of July, we had ordered 286K tests at a cost of £726K and plans were made for postal delivery of the devices.

At this time, many other suppliers were knocking on the door to sell kits to the Isle of Man, but there were issues with many of them. Even the ones approved by Public Health England often had no guarantee of adequate supply chain by the supplier. Additionally, the Path lab had been confirming positive LFDs with concurrent PCR testing and found that the kits in use were giving an impressive 94% specificity, so we were reluctant to move away from

them at this point. In October 2021, the Treasury commenced a procedure for formal awarding of future contracts.

In late October 2021, Manx Care advocated twice Weekly LFDs for all health care staff.

Demand increased throughout the year and into the next and as of July 2022 IOMG had purchased 3,766,100 tests.

A select supplier list has now been finalised

## **Waste Water Testing**

This was an environmental surveillance project proposed and funded by Isle of Man Public Health Department to monitor viral pathogens in the population of the island over a six month period. The preliminary cost for this work, to be carried out by the London School of Hygiene and Tropical Medicine was £83K.

In parallel to established testing methods, the aim of the study was to monitor the presence of the SARS-CoV-2 virus in wastewater from the main IOM treatment works. It was hoped that as we moved away from formal testing where epidemiological data could be easily collected to less closely monitored home testing, this data could help inform transmission pathways and outbreaks.

The theory was simple, viral RNA from SARS-CoV-2 and other pathogens including norovirus, enterovirus and influenza, are shed by infected individuals into the sewage system and can be detected / quantified using RT-PCR.

Preliminary discussions in July 2021 included representatives from Jersey and Guernsey who were interested in a joint venture to reduce costs, but their interest waned and by the time the proposal was formalised, the IOM was the only party willing to proceed.

Funding was organised by Public Health IOM and a steering group set up in January 2022 with the first samples sent to London in early March. Four samples were collected weekly from the Meary Veg sewerage processing works in Santon and despatched to LSHTM each Wednesday.

LSHTM also analysed our waste water for enterovirus, influenza and norovirus and the first results were received back on the 15<sup>th</sup> March. The prevalence estimated at that time closely matched what we were seeing on the island. The study was extended in October for academic purposes at no cost to the IOM and talks have been on-going about local testing at the Government Analysts lab.

Unfortunately, with the sudden departure of the Director of Public Health in May 2022, the project lost momentum and although we are still sending samples to the UK, the Pathology department are not privy to the results at this time

## **Procurement / Supplies**

At the start of the pandemic, everyone in the developed world had the same requirements, rapid and increased access to drugs, PPE, reagents, swabs, analysers, clinical supplies, tests – pretty much every health related supply chain was stretched beyond breaking point. On top of the increased demand, most of the things we were after stopped being produced in regular quantities due to countries going into lockdown and workers being furloughed.

Against this backdrop, it's amazing that the whole thing didn't come to a shuddering halt.

Additional problems were encountered on the Isle of Man due to our relative geographical isolation and lack of formal links with bodies such as NHS Supply Chain and NHS England. Indeed, the UK Government had ring-fenced many health care related supplies that were then allocated to the various trusts in the UK depending on perceived need. The IOM was often overlooked although various Government bodies were later tasked with assisting such as the Devolved Administration, Crown Dependencies and Overseas Territories group (DACDOT).

With established supply lines fractured, we were often dealing with suppliers we had never done business with before and there was a rush of entrepreneurship with many companies set up to promise delivery of things desperately needed. Unfortunately, many of these were not as genuine as we would have liked.

Due to lockdown, we also had the small problem of how we would get supplies over to the island even if we could source them due to an all island lockdown.

We did tremendously well to beg, steal and borrow our way out of the early days and certainly from a local perspective, had many examples of novel solutions (homemade hand sanitiser, second hand equipment refurbishment, helicopter supply of equipment, local oxygen generation, and reagent production)

Although not all financial regulations might have been adhered to, it was quite refreshing to have some layers of compliance temporarily removed. We sometime just did what we had to do.

## **Testing Capacity in the event of another Pandemic**

Unfortunately, this is something that is of concern at the moment. Most work on high risk HG3 pathogens such as SARS-CoV-2 have to be undertaken in a containment 3 lab (CL3). The CL3 area at Noble's is relatively small as befits our size but once you are performing hundreds of tests a day with multiple staff in an enclosed area, it becomes apparent that it is potentially unsafe.

The CL3 area was designed and built 20 years ago so once the pandemic settled down and became more manageable, we undertook a full review of the facilities here on the IOM.

There are multiple areas of concern including (but not restricted to), a lack of sufficient space to perform hazardous tasks, significant failures in the integrity of the room due to the initial design being inadequate, inability to fumigate the room in the event of an accidental spill of aerosolised pathogen (due to the lack of room integrity/leaks in the room), lack of washing and changing facilities post-exposure if a spill does occur and regular issues with doors which mean that the room is not kept in the required negative pressure at all times. Additionally, any autoclavable HG3 waste has to be taken from the room and across a corridor to be treated.

Many of these issues are a direct result of poor design at the planning stage of the current hospital, coupled with significant changes to CL3 H&S guidance in the 20 years since, but are compounded by the amount of work required to now be performed under CL3 conditions.

The scope of the current CL3 laboratory proved insufficient throughout the COVID pandemic, with the substantial and relentless workload preventing any opportunity for even minor changes to improve compliance with the SARS-CoV-2 workflows as recommended by PHE and we have serious staff safety concerns if any increase in testing or further (or new) pandemic work is required going forward.

To this end, we have produced a business case for the construction of a dedicated facility in August 2022 and this is currently awaiting approval by Treasury. In the meantime, we have liaised with the Estates department for Manx Care to undertake urgent remedial work.

## **My Team**

Absolute superstars!

I fully realise that many teams went above and beyond during the course of the pandemic and shout outs must be given to them all. But the Pathology team (yes, I'm biased here) from the very start were innovative, engaged, hardworking and fully committed to keeping this island safe. At this point I must make comment about the swabbing team, 111 Covid service and Track / Trace who we worked so closely with and were also a source of pride for the IOM.

For two years, Pathology took everything that the testing pathways could throw at them, often working until midnight before returning to work the next morning. They took great pride that every sample received during the pandemic was reported the very same day which is an exceptional service that could not be replicated in few other places. This happened through every wave and still took place when the island relaxed lockdowns and we were expected to absorb our 'business as usual work'

Unfortunately, the staff had to continue to do this when faced with criticism from certain individuals and politicians. Some of the flack that was directed at them when they were here 14 hours a day was deplorable.

## What went well? / What not so well?

It has to be remembered that we were all winging it to some extent and decisions needed to be made on the hoof, some good, some not as good. I think that the IOM as a whole did remarkably well in managing the outbreak and keeping our people safe.

### Highlights:

- Pathology and Dr Glover setting up a testing regime in very short order and the department increasing capacity / improving techniques when this relationship ended.
- The agility of the whole test, track and trace system being able to identify close contacts often on the same day.
- The roll out of the vaccination programme
- The quick intervention at Abbotswood – although sadly too late for many.
- Swabbing team were awesome as was the facility set up at the Grandstand
- Delaying the introduction of LFDs when their accuracy was poor unlike many other countries that purchased in haste.
- Many Governmental decisions were, I think, sound and allowed freedoms here not seen in the UK. Not always based on pure science, but balanced between that and the overall benefits to society as a whole.
- Private individuals helping us out such as the Fynoderee distillery, Salchem, Henson's ceramics, helicopter pilots, private individuals, (and lots of bakeries supplying cakes etc.) These should really be acknowledged at some stage as it was a great example of the community pulling together and just getting things done.

### Could do better:

- Too much micro management from some senior leaders. Asking for information before the work had even been finished. Information was definitely seen as power for some.
- Travel exemption system was very clunky at the start which led to delays getting essential workers over
- Information pathways had too many individuals and facts would often be changed before they got to ministerial level.
- Having a fire sale of LFDs once they were useful. Cost millions for every family to have a drawer full of them
- Some decision making not transparent / inclusive / asking the right people and lots of things then became urgent asks.
- Political interference and especially the Public Accounts Committee hearing in the middle of the Pandemic.



# The Independent Isle of Man Covid Review

## Submission to the Independent Review (Invited)

Are you submitting as an individual, or on behalf of an organisation, or group?

Individual

First Name\*

David

Surname\*

North

Please provide your email address if you are content for the Review Team to contact you further about your submission.\*

[REDACTED]

Are you content for your name and the contents of your submission to be published as part of the Chair's report if she wishes to do so?\*

Yes

Which of the following topics does your submission mainly relate to (Please select one only)?\*

Tracking data re health and testing

To assist your choice please click [here](#) to refer to a detailed list on our website.

Choose other topic

What would you like to tell the Chair about the Government's handling of the Covid pandemic?

(Limit of 5,000 characters).

I should like to submit a letter that I wrote to Dr. Ewart together with an added notation at a later date.

Please attach any supporting documentation using the button below (please note that there is a maximum aggregate file size of 25MB):

Upload

Dr EWART letter April 2021.docx

17.03KB

[REDACTED]  
[REDACTED]  
24<sup>th</sup> April, 2021

Dear Dr Ewart,

First, I should like to thank you for your reply which emanated from contacting my Member of Parliament, who happens to be the Chief Minister. I found the link to the U.K. DHSC very interesting and was surprised at the large number of companies listed and looking for validation. Do I take it that none have passed into Phase 3? I was pleased to learn that your division of the Cabinet Office is monitoring, continually, the situation.

Dr. Ewart, you are a highly qualified and well respected member of the medical profession. I am merely a layman, who has no scientific or any other qualifications, so please may I ask you to bear with me if I ask a few questions?

- 1) Which Lateral Flow Device is the U.K. issuing, free of charge, on a weekly basis?
- 2) Has their LFD passed through the Phase THREE stage discussed in the link which you kindly sent me?
- 3) What is the sensitivity % and the specificity % of the U.K. LFD?

When I have listened to you speaking on Manx Radio you appear to be, personally, against the LFD, so far, because, as you repeated this week, they are not accurate enough. Could I ask what level of sensitivity and specificity you are expecting?

For the past 5 years, I have been following the progress of Avacta plc, in particular, its progress with Affimers and potential new drugs using their unique pre I CISION technology. Suddenly, in February last year, Avacta, largely because already they had been involved with SARS and MARS, thought they could help with Covid19. Hence my interest as to where they might help the Isle of Man, at some future time.

Unless I am mistaken, which is perfectly possible, the LFD that is about to be launched in the early part of 2021, is the way forward, for the next few years, to enable our economy to recover fairly rapidly.

A large amount of funding to produce the vast number of LFD's required is being invested not only in manufacturing but training facilities, through people like Mologic, Abingdon Life Sciences and B.B.I.

Avacta itself, as you may have read, has announced publicly that it is launching, together with several partners globally, a COVID19 rapid diagnostic test. In the development process there has been, evidently, a notable reluctance to use the swab from up the nostril or the back of the throat because it is both unpleasant and caused some people to be sick. The Avacta based LFD requires an anterior nasal sample, which, apparently, is highly acceptable. As the new generation of LFD's will be approved for self-test by the end of this year, many of the old type, probably, will become obsolete. Within one year we shall have, evidently, a breathalyser that, within 60 seconds, will give a validated result. Incidentally, and this is public knowledge, some GP surgeries will have a miniaturised version



of an existing prototype that, in clinical trials, has identified 40 different diseases. That should ease the pressure on the GP's!!

The speed that things are moving will no doubt raise a lot of questions in the minds of many experts. My problem is that under the present policy of the Manx Government, as advised scientifically, partly by you, we are going to end up going in the wrong direction. I hope not!

I have to ask myself, who is right, Dr Henrietta Ewart, or, this Poor Old Fool who dared to stick out his neck??

In my humble opinion, with the new LFD, with its CE mark and a result downloadable into an iPhone, we are going to, without significant delay, be able to check everyone at each airport before they board the plane, if they haven't already had a self-administered LFT: likewise for all ferry passengers. TT week might be a little stressful!

There are many different scenarios possible, above is just the most obvious.

I should like to see us leading the way. We are small enough and with a nimble government, that has "less process and more outcome" we could be the envy of many other nations.

With the present Manx Government policy NOT to use the latest available validated technology, our economy will not perform as well as it could. We need to obtain a large quantity of the LFD's early in May, or before, so that we can catch, much quicker, any minor breakouts which will occur from time to time and switch to self-testing as soon as possible, after validation.

I look forward to watching closely the next few months and the progress being made.

Regards

David North



# The Independent Isle of Man Covid Review

## Submission to the Independent Review (Invited)

Are you submitting as an individual, or on behalf of an organisation, or group?

Individual

First Name\*

Amanda

Surname\*

Sumner

Please provide your email address if you are content for the Review Team to contact you further about your submission.\*

[REDACTED]

Are you content for your name and the contents of your submission to be published as part of the Chair's report if she wishes to do so?\*

Yes

Which of the following topics does your submission mainly relate to (Please select one only)?\*

Tracking data re health and testing

To assist your choice please click [here](#) to refer to a detailed list on our website.

Choose other topic

What would you like to tell the Chair about the Government's handling of the Covid pandemic?

(Limit of 5,000 characters).

Prior to the pandemic, I was employed as a Band 8a Care, Quality & Safety Coordinator for Community Health Services. On the 20/3/20, I went to help out at the Covid Swabbing Centre which had been hastily set up at the Grandstand on Glencrutchery Road. The unit was being manned by nurse tutors from Keyll Darree (Nurse Education Centre) and third year student nurses whose training had been suspended following the first confirmed case of Covid on the Island (19/3/20). The building had been cordoned off and swabbing was initially undertaken by staff in the pit lane - with specimen bottles and forms stored on a small table. The traffic was backed all the way up the main road and it became evident that the layout needed changing - and from the 21st we relocated to the Scrutineers Garage thus utilising the Grandstand car park for patients to queue in before exiting down past the front of the building. This worked well - it reduced traffic congestion, afforded patients a little more privacy, and gave staff a bigger area to work from and somewhere to store supplies. We had good support from the IP&C team who were on site for the first couple of days but then easily contactable for advice thereafter.

We had plenty of staff to cover our shifts, and adding new employees as bank staff was a swift process. Swabbing began at 10am - seven days a week. Finishing time varied according to availability of swabs. During the crisis at the nursing home, we came in early to carry out swabs on their staff to facilitate a prompter return to work. We also worked late when we began testing key workers so we were able to notify them as soon as results came through. IP&C procedures and guidance changed on a daily basis - but I doubt that was unique to the Island. We had a direct line to the Director of Nursing (via her PA) and communicated with her on a daily basis to report swabbing numbers and discuss any issues.

The usual 'red tape' (long associated with government departments) disappeared during the pandemic which made a difficult situation much easier. The weather, for example, was bitterly cold and our students struggled out in the elements. After raising it with management, we had M&S thermals delivered the next day - along with additional heaters for use in the garage. We were also provided with a large canopy to protect staff from the rain - again, there was no paperwork required, no queries regarding whose budget it was to be deducted from - it was simply identified as being needed and was, therefore, provided.

There was excellent collaborative working between many government departments during the pandemic. In addition to education staff, we also worked alongside the Police and employees from the Department of Transport. There was no hierarchy within the Grandstand - no job descriptions - no limitations. Just a sense of unity and a longing to get through the pandemic.

We had impromptu visits from the Lieutenant Governor, the Chief Minister, Minister for Health and the Director of Nursing - which boosted staff morale significantly. At least one member of the hospital executive leadership team was available at weekends and, as such, we felt well-supported as a team. The daily government briefings were informative and reassuring. They were also a useful means of notifying the public of any changes within the Grandstand (hours etc.) as the comms team were happy to convey messages to the Minister on our behalf.

I have little or no criticism of the government's handling of the pandemic... although we did identify (very early on) that patients were presenting with loss of taste/smell which we felt were linked to Covid. We suggested that the public may benefit from knowing this but our Public Health department wouldn't

deviate from PHE guidance - which I completely understand (anosmia and altered taste were, of course, later announced as being symptoms of Covid).

Not sure if any of this is of use - but I hope so. I've also attached our Service Specification and SOP (versions 1, 2 and 3) which I wrote whilst at the Grandstand (my surname was Phillips then).

Please attach any supporting documentation using the button below (please note that there is a maximum aggregate file size of 25MB):

Upload

Service Specification for GCSU & CST (May 2020).pdf	1.01MB
SOP for Grandstand COVID-19 Screening Unit (v1).pdf	757.28KB
SOP for Grandstand COVID-19 Screening Unit (v2).pdf	1.29MB
SOP for Grandstand COVID-19 Screening Unit (v3).pdf	1.28MB

# COVID-19 GRANDSTAND SWABBING UNIT & COMMUNITY TEAM

## **SERVICE SPECIFICATION**

AMANDA PHILLIPS  
MAY 2020

**COVID-19 GRANDSTAND SWABBING UNIT & COMMUNITY TEAM  
SERVICE SPECIFICATION**

<b>Title</b>	COVID-19 Grandstand Swabbing Unit and Community Team Service Specification
<b>Author</b>	Amanda Phillips, Care Quality & Safety Coordinator for Community Health Services
<b>Date of implementation</b>	7 <sup>th</sup> May 2020
<b>Previous version(s)</b>	n/a
<b>Ratified by</b>	Cath Quilliam (Director of Nursing) Bronze Command Team
<b>Review date</b>	August 2020

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# 1 OVERVIEW OF SERVICE

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Community-based testing teams have been introduced as part of the Island's response to the global Coronavirus pandemic. The Grandstand COVID-19 Swabbing Unit (GCSU) opened on the 20<sup>th</sup> March 2020, providing a drive-through service for symptomatic patients who have been assessed and referred by the 111 Helpline. Patients unable to attend the unit are swabbed by the Community Swabbing Team (CST).

## 1.1 Service outcomes

By assisting in the early identification of COVID-positive patients, results generated by the GCSU will provide vital epidemiological information to:

- Reduce the spread of COVID-19 amongst the Island population.
- Determine the incidence of the symptomatic disease on the island.
- Help predict disease patterns and subsequent health and social care needs.
- Minimise the impact on DHSC services and hospital/community bed availability.

## 2 SCOPE

### 2.1 Purpose and objectives

The purpose of the service is to:

- Undertake prompt testing of patients who display symptoms of COVID-19 infection.
- Facilitate the expeditious return to work of essential workers.

The principal objectives of the service are to:

- Undertake patient testing, for COVID-19, in a manner which causes minimal discomfort or upset to the patient.
- Safeguard the wellbeing of staff undertaking testing procedures.
- Obtain specimens, in a safe, timely and effective manner.

### 2.2 Current service arrangements

The GCSU is based at the TT Grandstand in Douglas. Administrative duties are undertaken in the Race Office, with testing carried out on the pit lane directly in front of the garages. The CST is located in the Tall Trees Resource Centre, in the grounds of Noble's Hospital.

SERVICE DETAILS		
	GCSU	CST
Availability	Seven days per week (including bank holidays).	Seven days per week (including bank holidays).
Hours	Testing hours: 10:00 - 12:00 (hours may be extended to accommodate increased demand). Staff working hours: 09:30 - 12.30. Unit Manager hours: 08:30 - 14:00.	Testing hours: 09:00-17:00hrs (may extend to 18:00hrs if required). Staff working hours: 08:00rs - 17:30hrs.
Min.no. of staff per shift	7	4
Skill mix	1 x Registered Nurse (Unit Manager). 4 x Registered Nurses, Student Nurses, Dental Nurses, AHP's or Senior Healthcare Assistants. 2 x Admin. staff.	1 x Team Coordinator. 2 x Registered Nurses, Student Nurses, Dental Nurses, AHP's or Senior Healthcare Assistants. 1 x Admin.

### 2.3 Description of service

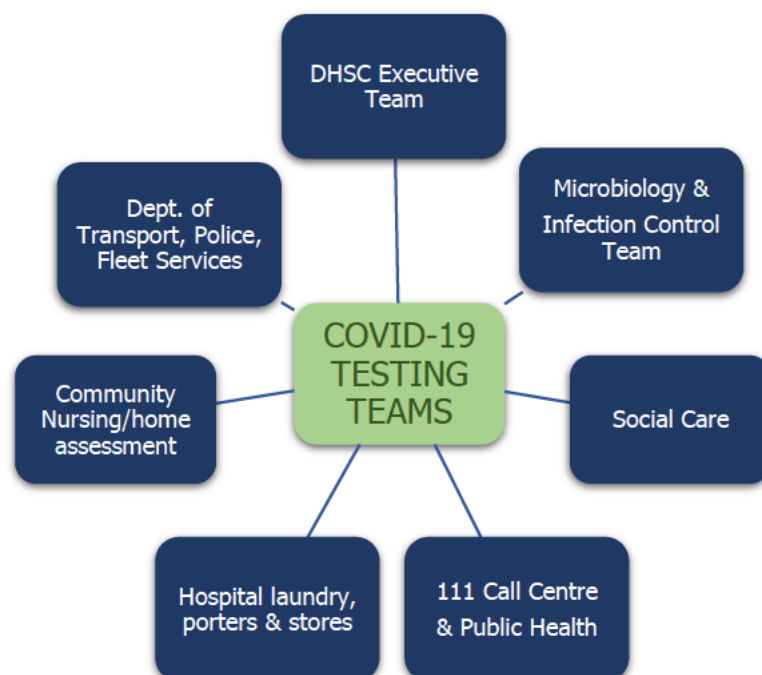
The GCSU and CST provide COVID-19 testing for patients who have been referred by the 111 Helpline. Patients attending the GCSU remain in their vehicle throughout the process, with healthcare workers retrieving specimens via the window. Home visits are undertaken by the CST.

Patients will be swabbed by a registered health professional, Student Nurse or Senior Healthcare Assistant. Due to restricted patient access at the GCSU, samples are retrieved using an oropharyngeal swab - followed by mid-turbinate swabs of both nostrils. Patients being visited at home, by the CST, will routinely undergo nasopharyngeal swabbing unless the procedure is likely to cause too much distress (in which case an oropharyngeal/mid-turbinate swab will be taken instead).

INCLUSION CRITERIA	
GCSU	CST
<ul style="list-style-type: none"> <li>▪ Symptomatic adult patients who are well enough (or able) to drive.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Symptomatic patients who are unable to drive due to illness or infirmity.</li> <li>▪ Patients with no access to a vehicle.</li> <li>▪ Community-based clusters of COVID-19.</li> <li>▪ Children (although parents may opt for attendance at the Grandstand).</li> </ul>

### 2.4 Interdependencies

To function effectively, the GCSU and CST are reliant on a number of services. Collaborative working, and regular communication with these services, will help ensure objectives are achieved and standards maintained.





## 3 SERVICE DELIVERY

### 3.1 Safety

To minimise the risk of harm to staff and patients, services are delivered in accordance with local legislation and policy, including:

- Infection, Prevention and Control
- Health and Safety at Work
- General Data Protection Regulations
- Lone Worker Policy

#### 3.1.1 Declaration of health conditions

Staff wishing to be considered for work in the GCSU or CST must first confirm that they do not suffer from any condition which may increase their susceptibility to Coronavirus. Details are available at the following site:

<https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19>

#### 3.1.2 Personal Protective Equipment (PPE)

Disposable PPE is available and will be utilised by staff undertaking any process which places them at risk of infection. The following guidelines indicate the level of protection required to undertake roles within the service. Additional duties may require increased protection and must be risk assessed beforehand. Roles highlighted in green are specific to GCSU.

	SCRUBS	GOWN	SURGICAL FACE MASK	GOGGLES OR VISOR	GLOVES	APRON
UNIT MANAGER	✓ *					
TEAM COORDINATOR						
INFORMATION COLLECTOR	✓		✓	✓	✓	
SAMPLE COLLECTOR - DIRTY	✓		✓	✓	✓	✓
SAMPLE COLLECTOR - CLEAN	✓		✓		✓	✓
COORDINATOR (RUNNER)	✓				✓ **	
ADMIN 1						
ADMIN 2						
ADMIN 3						
SECURITY/TRAFFIC FLOW			✓		✓	

\*Minimum requirement.

\*\*When handling used sample packs

### 3.1.3 Training

Prior to commencement of employment, clinical staff will complete training in:

- PPE donning and removal procedures.
- Throat and mid-turbinate nasal swabbing and/or nasopharyngeal swabbing techniques.

Training will be delivered by a member of the IP&C Team. Newly trained staff will be supervised by experienced personnel until deemed competent to safely undertake such procedures.

## 3.2 OPERATING PROCEDURES

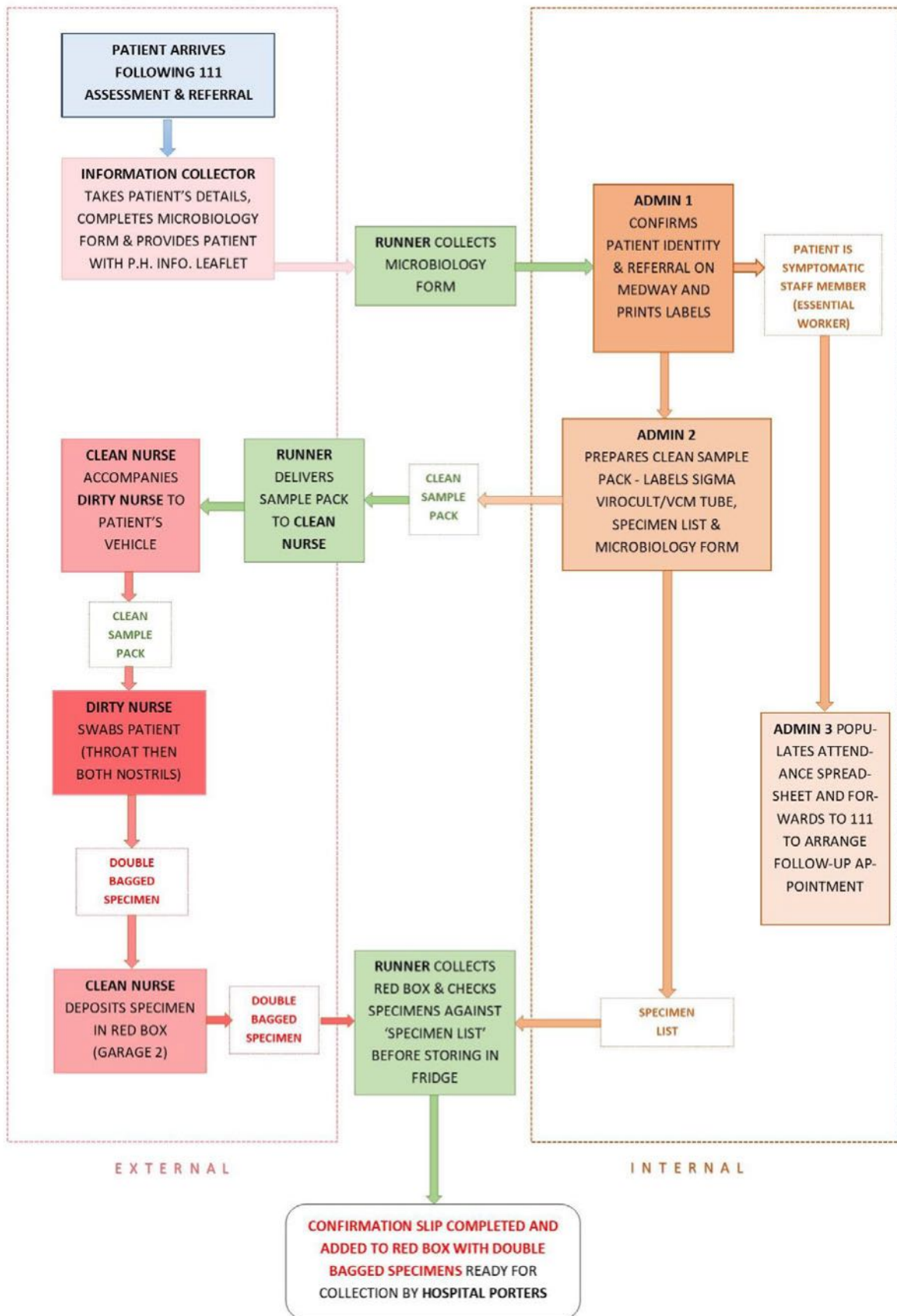
### 3.2.1 Grandstand Covid-19 Swabbing Unit

To minimise the risk of contamination, processes within the GCSU are divided into 'internal' and 'external' areas.

Position	Area	Role
Unit Manager (UM)	Internal	The Unit Manager is responsible for overseeing the running of the GCSU, in addition to performing one of the operational roles below.
Information Collector (IC)	External	IC's gather information from all patients arriving at the unit. In addition to obtaining details, IC's advise on the testing procedure, issue information leaflets (provided by Public Health) and assess the patient to ensure any specific needs are addressed.
Sample Collectors (SC)	External	Working in pairs (one 'dirty' and one 'clean' healthcare worker), SC's are responsible for performing oropharyngeal/mid-turbinate nasal swabs on all patients.
Coordinator (runner)	Corridor	Responsible for transferring labelled sample packs from admin to SC's; and checking in 'dirty' specimens ready for collection. The Coordinator has no patient contact.
Admin 1*	Internal	Locates patients on Medway and generates ICE labels.
Admin 2*	Internal	Labels sample tubes and forms.
Admin 3*	Internal	Populates the daily attendance spreadsheet for Essential Workers.
Traffic Flow/Security	External	Responsible for preventing unauthorised vehicles from entering the unit and helping maintain the flow of traffic. Roles undertaken by Dept. of Transport employees with support from the Police.

\*Roles are interchangeable (depending on patient numbers) with two staff able to perform all admin duties.

Grandstand COVID-19 Swabbing Unit Process

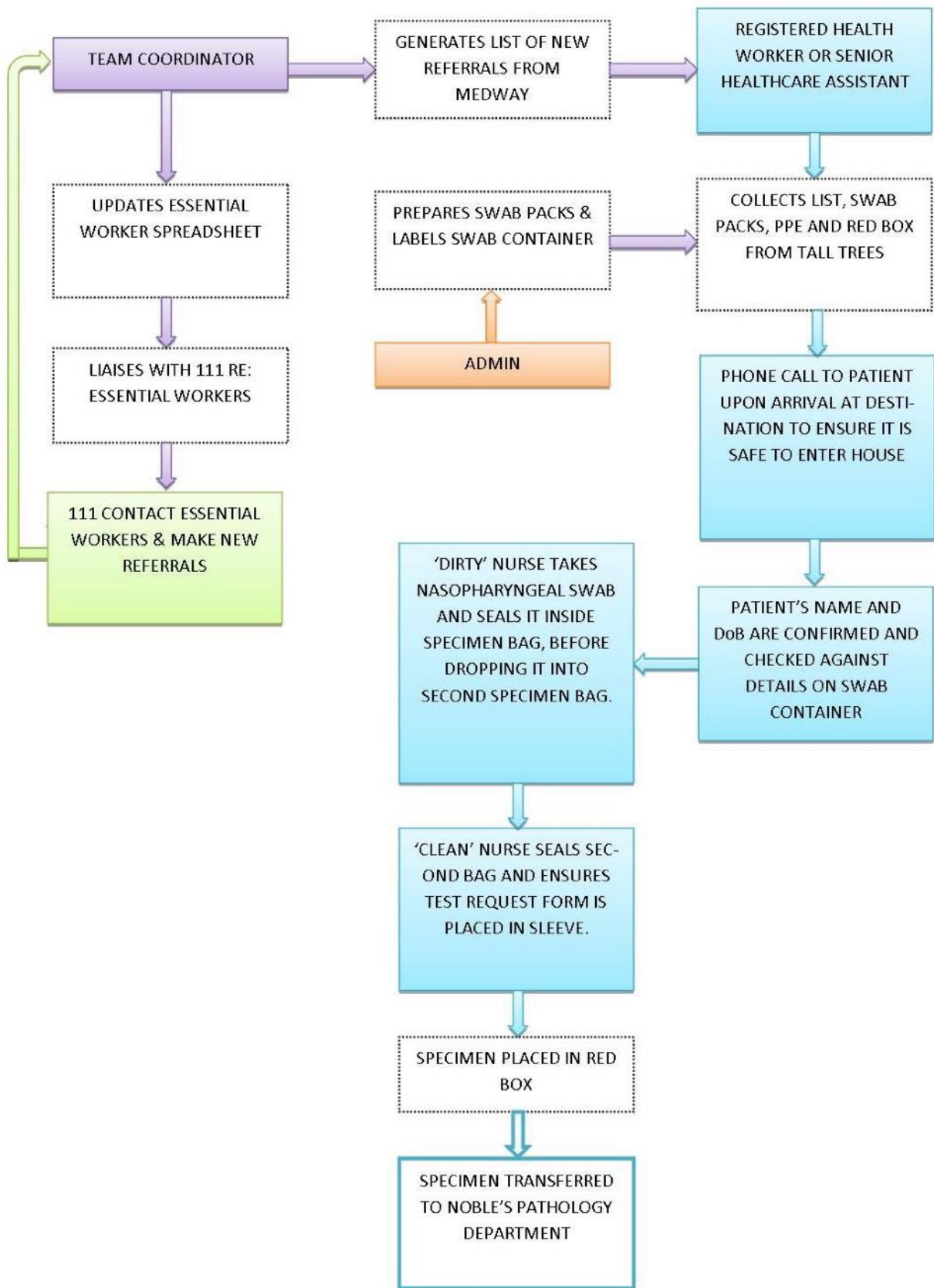


### 3.2.2 *Community Swabbing Team*

Although the CST is based at Tall Trees, no swabbing is undertaken on the premises.

Position	Area of work	Role
Team Coordinator (TC)	Tall Trees	Responsible for the day-to-day running of CST and the management of the Essential Worker swabbing process.
Sample Collectors (SC)	Community	Working in pairs (one 'dirty' and one 'clean' healthcare worker), SC's are responsible for performing nasopharyngeal swabs (or oropharyngeal/mid-turbinate nasal swabs, where necessary) on patients.
Admin.	Tall Trees	Responsible for general admin duties within the resource centre.

Community Swabbing Team Process



## 4 QUALITY ASSURANCE & RISK MANAGEMENT

### 4.1 Quality Assurance

Stringent quality control procedures are in place to ensure the following objectives are met:

<b>GRANDSTAND COVID-19 TESTING UNIT</b>	
<b>OBJECTIVE</b>	<b>ASSURANCE</b>
<b>SPECIMENS</b>	
All patients are correctly identified, and specimens accurately labelled.	<p>After obtaining patient details (on arrival at GCSU), the following identity checks will be undertaken:</p> <ul style="list-style-type: none"> <li>▪ COVID tab visible on Medway thus confirming patient has been referred via 111 Helpline.</li> <li>▪ Coordinator will ensure Microbiology form matches labelled tube prior to handing to Sample Collectors.</li> <li>▪ Sample Collectors confirm patient's name and DoB correspond with Microbiology form and labelled tube.</li> </ul>
Production of good quality specimens containing sufficient respiratory material.	<ul style="list-style-type: none"> <li>▪ All clinical staff will complete training to ensure they are competent in mid-turbinate and throat swabbing techniques.</li> <li>▪ Insufficient specimens will be promptly reported to Unit Manager to arrange for re-swabbing of patient. The issue will be raised with the staff member involved and further training/assessments undertaken.</li> </ul>
All specimens are correctly stored prior to transfer to laboratory.	<ul style="list-style-type: none"> <li>▪ All specimens received from 'clean' nurse, will be sealed and double-bagged.</li> <li>▪ All specimens will be stored in a designated refrigerator (temperature maintained between 2° and 8°C).</li> <li>▪ Minimum, maximum and current fridge temperature monitored (and recorded) daily.</li> <li>▪ Refrigerator cleaned daily with Chlor-Clean solution.</li> </ul>
All specimens will be accounted for and will be safely transferred to laboratory.	<ul style="list-style-type: none"> <li>▪ Specimens will be checked against the 'Specimen List' to ensure all are present.</li> <li>▪ All specimens will be counted out and a confirmation slip completed (stating number of specimens being transferred to laboratory); and placed in the red box when the porter attends the unit. The box is then transported directly to the laboratory by the porter.</li> </ul>

STAFF WELLBEING	
Staff wellbeing will be prioritised and risk of harm minimised in all areas.	<ul style="list-style-type: none"> <li>▪ PPE will be available thus providing protection during swabbing procedures.</li> <li>▪ All staff will be proficient in the donning and removal of PPE prior to undertaking swabbing procedures.</li> <li>▪ Procedure in place for the management of aggressive or problematic patients.</li> <li>▪ Support available for employees via unit/team managers, colleagues, and from Staff Welfare/Emotional Support Helpline.</li> </ul>
WORKING ENVIRONMENT	
The premises will remain free from infection and hazards minimised.	<ul style="list-style-type: none"> <li>▪ Cleaning of all work surfaces, I.T. equipment, telephones and chairs, using Chlor-Clean solution, at the end of each session.</li> <li>▪ Daily domestic duties undertaken at the end of each session (rooms vacuumed, toilet cleaned, kitchen area cleaned).</li> <li>▪ Domestic and clinical bags utilised, sealed and transferred into large storage bin at the end of each shift. Storage bin emptied daily by hospital porters.</li> <li>▪ Restricted access to offices to prevent cross-contamination.</li> <li>▪ Decontamination area clearly identified and pack (containing cleaning cloths, paper towels, yellow bag and set of disposable scrubs) available for use.</li> </ul>
PATIENT INFORMATION	
Patients will be fully informed of the swabbing process and provided with literature containing up-to-date (and accurate) information on COVID-19.	<ul style="list-style-type: none"> <li>▪ Process explained to patient by IC and reiterated by Sample Collectors.</li> <li>▪ All literature issued will be provided by Public Health and updates sought on a regular basis.</li> <li>▪ Patients advised to contact 111 with any questions pertaining to isolation periods, testing family members or fitness to return to work.</li> </ul>

<b>COMMUNITY SWABBING TEAM</b>	
<b>Objective</b>	<b>Assurance</b>
<b>SPECIMENS</b>	
All patients are correctly identified, and specimens accurately labelled.	<ul style="list-style-type: none"> <li>▪ List of patients generated from Medway thus confirming patient has been referred via 111 Helpline.</li> <li>▪ Sample Collectors confirm patient's name, address and DoB correspond with the request form and ensure Microbiology form and swab tube are completed accurately.</li> </ul>
Production of good quality specimens containing sufficient respiratory material.	<ul style="list-style-type: none"> <li>▪ All clinical staff will complete training to ensure they are competent in nasopharyngeal, mid-turbinate and throat swabbing techniques.</li> <li>▪ Insufficient specimens will be promptly reported to the Team Coordinator to arrange for re-swabbing of patient. The issue will be raised with the staff member involved and further training/assessments undertaken.</li> </ul>
All specimens will be safely transferred to laboratory.	<ul style="list-style-type: none"> <li>▪ All specimens are double-bagged and transported, in a secure red box.</li> <li>▪ Red box, containing swabs, transferred to Noble's Pathology Department by the practitioner.</li> </ul>
<b>STAFF WELLBEING</b>	
Staff wellbeing will be prioritised and the risk of harm minimised in all areas.	<ul style="list-style-type: none"> <li>▪ PPE will be available thus providing protection during swabbing procedures.</li> <li>▪ All staff will be proficient in the donning and removal of PPE prior to undertaking swabbing procedures.</li> <li>▪ Phone calls made to households, prior to visit, to facilitate staff safety.</li> <li>▪ Implementation of Lone Worker policy.</li> <li>▪ Support available for employees via unit/team managers, colleagues and from Staff Welfare/Emotional Support Helpline.</li> </ul>



## **4.2 Risk Management**

The usual DHSC governance framework will be applied to the management of risk at GCSU and CST. A register will be maintained to monitor risks associated with service delivery and will be reviewed every two weeks. Unit Managers/Team Coordinators are responsible for:

- Monitoring and updating existing risks.
- Adding new risks and bringing them to the attention of the team.
- Escalating any risks, which are proving unmanageable or increasing in severity, to the Senior Executive Team.

All staff will be encouraged to report concerns to the Unit Managers/Team Coordinators as soon as possible.

## **4.3 Untoward Incidents**

The GCSU and CST are staffed by employees from a number of areas across the Government. As such, the use of Datix as a reporting tool will prove problematic.

Incidents (which result in no harm) will, therefore, be recorded locally and held by the Unit Manager (see Appendix 2). Serious incidents (or those resulting in harm) will be recorded on Datix and escalated to the Director of Nursing.

## **4.4 Complaints**

Any complaints raised about staff or service provision will be managed as per DHSC complaints procedure.

## RISK REGISTER

DATE	RISK DESCRIPTION	OWNER	MITIGATION	UPDATE	RISK LEVEL
2/5/20	Potential for contamination of staff or working areas.	A Phillips/B Devlin (GCSU) S Graham/R Dooley (CST)	<ul style="list-style-type: none"> <li>▪ PPE available and all staff proficient in its use.</li> <li>▪ Staff encouraged to check each other's PPE use and highlight any discrepancies</li> <li>▪ Stringent hand washing.</li> <li>▪ Restricted movement between external and internal staff to prevent cross-contamination at GCTU.</li> <li>▪ Decontamination procedure implemented: Designated area identified, containing cleaning materials and change of clothing.</li> <li>▪ All working areas, surfaces and equipment cleaned at the end of each shift using Chlor-Clean.</li> </ul>		SEVERE
2/5/20	Production of invalid swabs.	A Phillips/B Devlin (GCSU) S Graham/R Dooley (CST)	<ul style="list-style-type: none"> <li>▪ Quality assurance measures implemented (see Section 4.1).</li> </ul>		MOD
2/5/20	Restricted availability of PPE due to supply interruptions.	A Phillips/B Devlin (GCSU) S Graham/R Dooley (CST)	<ul style="list-style-type: none"> <li>▪ Utilisation of reusable scrubs.</li> <li>▪ Patients risk assessed to ensure appropriate use of PPE (as per SOP and IP&amp;C guidelines).</li> </ul>		HIGH
2/5/20	Service disruption due to illness.	A Phillips/B Devlin (GCSU) S Graham/R Dooley (CST)	<ul style="list-style-type: none"> <li>▪ Appropriate measures taken to minimise risk of infection (see above).</li> <li>▪ Comprehensive SOP and GCSU/CST Process Algorithm available to assist initiation of replacement staff if required.</li> </ul>		MOD

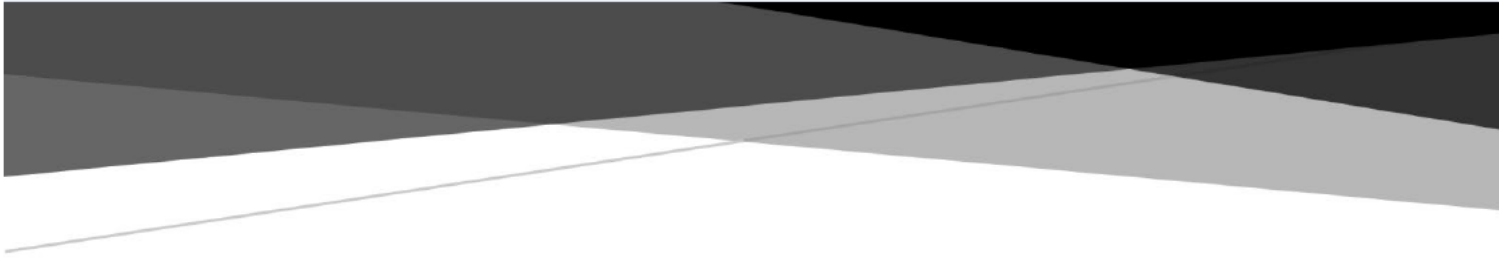
Appendix 2

GRANDSTAND COVID-19 TESTING UNIT/COMMUNITY SWABBING TEAM

UNTOWARD INCIDENT LOG

TO BE USED FOR THE REPORTING OF MINOR INCIDENTS ONLY. SERIOUS INCIDENTS, OR THOSE RESULTING IN HARM, MUST BE REPORTED VIA DATIX.

DATE	AREA(S) INVOLVED	DETAILS OF INCIDENT	NAME(S) OF PERSON(S) INVOLVED	ACTION/OUTCOME	INCIDENT MANAGER	INCIDENT STATUS



# GRANDSTAND COVID-19 SCREENING UNIT

## STANDARD OPERATING PROCEDURE

Amanda Phillips  
April 2020

**STANDARD OPERATING PROCEDURE FOR THE  
GRANDSTAND COVID-19 SCREENING UNIT**

<b>Title</b>	Standard Operating Procedure for the Grandstand COVID-19 Screening Unit
<b>Author</b>	Amanda Phillips, Care Quality & Safety Coordinator for Community Health Services
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<b>Ratified by</b>	Due to the temporary suspension of all non-essential DHSC committees, this SOP has been ratified by: Amanda Phillips, Department of Health and Social Care (DHSC) Michael Fleming, Department of Education, Sport and Culture (DESC) Bernadette Devlin (DESC) Vicky Taylor (DESC)
<b>Review date</b>	Fortnightly (next due 23/4/20)

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## **1 INTRODUCTION**

The Grandstand COVID-19 Screening Unit (GCSU) opened on the 20<sup>th</sup> March 2020, in response to the global Coronavirus pandemic; and provides a drive-through screening service for symptomatic patients who have been assessed and referred by the 111 Helpline. Results generated by this service will provide vital epidemiological information to:

- Determine the prevalence of COVID-19 on the island.
- Help predict disease patterns and subsequent health and social care needs.
- Minimise the impact on DHSC services and hospital bed availability.

The GCSU is based at the TT Grandstand. Administrative duties are undertaken in the Race Office, with screening carried out on the pit lane in front of garages 1 and 2 (see Appendix 1).

### **1.1 Scope**

This Standard Operating Procedure is applicable to all IOM Government employees deployed at the GCSU and will remain effective until the unit is disbanded.

### **1.2 Policies**

This SOP must be used in conjunction with current IOM Government legislation pertaining to:

- Infection Control and Prevention
- Health and Safety at Work
- Fairness at Work
- Data Protection

Registered health professionals must continue to practice in accordance with standards set by their regulatory body.

## 2 PROCEDURE

The GCSU operates seven days a week, screening patients between 10am and 2pm. Staff commence duty at 09:30 and finish at 2.30pm. Screening hours may be extended at short notice to accommodate demand.

The GCSU requires 12 staff to function effectively (one of which will be Unit Manager):

6 sample collectors (Registered Nurses, Allied Health Professionals, senior Healthcare Assistants or student nurses).

2 information collectors (RN's or Senior HCA's).

3 administration staff.

1 coordinator/runner (RN or Senior HCA).

### 2.1 Unit Manager

Unit Managers are responsible for the daily running of the GCSU, including student welfare, staffing and communication.

The role includes:

- Unlocking the screening unit and preparing it for use.
- Ensuring all employees sign in.
- Allocating daily roles and ensuring employees wear the appropriate PPE.
- Facilitating meetings prior to (and following) each shift to ensure staff are confident to undertake the duties expected of them; and to discuss any problem areas.
- Overseeing stock control and cleaning duties.
- Ensuring staff are adhering to infection control guidance and are competent in the use of PPE.
- Liaising with police/Department of Transport personnel based at the GCSU.
- Monitoring and safeguarding employee's mental and physical wellbeing.
- Ensuring staff act in such a way as to prevent the service from reputational harm.
- Acting as a representative for the GCSU when required (including dealing with Ministerial or press enquiries).
- Securing the premises and minimising the risk of damage to property or goods.
- Minimising unnecessary waste.
- Preparing a working rota, one week in advance, containing the appropriate skill mix to undertake all required duties.
- Safeguarding patient wellbeing.
- Liaising with Infection Prevention and Control and senior DHSC managers as necessary.



- Reporting the number of completed swabs to members of the Executive Team, and the 111 COVID Helpline, each day.
- Advising on the management of complainants or difficult patients.
- Ensuring changes to procedures are promptly communicated to all staff.
- Responding to requests, from the DHSC Executive Team, to extend working hours or implement change.
- Liaising with pertinent departments at Noble's Hospital (including microbiology, catering, porters etc.).
- Ensuring any maintenance needs are promptly addressed.
- Coordinating and authorising time sheets for students and bank staff.

## 2.2 Information Collector

Information Collectors (ICs) should don PPE as stipulated in Section 3 and Appendix 2. At commencement of duty they should collect blank Microbiology forms, information leaflets, clipboard and pen before making their way to the awaiting vehicles.

- Starting with the vehicle nearest the canopy, the IC must:
  - Stand (at least) one metre from the side of the vehicle.
  - Instruct the vehicle occupant to lower their window.
  - If there is more than one person in the vehicle, ascertain which one requires swabbing before positioning themselves at the appropriate side of the vehicle (only one window should be lowered at a time).
  - Try to maintain a safe distance from the occupants and avoid leaning against, or reaching into, the vehicle.
  - Explain their role and the screening process, providing reassurance where necessary.
  - Advise the patient of any potential delays.
  - Include the following details on the Microbiology form:
    - Full name.*
    - Date of birth.*
    - Address.*
    - Contact number.*
    - Car registration number (to assist the sample collector in locating the patient).*
    - Date.*
    - Any Coronavirus-related symptoms.*
    - Current or chronic illnesses.*
    - Details of recent off-island travel or potential exposure to COVID-19.*
  - Provide the patient with a self-isolation information leaflet before instructing the occupant(s) to remain in the vehicle with the windows closed.

- If the IC is concerned that their PPE may have become contaminated whilst collecting information, they must return to Garage 1 to change their equipment before moving on to the next vehicle.
- Depending on the volume of traffic, IC's should try to restrict the number of microbiology forms, completed at any one time, to five.
- Completed forms must be returned to the clean desk in Garage 2 and the Coordinator (Runner) informed.
- Face masks must be changed every half hour and PPE gowns changed at break times (i.e. every 45 - 60 minutes).

The IC must inform the Unit Manager of any vehicle occupants who:

- Have become acutely unwell whilst waiting.
- Are being aggressive, argumentative or non-compliant.

Information Collectors must not enter the corridor, or GCSU base, until they have safely discarded used PPE and cleansed their hands using alcohol-based sanitiser (minimum 70% base) or soap and water (in the utility room).

### 2.3 Sample Collectors

Sample Collectors must work in pairs comprising of one 'clean' nurse and one 'dirty' nurse. Staff allocated the role of Sample Collectors must don PPE as stipulated in Section 3 and Appendix 2.

- After collecting the clean sample pack from the desk in Garage 2, the clean nurse must:
  - Inspect the pack to ensure it contains a labelled Sigma Virocult/VCM swab/tube and second specimen bag.
  - Check the details on the tube correlate with those on the accompanying form.
  - Check the registration number on the Microbiology form against the car at the front of the queue.
- After indicating to the driver to position his/her vehicle under the canopy, they must ask them to lower their window and switch off the engine.
- The dirty nurse will approach the vehicle and ask for confirmation of the patient's name and date of birth. The clean nurse, remaining two metres from the vehicle, will check this against the details contained in the unused sample kit. If more than one occupant requires swabbing, this should **not** be carried out simultaneously.
- The dirty nurse must explain the procedure to the patient.
- The clean nurse will pass the Sigma Virocult/VCM tube and swab to the dirty nurse whilst maintaining a safe distance.
- The dirty nurse will approach the vehicle to obtain the specimen (see Appendix 3).
- Once retrieved, the dirty nurse places the swab into the tube, snaps off the handle and tightens the lid on the tube.

- The clean nurse opens the second specimen bag for the dirty nurse to drop the tube into.
- The bag is sealed, by the clean nurse, before being placed inside the bag containing the patient's details. The outer bag is then sealed before being placed in the red specimen box in Garage 2.
- The dirty nurse must inform patients that:
  - They will have to wait, a minimum of, 72 hours for results.
  - They will be informed of their result if negative **or** positive.
  - They must continue to self-isolate for the specified period.
- Vehicle occupants must be asked to close their windows before leaving the unit.
- The dirty nurse and clean nurse must change their masks every 30 minutes; and change other PPE at break times (i.e. every 45 - 60 minutes).

Sample Collectors must inform the Unit Manager of any vehicle occupants who:

- Have become acutely unwell whilst waiting.
- Are being aggressive, argumentative or non-compliant.

Sample Collectors must not enter the corridor, or GCSU base, until they have safely discarded used PPE and cleansed their hands using alcohol-based sanitiser (minimum 70% base) or soap and water (in the utility room).

#### **2.4 Coordinator (Runner)**

The staff member assigned Coordinator (or Runner) acts as the link between internal and external operations. They must wear disposable scrubs whilst undertaking their role. The Coordinator must:

- Transfer all completed Microbiology forms from Garage 2 to Admin 1 (Inputter) for processing.
- Ensure a supply of unused sample packs are available for Admin 2 (Labeller). Packs should be easily accessible and ready for use.
- Transfer labelled (clean) sample packs from the admin office to the clean desk in Garage 2 (checking to ensure the tube label matches the name on the request form).
- Inform the Sample Collectors of any additional risks or needs associated with the patient.
- Regularly collect completed PHE forms from Admin 3 (PHE Form Populator) and place them on the Specimen Store counter in alphabetical order.
- Deal with telephone queries or requests from co-workers.
- Transfer dirty samples from Garage 2 to the fridge in the Specimen Store. This should be done on a regular basis using the following process:
  - Wearing disposable gloves, close the lid on the red box and transfer it to the specimen store.

- Place an empty red box in Garage 2.
- Transfer the samples from the red box to the fridge. The NHS number on each sample must be checked against the PHE form before it is placed in the fridge (a member of the Admin team can assist by reading the number from the corresponding form).
- Record the NHS number, along with the time, on the daily screening list.
- Place the checked PHE forms in a clear plastic bag to accompany the specimens.
- Dispose of gloves, at the end of the process, and ensure hands are cleansed with soap and water or alcohol-based sanitiser (minimum 70% base).
- Ensure clean, unlabelled packs are made up ready for the following day (each containing two Sigma Virocult/VCM swab/tubes and one folded specimen bag).
- Coordinate refreshment breaks for administrative staff.

When the porters arrive, any specimens held in the fridge, should be carefully transferred into a red box (along with the bagged PHE forms) and the lid secured. Gloves must be worn for this procedure.

The porter will then transfer the swabs to Noble's Microbiology Department for testing. He/she should be asked to return a clean red box when next visiting the GCSU.

## 2.5 Admin 1 (Inputter)

Admin 1 is responsible for locating patients on Medway and generating ICE labels. Before commencing their role, they must log on to the computer (nearest the label printer) with the Username: **nopan21** and Password: **CallCentre111\*** and open the Medway system (using the same username and password).

Upon receiving a completed Microbiology form from the Coordinator, Admin 1 should:

- Enter the patient's date of birth and locate them from the list (if they cannot be found, search using the name instead). If the patient cannot be located by date of birth, address or name; the form must be returned (via the Coordinator) to the Information Collector to request confirmation of details.
- Request a COVID-19 ICE form and input details of the patient's symptoms (any details proving difficult to decipher should be brought to the attention of the Coordinator for clarification).
- Print the ICE form and pass it to Admin 2 - along with the original Microbiology form.
- Assist with checking in dirty samples or making up new packs.

## 2.6 Admin 2 (Labeller)

Admin 2 is responsible for labelling samples and forms (PHE and Microbiology). Upon receiving the ICE and Microbiology forms they must:

- Remove four stickers from the ICE form, placing one each on the Sigma Virocult/VCM tubes, the PHE form and the Microbiology form.
- Return the labelled tube to the opened swab packet; and place back into the clean sample pack.
- Fold the ICE form and place it, along with the Microbiology form, in the sample pack sleeve (with the patient's NHS number visible).
- Inform the Coordinator that the pack is ready for use.
- Pass the labelled PHE form to Admin 3.
- Assist with checking in dirty samples or making up new packs.

## 2.7 Admin 3 (PHE Form Populator)

Admin 3 is responsible for transferring the details contained on the patient's 111 COVID screening tab to the PHE form. They must:

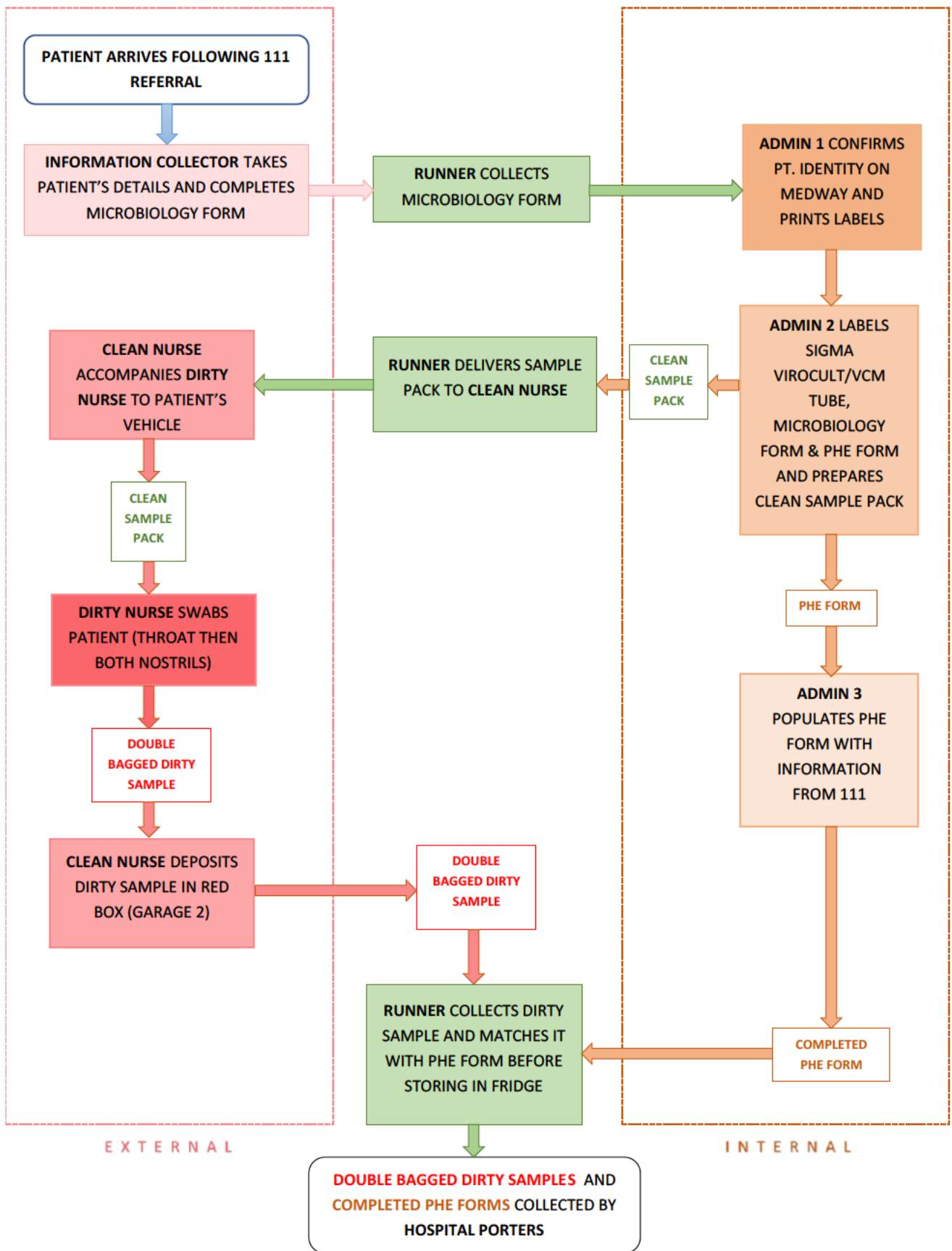
- Log on to the computer, next to the Konica Minolta printer, using the Username: **nopan21** and Password: **CallCentre111\*** before logging on to the Medway system (using the same user and password).
- Upon receiving a labelled PHE form from Admin 2, locate the patient and their 111 COVID screening tab.
- Populate the PHE form using the information contained in the screening tab.
- Assist with checking in dirty samples or making up new packs.

## 2.8 Security/Traffic Flow

Two Department of Transport employees are on duty each day. They are responsible for preventing unauthorised vehicles from entering the slip road and helping maintain the flow of traffic through the screening unit.

At least one police officer is also in attendance at the GCSU to respond to any incidents involving non-compliance or aggressive behaviour. In an emergency, police must be summonsed using a 999 call.

## 2.9 GCSU Process



### 3 PERSONAL PROTECTIVE EQUIPMENT (PPE)

The level of PPE required by staff is dictated by exposure to risk. The following guidelines indicate the level of protection *routinely* required to undertake each role. Additional duties may require increased protection and must be risk assessed beforehand.

	SCRUBS	GOWN	SURGICAL FACE MASK	GOGGLES OR VISOR	GLOVES	APRON
UNIT MANAGER	✓*					
INFORMATION COLLECTOR	✓	✓	✓	✓	✓	
SAMPLE COLLECTOR - DIRTY	✓	✓	✓	✓	✓	
SAMPLE COLLECTOR - CLEAN	✓		✓		✓	✓
COORDINATOR (RUNNER)	✓				✓**	
ADMIN 1						
ADMIN 2						
ADMIN 3						
SECURITY/TRAFFIC FLOW			✓		✓	

\*Minimum requirement

\*\*When handling used sample packs

#### 3.1 Frequency of PPE Changes

- If PPE is contaminated or damaged it must be changed at the soonest opportunity.
- Surgical face masks must be changed every half hour.
- PPE must be changed at break times (i.e. every 45 - 60 minutes).

## 4 EMERGENCIES

### 4.1 Potential Threats to Personal Safety

Patients (or other vehicle occupants) who are hostile or engaging in inappropriate behaviour (including photographing or recording events) must be reported to the Unit Manager.

The Unit Manager will do his/her best to de-escalate the situation and (if pertinent) should consider the following options:

- Moving the patient's position in the queue to expedite the process or delay swabbing (i.e. to allow a 'cooling off' period).
- Offer a home visit by the Community Screening Team.

If the patient is accompanied, they may be asked if they would prefer another person (in the vehicle) to carry out the screening process. Patients must, however, be informed of the risks; and the person swabbing must be supervised/instructed throughout.

If the UM is unable to de-escalate the situation, the incident will be referred to the police. The police must also be asked to attend if a patient (or vehicle occupant):

- Attempts to grab or assault any member of staff.
- Makes threats towards the staff member.
- Threatens to leave the car.

Vehicle occupants who continue to act in an aggressive manner may be asked to leave the unit, and return the following day; if the Unit Manager feels their behaviour poses a threat to staff.

### 4.2 Physical Assault or Reckless Behaviour

To ensure the wellbeing of employees, the GCSU service will be suspended if any member of staff:

- Is intentionally grabbed or restrained.
- Is physically assaulted (including being spat at or deliberately coughed on).
- Has his or her PPE deliberately removed or destroyed.

Staff who have experienced any of the above are at high risk of contamination and must (along with any colleagues coming to their aid) withdraw to the Decontamination Room in Garage 1 (see Section 4.3). The Coordinator/Runner should be instructed to call the police.

In the event of an individual stepping out of their car, staff must:

- Move to a safe distance (a minimum of two meters).
- Demand that the person gets back into the car.



If they refuse to get back into their vehicle, all staff must withdraw to Garage 2 and lower the shutters. If time allows, the occupants of other vehicles should be visually instructed to lock their doors; however, this act must not delay staff from seeking safety themselves.

If there is insufficient time to lower the shutters, staff should assemble in the corridor and lock the outer door. The Coordinator/Runner should be instructed to call the police.

#### 4.3 Contamination

Staff who have (or are concerned they may have) become contaminated must immediately relocate to the Decontamination Room in Garage 1.

- Screening may be halted if necessary.
- The staff member should be accompanied by a colleague, wearing protective equipment, who will collect and dispose of the contaminated PPE.
- The affected staff member must wash themselves using soap and water. Jay cloths and white paper cloths (for drying) can be found in the Decontamination Pack along with a clean set of scrubs.
- If personal clothing has become contaminated, it should be sealed in a red (soluble) and placed inside a clear plastic bag. Arrangements must then be made for it to be laundered at Noble's Hospital. Staff must be mindful of the fact that the hospital laundering process is not suitable for all clothing types.
- Advice must be sought from Occupational Health and/or Public Health on the need to undergo COVID-19 testing and commence isolation.
- The wash basin and surrounding areas must be thoroughly cleansed using Chlor-Clean solution\* following use.
- The affected staff member must be given emotional support and checked on later (via telephone or Whatsapp) by the Unit Manager.

*\*Made up of one Chlor-Clean tablet per litre of cold water.*

#### 4.4 Medical Emergencies

GCSU staff should take great care when dealing with medical emergencies involving vehicle occupants and must wear full PPE before approaching the casualty.

In the event of a vehicle occupant suffering a cardiac arrest, staff must:

- Call for an emergency ambulance, informing them that the patient is a high risk for COVID-19.
- Retrieve the defibrillator from the Grandstand (the call handler will supply the access code).
- Utilise the defibrillator to deliver a shock (if indicated by the AED).

Contrary to standard practice (and AED instructions) chest compressions must **not** be initiated due to the potential for contaminated air being expelled from the patient's nose and mouth. Should occupants (from the same vehicle) wish to commence CPR, staff must retreat to a safe distance to observe and provide guidance where necessary.

#### **4.5 Fire**

In the event of fire, GCSU admin staff must leave the building via the back entrance and assemble on the grassed area near the car park. Staff working in the garage should exit via the garage and make their way around to the assembly point at the rear. The Unit Manager must use the daily attendance sheet to ensure all staff are safely accounted for.

Should a patient's vehicle catch fire whilst awaiting screening, staff should:

- Instruct the occupants to exit the vehicle and to stand in a specified area, away from the hazard and staff.
- Place an emergency call to the fire service, informing them that the vehicle occupants are being screened for COVID-19.
- Summon the police (in an emergency, police based at GCSU, should be contacted using a 999 call).
- Instruct other drivers to move their vehicles away from the hazard. Occupants must be discouraged from exiting their vehicles unless life is at risk. In such instances, they must be instructed to stand in a designated area away from others.

## 5 STAFF SICKNESS

Due to the highly infectious nature of COVID-19, staff must inform one of the Unit Managers if:

- They develop symptoms associated with Coronavirus infection.
- A member of their household has symptoms of (or has tested positive for) COVID-19.

Staff who develop symptoms whilst on duty must immediately inform the Unit Manager and leave the premises as soon as possible. Advice must be sought from Occupational Health and/or Public Health on the need to undergo COVID-19 testing and commence isolation. The DHSC Executive Team must also be made aware of the potential disruption to service.

Screening will be suspended to allow for cleaning of the GCSU.

## 6 MISCELLANEOUS

### 6.1 Patient Identifiable Information

Surplus paperwork containing patient identifiable information must be placed in the 'Confidential Shredding' folder. The contents of the folder will be taken to Crookall House (or Keyll Darree) where they will be shredded.

### 6.2 Cleaning Rota

The Unit Manager is responsible for ensuring the department is cleaned at the end of every shift.

- Clinical and domestic waste bags must be sealed and placed in the bins in Garage 1.
- Chlor-Clean solution or Sani-Cloth(Chlor) should be used to wipe down all surfaces including desks, chairs, telephones and worktops.
- Door handles must also be wiped.

### 6.3 Specimen Refrigerator

The specimen fridge must be cleaned at the end of each shift (or more frequently if there is increased risk of contamination) using a Chlor-Clean solution or Sani-Cloth(Chlor). This should then be recorded on the fridge daily log.

The fridge must only be cleaned when completely empty. If specimens are held overnight, cleaning should be carried out the following morning once the samples have been transferred to hospital.

### 6.3.1 Temperature Checks

The refrigerator must be checked to ensure the appropriate temperature has been maintained (+2 - +8°). The following must be recorded daily:

- Maximum temperature
- Minimum temperature
- Current temperature

The Microbiology Department must be contacted for advice in the event of refrigerator malfunction.

### 6.4 **General Household Duties**

- General cleaning duties must be shared between members of the GCSU.
- The general waste and clinical waste bins, located in Garage 1, are emptied daily by the porters (access is via the garage door/shutter).

## 7 **STOCK CONTROL/SUPPLIES**

Due to the ongoing review of services, stock should be requested twice weekly and must not be ordered in bulk.

<b>Goods</b>	<b>Supplier</b>	<b>Distribution</b>
PPE	Noble's Radiology Dept.	Ask porters to collect and deliver
Sigma Virocult/VCM swab/tubes and specimen bags	Microbiology Dept.	As above
All other hospital supplies	Stores	As above
Stationery	Crookall House/Keyll Darree	Arranged by staff

Refreshments are provided by Noble's Catering Department and delivered daily by the porters. The Catering Dept. must be given a day's notice should requirements change.

## 8 PREMISES

### 8.1 Maintenance

Although the building remains the property of the Department for Enterprise, any maintenance work or alterations must be requested through the Estates Department at Noble's Hospital.

### 8.2 Security

Three keys have been issued by the DoE. Before leaving the building at the end of a shift, the Unit Manager must ensure:

- All windows are closed and secured.
- Portable heaters are unplugged.
- Garage shutters are down.
- All doors are locked.
- All lights are turned off.

## 9 FURTHER RESOURCES

The following IOM Government resources are available:

Infection Prevention and Control:

<https://www.gov.im/about-the-government/departments/health-and-social-care/guidance-centre/disease-control/>

Coronavirus: COVID-19

<https://covid19.gov.im/>

Health and Safety at Work Inspectorate:

<https://www.gov.im/about-the-government/departments/environment-food-and-agriculture/environment-safety-and-health-directorate/health-and-safety-at-work-inspectorate/>

Data Protection and GDPR on the Isle of Man:

<https://www.gov.im/about-the-government/data-protection-gdpr-on-the-isle-of-man/>

Fairness at Work:

<https://hr.gov.im/fairness-at-work/>

## 10 REFERENCES

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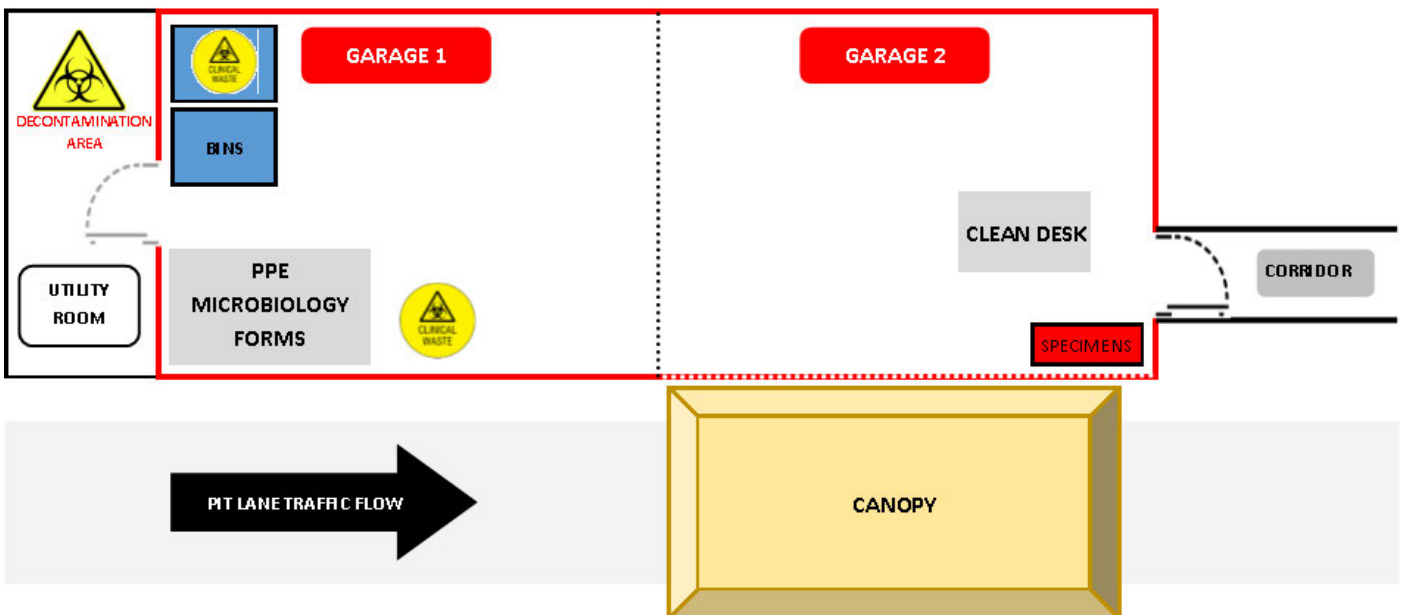
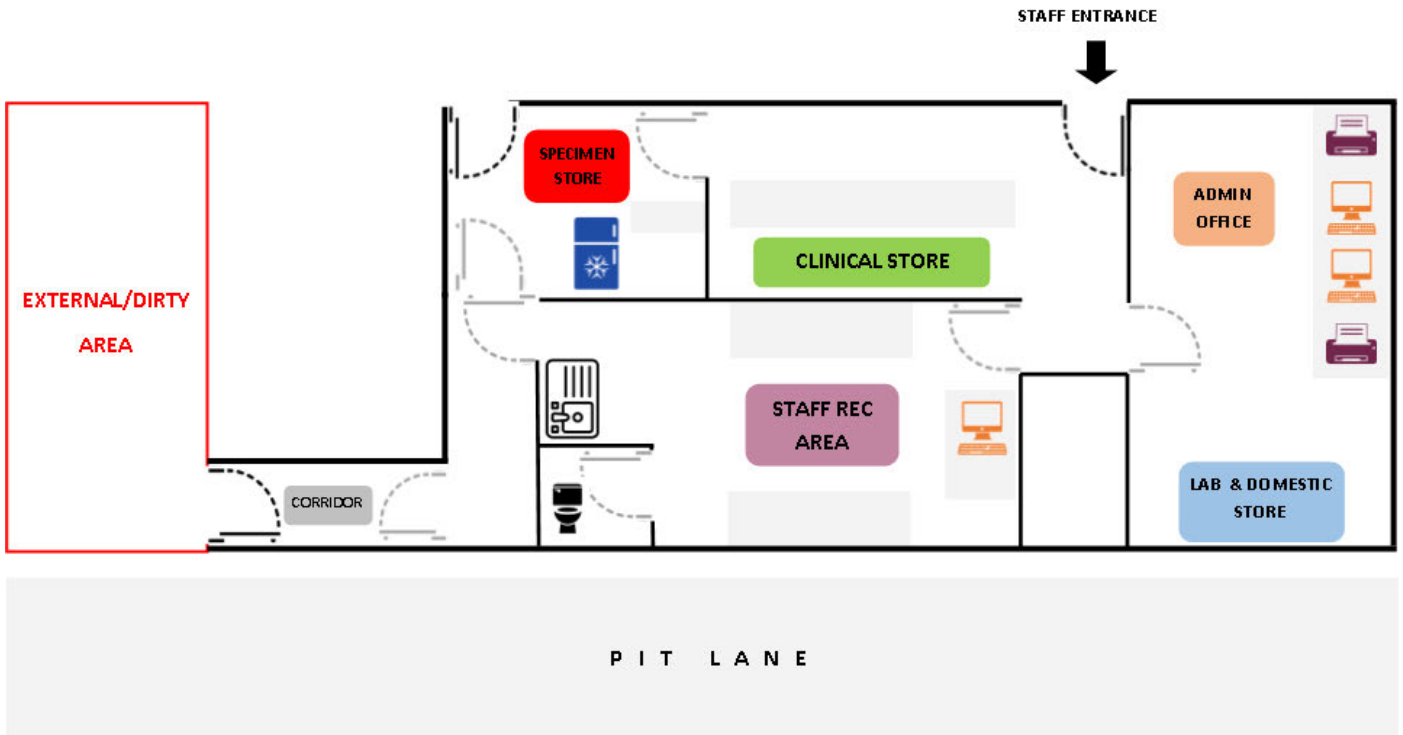
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APPENDIX 1

GRANDSTAND COVID-19 SCREENING UNIT LAYOUT



## APPENDIX 2

\*\*\*This is for reference only and does **not** replace the need for training in PPE use\*\*\*



# Putting on personal protective equipment (PPE) for non-aerosol generating procedures (AGPs)\*

Please see donning and doffing video to support this guidance: [https://youtu.be/-GncQ\\_ed-9w](https://youtu.be/-GncQ_ed-9w)

## Pre-donning instructions:

- Ensure healthcare worker hydrated
- Remove jewellery
- Tie hair back
- Check PPE in the correct size is available

- 1** Perform hand hygiene before putting on PPE.



- 2** Put on apron and tie at waist.



- 3** Put on facemask – position upper straps on the crown of your head, lower strap at nape of neck.



- 4** With both hands, mould the metal strap over the bridge of your nose.



- 5** Don eye protection if required.



- 6** Put on gloves.



\*For the PPE guide for AGPS please see: [www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures](https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures)

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Public Health  
England

# Taking off personal protective equipment (PPE) for non-aerosol generating procedures (AGPs)\*

Please see donning and doffing video to support this guidance: [https://youtu.be/-GncQ\\_ed-9w](https://youtu.be/-GncQ_ed-9w)

• PPE should be removed in an order that minimises the risk of self-contamination

• Gloves, aprons (and eye protection if used) should be taken off in the patient's room or cohort area

**1** Remove gloves. Grasp the outside of glove with the opposite gloved hand; peel off. Hold the removed glove in the remaining gloved hand.



Slide the fingers of the un-gloved hand under the remaining glove at the wrist.

Peel the remaining glove off over the first glove and discard.



**2** Clean hands.



**3** Apron. Unfasten or break apron ties at the neck and let the apron fold down on itself.



Break ties at waist and fold apron in on itself – do not touch the outside – **this will be contaminated.** Discard.



**4** Remove eye protection if worn. Use both hands to handle the straps by pulling away from face and discard.



**5** Clean hands.



**6** Remove facemask once your clinical work is completed.



Untie or break bottom ties, followed by top ties or elastic, and remove by handling the ties only. Lean forward slightly. Discard. DO NOT reuse once removed.

**7** Clean hands with soap and water.



\*For the PPE guide for AGPs please see: [www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures](http://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures)

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## APPENDIX 3

## THROAT AND NASAL SWABBING FOR COVID-19

\*\*\*This is for reference only and does **not** replace the need for training prior to undertaking throat and nasal swabbing\*\*\*

- Don PPE as per Appendix 2.
- Confirm patient's identity and check details match labelled tubes.
- Explain procedure to patient.
- Throat swab collection:  
Remove swab from packaging and insert into patient's mouth, swabbing the posterior pharynx and tonsillar areas. Avoid the tongue and cheek (see diagram 1).  
*Be aware that process may initiate gag reflex or cause patient to cough.*
- The same swab is then used to collect the nasal specimen:  
Tilt the patient's head back 70 degrees.  
While gently rotating the swab, insert it less than one inch into nostril - until resistance is met at turbinates (see diagram 2).  
Rotate the swab several times against nasal wall and repeat in other nostril.  
*Be aware that process may cause patient to sneeze.*
- Place the tip of swab into sterile transport media tube and break off applicator stick.

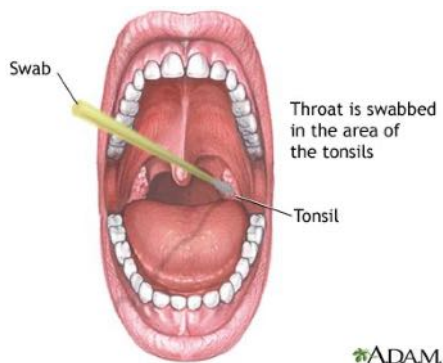


Diagram 1: Throat swabbing

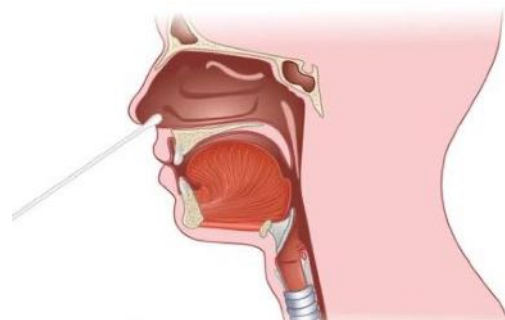


Diagram 1: Nasal swabbing

# GRANDSTAND COVID-19 SWABBING UNIT

## STANDARD OPERATING PROCEDURE

Amanda Phillips  
April 2020

**STANDARD OPERATING PROCEDURE FOR THE  
GRANDSTAND COVID-19 SWABBING UNIT**

<b>Title</b>	Standard Operating Procedure for the Grandstand COVID-19 Swabbing Unit
<b>Author</b>	Amanda Phillips, Care Quality & Safety Coordinator for Community Health Services
<b>Date of implementation</b>	11 <sup>th</sup> May 2020 (Version 2)
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<b>Changes since previous version</b>	<ul style="list-style-type: none"> <li>• Changes to Coordinator, Admin 1, 2 and 3 roles to reflect introduction of EW sheet, confirmation slip and specimen checklist.</li> <li>• Changes to Admin 3 role to reflect discontinuation of PHE form and introduction of Essential Worker spreadsheet.</li> <li>• Changes to PPE information.</li> <li>• Placement Prerequisites section added.</li> <li>• Safety information on the use of Chlor-Clean added (Appendix 4).</li> <li>• Inclusion of information on resetting the refrigerator after checking temperature.</li> <li>• Inclusion of further information on PPE use and laundering of reusable scrubs.</li> <li>• Additional information on protocol for large bin emptying (by porters).</li> <li>• Amendment to fire procedure.</li> <li>• Change to SOP review period.</li> <li>• Change to screening/working times.</li> <li>• Swabbing diagrams changed.</li> </ul>
<b>Ratified by</b>	<p>Due to the temporary suspension of all non-essential DHSC committees, this SOP has been agreed by: Amanda Phillips, Department of Health and Social Care (DHSC) Michael Fleming, Department of Education, Sport and Culture (DESC) Bernadette Devlin (DESC) Vicky Taylor (DESC) and ratified by: Cath Quilliam (Director of Nursing) Bronze Command</p>
<b>Review date</b>	Monthly (next due 11/6/20)

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## 1 INTRODUCTION

The Grandstand COVID-19 Swabbing Unit (GCSU) opened on the 20<sup>th</sup> March 2020, in response to the global Coronavirus pandemic; and provides a drive-through screening service for symptomatic patients who have been assessed and referred by the 111 Helpline. Results generated by this service will provide vital epidemiological information to:

- Determine the prevalence of COVID-19 on the island.
- Help predict disease patterns and subsequent health and social care needs.
- Minimise the impact on DHSC services and hospital bed availability.

The GCSU is based at the TT Grandstand. Administrative duties are undertaken in the Race Office, with screening carried out on the pit lane in front of garages 1 and 2 (see Appendix 1).

### 1.1 Scope

This Standard Operating Procedure is applicable to all IOM Government employees deployed at the GCSU and will remain effective until the unit is disbanded.

### 1.2 Policies

This SOP must be used in conjunction with current IOM Government legislation pertaining to:

- Infection Control and Prevention
- Health and Safety at Work
- Fairness at Work
- Data Protection

Registered health professionals must continue to practice in accordance with standards set by their regulatory body.

## 2 PROCEDURE

The GCSU operates seven days a week, screening patients between 10:00hrs and 12:00hrs. Staff commence duty at 09:30 and finish at 12.30pm. Screening hours may be extended at short notice to accommodate demand.

The GCSU requires a minimum of 7 staff to function effectively:

2 sample collectors (Registered Nurses, Allied Health Professionals, senior Healthcare Assistants or student nurses).

1 information collector (RN's or Senior HCA's).

2 administration staff.

1 coordinator/runner (RN or Senior HCA).

1 Unit Manager.

Additional information collectors and sample collectors will be required should swabbing numbers increase.

### 2.1 Employment Prerequisites

#### 2.1.1 Declaration of health conditions

Prior to commencing employment at the GSCU, employees must first confirm that they do not suffer from any condition which places them at increased risk. An up-to-date list on such conditions can be viewed at the following Gov.UK site:

<https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19>

#### 2.1.2 Training

- PPE training (including donning and removal procedures) must be undertaken prior to carrying out any role involving close patient contact.
- Sample Collectors must also undergo training in oropharyngeal and mid-turbinate nasal swabbing techniques.

Training for the above must be delivered by a member of the Infection Prevention and Control Team (IP&C) prior to commencement of work.

### 2.2 Unit Manager

Unit Managers are responsible for the daily running of the GCSU, including student welfare, staffing and communication. The role includes:

- Unlocking the swabbing unit and preparing it for use.
- Ensuring all employees sign in.
- Allocating daily roles and ensuring employees wear the appropriate PPE.

- Facilitating meetings prior to (and following) each shift to ensure staff are confident to undertake the duties expected of them; and to discuss any problem areas.
- Overseeing stock control and cleaning duties.
- Ensuring staff adhere to infection control guidance and are competent in the use of PPE.
- Liaising with police/Department of Transport personnel based at the GCSU.
- Monitoring and safeguarding employee's mental and physical wellbeing.
- Ensuring staff act in such a way as to prevent the service from reputational harm.
- Acting as a representative for the GCSU when required (including dealing with Ministerial or press enquiries).
- Securing the premises and minimising the risk of damage to property or goods.
- Minimising unnecessary waste.
- Preparing a working rota, one week in advance, containing the appropriate skill mix to undertake all required duties.
- Safeguarding patient wellbeing.
- Liaising with Infection Prevention and Control and senior DHSC managers as necessary.
- Reporting the number of completed swabs to members of the Executive Team, and the 111 COVID Helpline, each day.
- Advising on the management of complainants or difficult patients.
- Ensuring procedural changes are promptly communicated to all staff.
- Responding to requests, from the DHSC Executive Team, to extend working hours or implement change.
- Liaising with pertinent departments at Noble's Hospital (including microbiology, catering, porters etc.).
- Ensuring any maintenance needs are promptly addressed.
- Coordinating and authorising time sheets for students and bank staff.

### 2.3 Information Collector

Information Collectors (ICs) should don PPE as stipulated in Section 3 and Appendix 2. At commencement of duty they should collect blank Microbiology forms (standard and Essential Worker forms), information leaflets, clipboard and pen before making their way to the awaiting vehicles.

- Starting with the vehicle nearest the canopy, the IC must:
  - Stand (at least) one metre from the side of the vehicle.
  - Instruct the vehicle occupant to lower their window.
  - If there is more than one person in the vehicle, ascertain which one requires swabbing before positioning themselves at the appropriate side of the vehicle (only one window should be lowered at a time).
  - Try to maintain a safe distance from the occupants and avoid leaning against, or reaching into, the vehicle.



- Explain their role and the screening process, providing reassurance where necessary.
- Advise the patient of any potential delays.
- Ascertain if the patient is an essential worker and use the appropriate Microbiology form to document the following details:

*Full name.*

*Date of birth.*

*Address.*

*Contact number.*

*Car registration number (to assist the sample collector in locating the patient).*

*Date.*

*Any Coronavirus-related symptoms.*

*Current or chronic illnesses.*

*Details of potential exposure to COVID-19.*

*Workplace and role (for Essential Workers only)*

- Provide the patient with a self-isolation information leaflet before instructing the occupant(s) to remain in the vehicle with the windows closed.
  - If the IC is concerned that their PPE may have become contaminated whilst collecting information, they must return to Garage 1 to change their equipment before moving on to the next vehicle.
  - Depending on the volume of traffic, IC's should try to restrict the number of microbiology forms, completed at any one time, to four; and should number them to ensure they remain in car order.
  - Completed forms must be returned to the clean desk in Garage 2 and the Coordinator (Runner) informed.
  - Face masks may remain in situ for up to six hours providing there are no contamination concerns.

The IC must inform the Unit Manager of any vehicle occupants who:

- Have become acutely unwell whilst waiting.
- Are being aggressive, argumentative or non-compliant.

Information Collectors must not enter the corridor, or GCSU base, until they have safely discarded used PPE and cleansed their hands using alcohol-based sanitiser (minimum 70% base) or soap and water (in the utility room).

## 2.4 Sample Collectors

Sample Collectors must work in pairs comprising of one 'clean' nurse and one 'dirty' nurse. Staff allocated the role of Sample Collectors must don PPE as stipulated in Section 3 and Appendix 2.

- After collecting the clean sample pack from the desk in Garage 2, the clean nurse must:

- Inspect the pack to ensure it contains a labelled Sigma Virocult/VCM swab/tube (in date) and second specimen bag.
- Check the details on the tube correlate with those on the accompanying form.
- Check the registration number on the Microbiology form against the car at the front of the queue.
- After indicating to the driver to position his/her vehicle under the canopy, they must ask them to lower their window and switch off the engine.
- The dirty nurse will approach the vehicle and ask for confirmation of the patient's name and date of birth. The clean nurse, remaining two metres from the vehicle, will check this against the details contained in the unused sample kit. If more than one occupant requires swabbing, this should **not** be carried out simultaneously.
- The dirty nurse must explain the procedure to the patient.
- The clean nurse will pass the Sigma Virocult/VCM tube and swab to the dirty nurse whilst maintaining a safe distance.
- The dirty nurse will approach the vehicle to obtain the specimen (see Appendix 3).
- Once retrieved, the dirty nurse places the swab into the tube, snaps off the handle and tightens the lid on the tube.
- The clean nurse opens the second specimen bag for the dirty nurse to drop the tube into.
- The bag is sealed, by the clean nurse, before being placed inside the bag containing the patient's details. The outer bag is then sealed before being placed in the red specimen box in Garage 2.
- The dirty nurse must inform patients that:
  - They will be informed of their result, whether negative **or** positive, within 24 to 48 hours.
  - They must continue to self-isolate until told otherwise.
- Patients requesting information on COVID-19 (including isolation periods and fitness to return to work) must be advised to ring 111.
- Vehicle occupants must be asked to close their windows before leaving the unit.
- The dirty nurse and clean nurse must change their gloves and apron after each patient contact or procedure. Face masks may remain in situ for up to six hours providing there are no contamination concerns.

Sample Collectors must inform the Unit Manager of any vehicle occupants who:

- Have become acutely unwell whilst waiting.
- Are being aggressive, argumentative or non-compliant.

Sample Collectors must not enter the corridor, or GCSU base, until they have safely discarded used PPE and cleansed their hands using alcohol-based sanitiser (minimum 70% base) or soap and water (in the utility room).

## 2.5 Coordinator (Runner)

The staff member assigned Coordinator (or Runner) acts as the link between internal and external operations. They must wear disposable scrubs whilst undertaking their role. The Coordinator must:

- Transfer all completed Microbiology forms from Garage 2 to Admin 1 (Inputter) for processing.
- Ensure a supply of unused sample packs are available for Admin 2 (Labeller). Packs should be easily accessible and ready for use.
- Transfer labelled (clean) sample packs from the admin office to the clean desk in Garage 2 (checking to ensure the tube label matches the name on the request form).
- Inform the Sample Collectors of any additional risks or needs associated with the patient.
- Deal with telephone queries or requests from co-workers.
- Transfer specimens (dirty samples) from Garage 2 to the fridge in the Specimen Store. This should be done on a regular basis using the following process:
  - Collect the Specimen Checklist from Admin 1 and place it on the counter in the Specimen Store.
  - Wearing disposable gloves: close the lid on the red box (containing samples) in Garage 2; before transferring it to the Specimen Store (replace with a clean red box).
  - Transfer the samples from the red box to the fridge. The name and DoB on each sample must be checked and ticked off on the Specimen Checklist before being placed in the fridge (a member of the Admin team will assist).
  - Record the time the sample was placed in the fridge on the Specimen Checklist.
  - Dispose of gloves, at the end of the process, and ensure hands are cleansed with soap and water or alcohol-based sanitiser (minimum 70% base).
- Ensure clean, unlabelled packs are made up ready for the following day (each containing one Sigma Virocult/VCM swab/tube and one folded specimen bag).
- Ensure appropriate resources are available for the following day (i.e. forms, Virocult/VCM tubes, labels and specimen bags)
- Coordinate refreshment breaks for administrative staff.

When the porters arrive, any samples held in the fridge, should be carefully transferred into a red box. A confirmation slip, containing the number of samples being sent to the lab, must be completed and placed in the box before securing the lid. Gloves must be worn for this procedure.

The porter will then transfer the swabs to Noble's Microbiology Department for testing. He/she should be asked to return a clean red box when next visiting the GCSU.

## **2.6 Admin 1 (Patient identification)**

Admin 1 is responsible for locating patients on Medway and generating ICE labels. Before commencing their role, they must log on to the computer with the Username: **nopan21** and Password: **CallCentre111\*** and open the Medway system (using the same username and password).

Upon receiving a completed Microbiology form from the Coordinator, Admin 1 should:

- Enter the patient's date of birth and locate them from the list (if they cannot be found, search using the name instead). If the patient cannot be located by date of birth, address, or name; the form must be returned (via the Coordinator) to the Information Collector to request confirmation of details.
- Check the patient's COVID tab (on Medway) to ensure they have been referred for a test.\*
- Add the patient's Hospital Number to the Microbiology form.
- Request a COVID-19 ICE form and input details of the patient's symptoms (any details proving difficult to decipher should be brought to the attention of the Coordinator for clarification).
- Print the ICE form and pass it to Admin 2 - along with the original Microbiology form.
- If patient is an asymptomatic staff member (Essential Worker), add ID label to an EW form and alert Admin 3.
- Assist with checking in dirty samples or making up new packs.

\* Patients with no COVID tab on Medway, or those whose assessment concluded with no test being necessary; cannot be swabbed. Instead, the Microbiology form must be handed back to the Coordinator and the patient informed of the discrepancy before being asked to leave the GCSU.

## 2.7 Admin 2 (Labeller)

Admin 2 is responsible for labelling sample tubes and forms. Upon receiving the ICE and Microbiology forms they must:

- Remove labels from the ICE form, placing one on the Sigma Virocult/VCM tube, one on the Specimen Checklist and one on the Microbiology form. If the patient is an Essential Worker a label must also be added to an EW slip, along with the patients contact number, workplace, and role.
- Add the Hospital Number to the label on the Specimen Checklist.
- Return the labelled tube to the opened swab packet, and place back into the clean sample pack.
- Fold the ICE form and place it, along with the Microbiology form, in the sample pack sleeve (with the patient's NHS number visible).
- Inform the Coordinator that the pack is ready for use.
- Forward any completed Essential Worker slips to Admin 3.
- Assist with checking in dirty samples or making up new packs.

## 2.8 Admin 3 (Attendance Spreadsheet)

Admin 3 is responsible for populating the daily attendance spreadsheet (Excel). They should:

- Log on to the computer using the Username: **nopan21** and Password: **CallCentre111\*** before logging on to the Medway system (using the same user and password).
- Retrieve the black USB from the locked blue box and open up the Daily Attendance folder and excel spreadsheet (the password for which can be found in the folder name).
- Use the Specimen Checklist to populate the spreadsheet with the following information:
  - Non-essential workers:  
*Surname, first name, hospital number, sex, and date of birth.*
  - Essential workers:  
*Place of work, role, surname, first name, hospital number, sex, date of birth, and contact number.*
- Email the spreadsheet, at the end of the session, to [Suzanne.graham@gov.im](mailto:Suzanne.graham@gov.im) and [Rebecca.dooley@gov.im](mailto:Rebecca.dooley@gov.im)
- Check to ensure the email has been sent before closing the spreadsheet without saving it.\*
- Return the USB to the blue box for safekeeping.
- Assist with checking in dirty samples or making up new packs.

\*If there is a problem sending the email, a temporary copy of the spreadsheet may be saved (on the USB) using the date as the file name. This copy must, however, be deleted once the spreadsheet has been successfully emailed.

## 2.9 Security/Traffic Flow

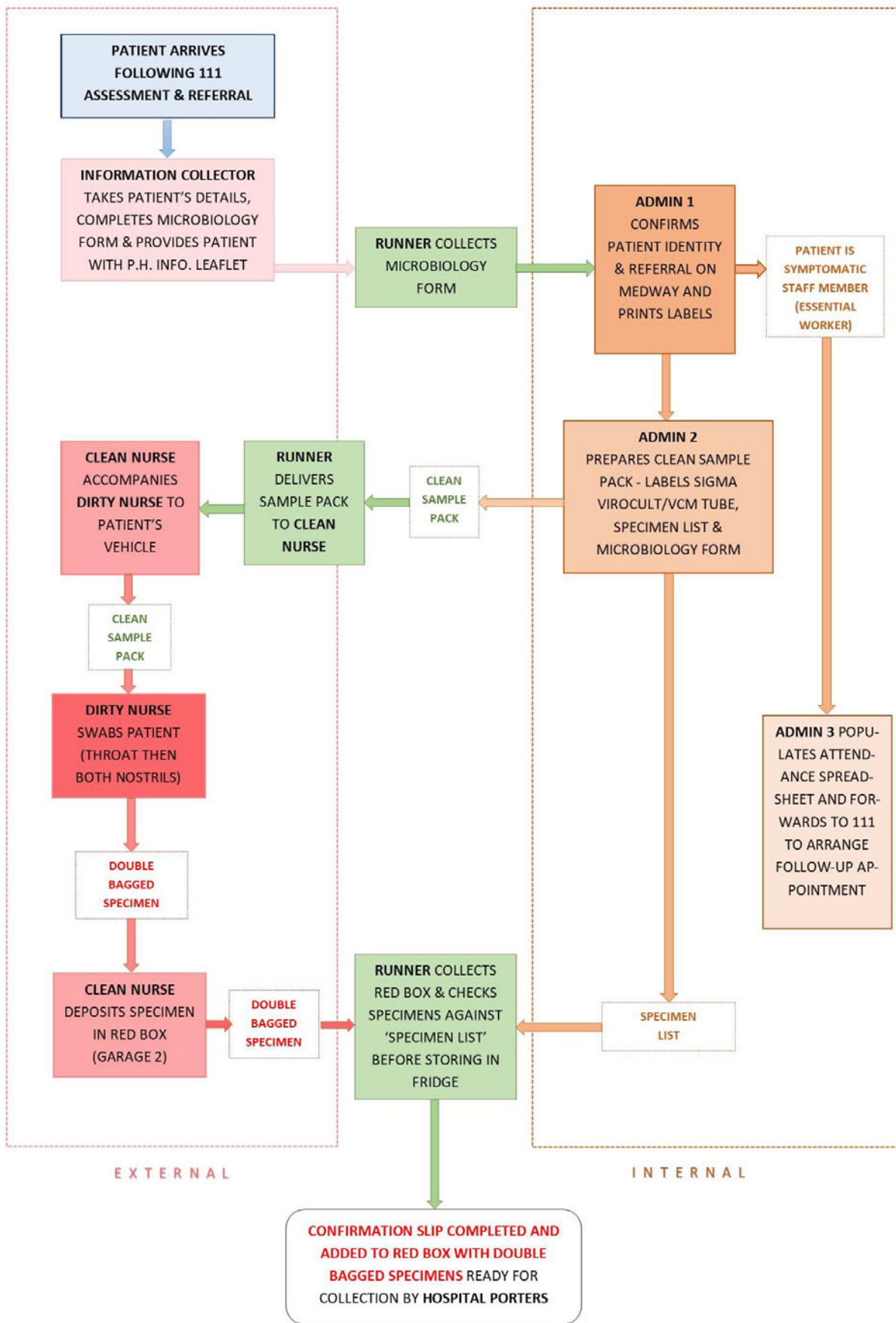
Two Department of Transport employees are on duty each day. They are responsible for:

- Preventing unauthorised vehicles from entering the slip road.
- Checking with the vehicle occupants, upon arrival, to ensure they have been referred via 111.\*
- Maintaining the flow of traffic through the unit.

\*Vehicle occupants who have not been referred via 111 cannot be tested and must be politely asked to leave the premises. Those refusing to do so must be brought to the attention of the Unit Manager.

At least one police officer is also in attendance at the GCSU to respond to any incidents involving non-compliance or aggressive behaviour. In an emergency, police must be summonsed using a 999 call.

## 2.10 GCSU Process



### 3 UNTOWARD INCIDENTS AND RISK MANAGEMENT

#### 3.1 Incident Reporting

All minor/moderate incidents must be reported to the Unit Manager and logged on the Untoward Incident log (Appendix 5) as soon as possible. Serious incidents (or those resulting in harm) must be immediately reported to the Unit Manager who will then record the event on Datix and inform the Director of Nursing.

#### 3.2 Risk Register

The GCSU's Risk Register is maintained by the Unit Manager. Staff must inform the Unit Manager if:

- The severity of a risk (already on the register) increases.
- A new risk is identified within the department.

The Untoward Incident log and GCSU Risk Register can be found on the black USB.

### 4 PERSONAL PROTECTIVE EQUIPMENT (PPE)

The level of PPE required by staff is dictated by exposure to risk. The following guidelines indicate the level of protection required to undertake each role. Additional duties may require increased protection and must be risk assessed beforehand.

	SCRUBS	GOWN	SURGICAL FACE MASK	GOGGLES OR VISOR	GLOVES	APRON
UNIT MANAGER	✓*					
INFORMATION COLLECTOR	✓		✓	✓	✓	✓
SAMPLE COLLECTOR - DIRTY	✓		✓	✓	✓	✓
SAMPLE COLLECTOR - CLEAN	✓		✓		✓	✓
COORDINATOR (RUNNER)	✓				✓**	
ADMIN 1						
ADMIN 2						
ADMIN 3						
SECURITY/TRAFFIC FLOW			✓		✓	

\*Minimum requirement

\*\*When handling used sample packs

To promote safety, and minimise cross-contamination, staff must:

- Always select the correct sized scrubs and gloves prior to use.
- Ensure they are familiar with PPE donning and doffing techniques.
- Regularly check each other's PPE use and highlight any discrepancies to colleagues.
- Promptly raise any concerns, involving PPE use, with the Unit Manager.

#### 4.1 Frequency of PPE Changes

PPE must be changed at the soonest opportunity if:

- It becomes contaminated.
- It is damaged during a procedure.
- It shows signs of deterioration (e.g. dampening of face masks).

In the absence of any of the above, PPE should be changed as follows:

	FOLLOWING EACH PATIENT CONTACT	AT THE END OF EACH SESSION (2 - 4hrs)	DAILY
GLOVES	✓		
APRON	✓		
SURGICAL FACE MASK		✓*	
GOGGLES OR VISOR		✓	
SCRUBS			✓

*\*May be worn for up to 6hrs if no signs of deterioration*

#### 4.2 Scrubs

Reusable scrubs should be donned at the start of duty and removed prior to leaving the unit. Dirty scrubs should be placed inside a red soluble bag which should then be placed in a clear plastic bag (both bags must be tied). This must be placed into a red, material, laundry bag (labelled 'Grandstand') and returned to Noble's for laundering. Under no circumstances must staff take scrubs home with them.





## 5 EMERGENCIES

### 5.1 Potential Threats to Personal Safety

Patients (or other vehicle occupants) who are hostile or engaging in inappropriate behaviour (including photographing or recording events) must be reported to the Unit Manager.

The Unit Manager will do his/her best to de-escalate the situation and (if pertinent) should consider the following options:

- Moving the patient's position in the queue to expedite the process or to delay swabbing (i.e. to allow a 'cooling off' period).
- Offer a home visit by the Community Screening Team.

If the patient is accompanied, they may be asked if they would prefer another person (in the vehicle) to carry out the screening process. Patients must, however, be informed of the risks; and the person swabbing must be supervised/instructed throughout.

If the UM is unable to de-escalate the situation, the incident will be referred to the police. The police must also be asked to attend if a patient (or vehicle occupant):

- Attempts to grab or assault any member of staff.
- Makes threats towards the staff member.
- Threatens to leave the car.

Vehicle occupants who continue to act in an aggressive manner may be asked to leave the unit, and return the following day; if the Unit Manager feels their behaviour poses a threat to staff.

### 5.2 Physical Assault or Reckless Behaviour

To ensure the wellbeing of employees, the GCSU service will be suspended if any member of staff:

- Is intentionally grabbed or restrained.
- Is physically assaulted (including being spat at or deliberately coughed on).
- Has his or her PPE deliberately removed or destroyed.

Staff who have experienced any of the above are at high risk of contamination and must (along with any colleagues coming to their aid) immediately withdraw to the Decontamination Room in Garage 1 (see Section 5.3). The Coordinator/Runner should be instructed to call the police for assistance.

In the event of a patient (or other vehicle occupant) stepping out of their car, staff must:

- Move to a safe distance (a minimum of two meters).
- Demand that the person gets back into the car.

If they refuse to get back into their vehicle, all staff must withdraw to Garage 2 and lower the shutters. If time allows, the occupants of other vehicles should be visually instructed to lock their doors; however, this act must not delay staff from seeking safety themselves.

If there is insufficient time to lower the shutters, staff should assemble at the bottom of the corridor behind the first lockable door (they must not, however, enter the race office until all PPE has been removed). The Coordinator/Runner should be instructed to call the police.

### 5.3 Contamination

Staff who have (or are concerned they may have) become contaminated must immediately relocate to the Decontamination Room in Garage 1. Should this occur:

- Screening may be halted if necessary.
- The staff member should be accompanied by a colleague, wearing protective equipment, who will collect and dispose of the contaminated PPE.
- The affected staff member must wash themselves using soap and water. Jay cloths and white paper cloths (for drying) can be found in the Decontamination Pack along with a clean set of scrubs.
- If personal clothing has become contaminated, it should be sealed in a red (soluble) bag and placed inside a clear plastic bag. Arrangements must then be made for it to be laundered at Noble's Hospital. Staff must be mindful of the fact that the hospital laundering process is not suitable for all clothing types.
- Advice must be sought from Occupational Health and/or Public Health on the need to undergo COVID-19 testing and commence isolation.
- The wash basin and surrounding areas must be thoroughly cleansed using Chlor-Clean solution\* following use.
- The affected staff member must be given emotional support and checked on later by the Unit Manager.

*\*Made up of one Chlor-Clean tablet per litre of cold water.*

### 5.4 Medical Emergencies

GCSU staff should take great care when dealing with medical emergencies involving vehicle occupants and must wear full PPE before approaching the casualty.

In the event of a vehicle occupant suffering a cardiac arrest, staff must:

- Call for an emergency ambulance, informing them that the patient is a high risk for COVID-19.
- Retrieve the defibrillator from the Grandstand (the call handler will supply the access code).
- Utilise the defibrillator to deliver a shock (if indicated by the AED).

Contrary to standard practice (and AED instructions) chest compressions must **not** be initiated due to the potential for contaminated air being expelled from the casualty's nose and mouth. Should occupants (from the same vehicle) wish to commence CPR, staff must retreat to a safe distance to observe and provide guidance where necessary.

If cardiopulmonary circulation is restored (following use of the defibrillator, for example) the casualty may be placed in the recovery position whilst awaiting the ambulance.

## 5.5 Fire

In the event of fire staff must:

- Raise the alarm.
- Dial 999, informing the call handler of the fire and additional COVID-19 risk.

GCSU admin staff must leave the building via the back entrance and assemble on the grassed area near the car park. Staff working in the garage should exit, via the garage doors, and make their way around to the assembly point at the rear. The Unit Manager must use the daily attendance sheet to ensure all staff are safely accounted for.

Should a patient's vehicle catch fire whilst awaiting screening, staff should:

- Instruct the occupants to exit the vehicle and to stand in a specified area, away from the hazard and staff.
- Place an emergency call to the fire service, informing them that the vehicle occupants are being screened for COVID-19.
- Summon the police (in an emergency, police based at GCSU, should be contacted using a 999 call).
- Instruct other drivers to move their vehicles away from the hazard. Occupants must be discouraged from exiting their vehicles unless life is at risk. In such instances, they must be instructed to stand in a designated area away from others.

## 6 STAFF SICKNESS

Due to the highly infectious nature of COVID-19, staff must inform one of the Unit Managers if:

- They develop symptoms associated with Coronavirus infection.
- A member of their household has symptoms of (or has tested positive for) COVID-19.

Staff who develop symptoms whilst on duty must immediately inform the Unit Manager and leave the premises as soon as possible. Advice must be sought from Occupational Health and/or Public Health on the need to undergo COVID-19 testing and commence isolation. The DHSC Executive Team must also be made aware of the potential disruption to service.

Screening may need to be suspended to allow for cleaning of the GCSU.

## 7 MISCELLANEOUS

### 7.1 Patient Identifiable Information

Surplus paperwork containing patient identifiable information must be placed in the 'Confidential Shredding' folder. The contents of the folder will be taken to Crookall House (or Keyll Darree) where they will be shredded.

### 7.2 Cleaning Rota

The Unit Manager is responsible for ensuring the department is cleaned at the end of every shift.

- Clinical and domestic waste bags must be sealed and placed in the bins in Garage 1.
- Chlor-Clean solution\* or Sani-Cloth(Chlor) should be used to wipe down all surfaces including desks, chairs, telephones, computer keyboards/mouse and worktops.
- Door handles must also be wiped.

\*Information on the use of Chlor-Clean (including first aid measures, handling, storage, and toxicological details) can be found in Appendix 4.

### 7.3 Specimen Refrigerator

The specimen fridge must be cleaned at the end of each shift (or more frequently if there is increased risk of contamination) using a Chlor-Clean solution or Sani-Cloth(Chlor). This should then be recorded on the fridge daily log.


The fridge must only be cleaned when completely empty. If samples are held overnight, cleaning should be carried out the following morning once the specimens have been transferred to hospital.

### 7.3.1 Temperature Checks



The refrigerator must be checked to ensure the appropriate temperature has been maintained (+2 - +8°). The following must be recorded daily:

- Maximum temperature
- Minimum temperature
- Current temperature

To check max/min temperature:

- Press the Hi/Lo button  once. The highest temperature will be displayed first, followed by the lowest.

After recording the temperatures, the unit must be reset as follows:

- Press and hold the Hi/Lo button  until it beeps.
- Press and hold the tick button  until it beeps.

The Microbiology Department must be contacted for advice in the event of refrigerator malfunction.

## 7.4 General Household Duties

General cleaning duties must be shared between members of the GCSU. The general waste and clinical waste bins, located in Garage 1, are emptied daily by the porters (access is via the rear door/shutter in Garage 1). This process is overseen by the DoT Traffic Flow Officers to ensure that porters are not exposed to awaiting symptomatic patients.

## 8 STOCK CONTROL/SUPPLIES

Due to the ongoing review of services, stock should be requested twice weekly and must not be ordered in bulk.

Goods	Supplier	Distribution
PPE	Noble's Radiology Dept.	Ask porters to collect and deliver
Sigma Virocult/VCM swab/tubes and specimen bags	Microbiology Dept/Specimen Reception.	As above
All other hospital supplies	Stores	As above
Stationery	Crookall House/Keyll Darree	Arranged by staff

Refreshments are provided by Noble's Catering Department and delivered daily by the porters. The Catering Dept. must be given a day's notice should requirements change.

## 9 PREMISES

### 9.1 Maintenance

Although the building remains the property of the Department for Enterprise, any maintenance work or alterations must be requested through the Estates Department at Noble's Hospital.

### 9.2 Security

Three keys have been issued by the DoE. Before leaving the building at the end of a shift, the Unit Manager must ensure:

- All windows are closed and secured.
- Portable heaters are unplugged.
- Garage shutters are down.
- All doors are locked.
- All lights are turned off.

## 10 FURTHER RESOURCES

The following IOM Government resources are available:

Infection Prevention and Control:

<https://www.gov.im/about-the-government/departments/health-and-social-care/guidance-centre/disease-control/>

Coronavirus: COVID-19

<https://covid19.gov.im/>

Health and Safety at Work Inspectorate:

<https://www.gov.im/about-the-government/departments/environment-food-and-agriculture/environment-safety-and-health-directorate/health-and-safety-at-work-inspectorate/>

Data Protection and GDPR on the Isle of Man:

<https://www.gov.im/about-the-government/data-protection-gdpr-on-the-isle-of-man/>

Fairness at Work:

<https://hr.gov.im/fairness-at-work/>

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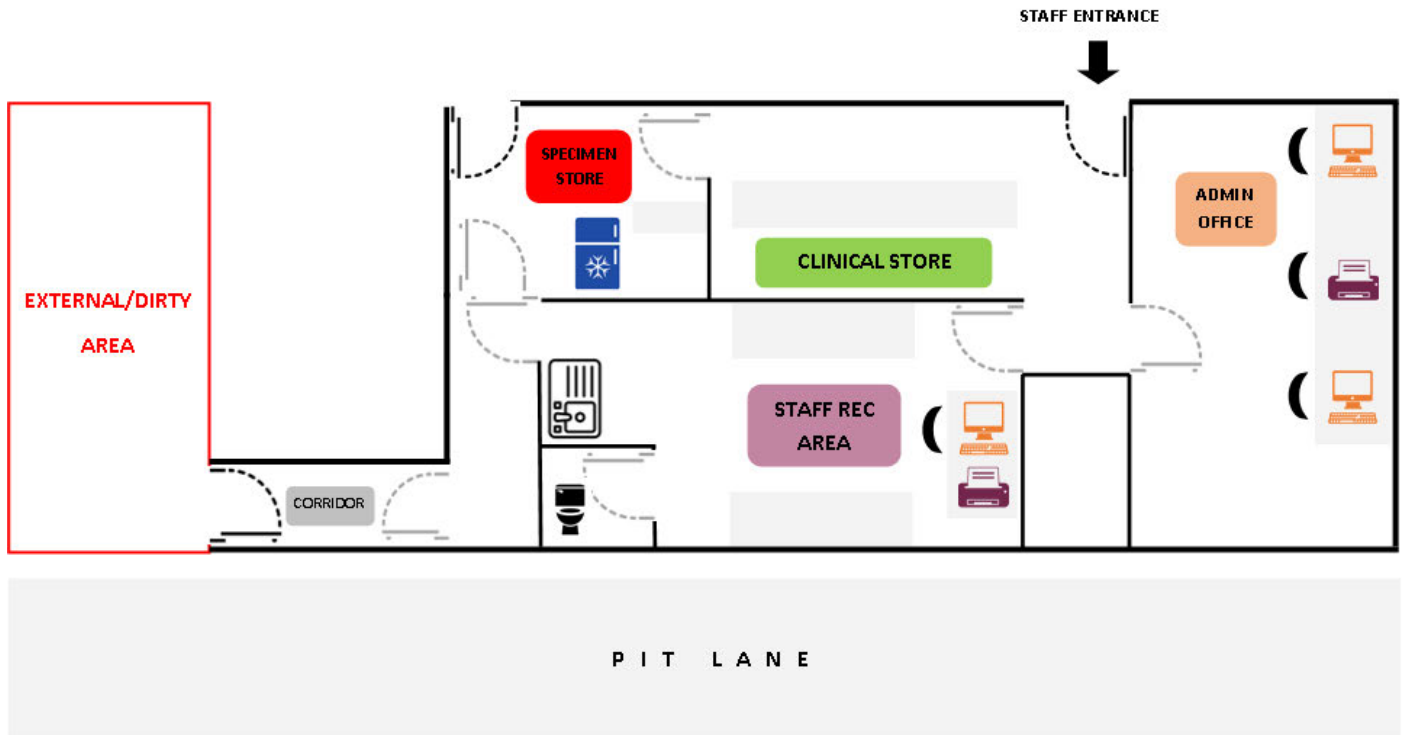
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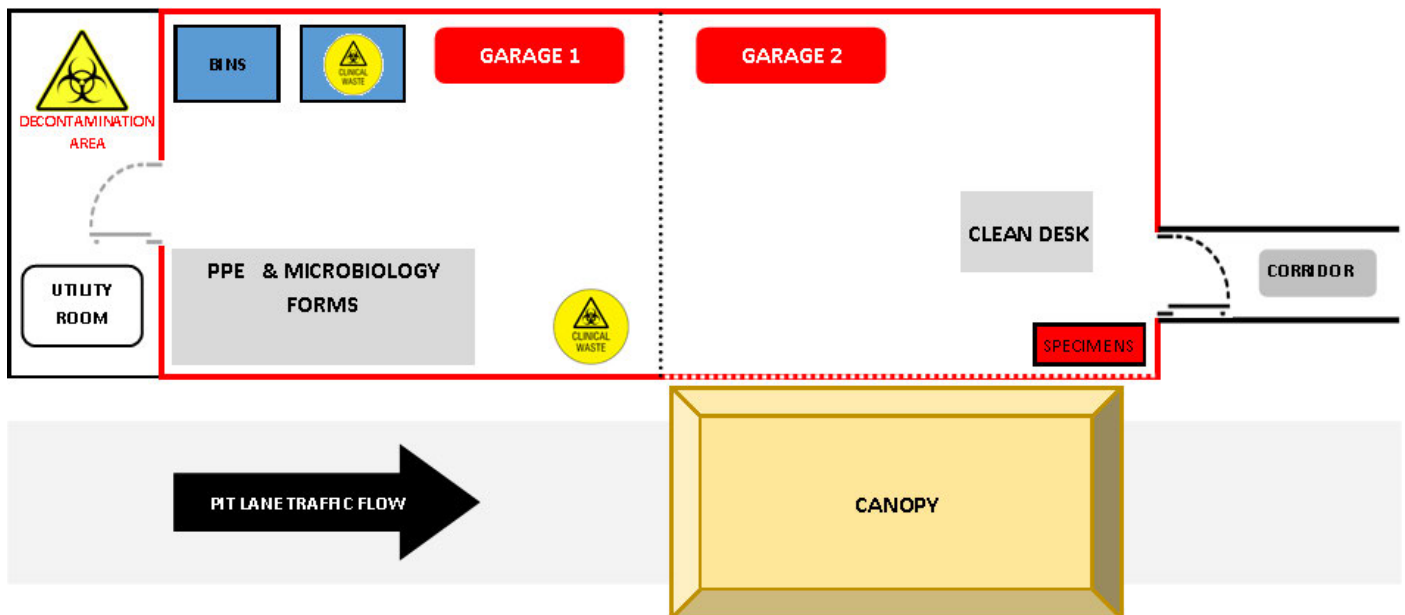
[Accessed 9/5/20]

APPENDIX 1

GRANDSTAND COVID-19 SCREENING UNIT LAYOUT



Internal



External



## APPENDIX 2

\*\*\*This is for reference only and does **not** replace the need for training in PPE use\*\*\*



# Putting on personal protective equipment (PPE) for non-aerosol generating procedures (AGPs)\*

Please see donning and doffing video to support this guidance: [https://youtu.be/-GncQ\\_ed-9w](https://youtu.be/-GncQ_ed-9w)

## Pre-donning instructions:

- Ensure healthcare worker hydrated
- Remove jewellery
- Tie hair back
- Check PPE in the correct size is available

- 1** Perform hand hygiene before putting on PPE.



- 2** Put on apron and tie at waist.



- 3** Put on facemask – position upper straps on the crown of your head, lower strap at nape of neck.



- 4** With both hands, mould the metal strap over the bridge of your nose.



- 5** Don eye protection if required.



- 6** Put on gloves.



\*For the PPE guide for AGPS please see:

[www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures](https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures)

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Public Health  
England

# Taking off personal protective equipment (PPE) for non-aerosol generating procedures (AGPs)\*

Please see donning and doffing video to support this guidance: [https://youtu.be/-GncQ\\_ed-9w](https://youtu.be/-GncQ_ed-9w)

• PPE should be removed in an order that minimises the risk of self-contamination

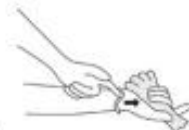
• Gloves, aprons (and eye protection if used) should be taken off in the patient's room or cohort area

**1** Remove gloves. Grasp the outside of glove with the opposite gloved hand; peel off. Hold the removed glove in the remaining gloved hand.



Slide the fingers of the un-gloved hand under the remaining glove at the wrist.

Peel the remaining glove off over the first glove and discard.



**2** Clean hands.



**3** Apron. Unfasten or break apron ties at the neck and let the apron fold down on itself.



Break ties at waist and fold apron in on itself – do not touch the outside – **this will be contaminated**. Discard.



**4** Remove eye protection if worn. Use both hands to handle the straps by pulling away from face and discard.



**5** Clean hands.



**6** Remove facemask once your clinical work is completed.



Untie or break bottom ties, followed by top ties or elastic, and remove by handling the ties only. Lean forward slightly. Discard. DO NOT reuse once removed.

**7** Clean hands with soap and water.



\*For the PPE guide for AGPs please see:

[www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures](https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures)

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## APPENDIX 3

## OROPHARYNGEAL AND MID-TURBINATE NASAL SWABBING FOR COVID-19

\*\*\*This is for reference only and does **not** replace the need for training prior to undertaking throat and nasal swabbing\*\*\*

- Don PPE as per Appendix 2.
- Confirm patient's identity, ensure details match labelled tubes, and check tube expiry date.
- Explain procedure to patient.
- Swab using the following procedure:

Oropharyngeal swab collection

Remove swab from packaging and insert into patient's mouth, swabbing the posterior pharynx and tonsillar areas. Avoid the tongue and cheek (see diagram 1).

*Be aware that process may initiate gag reflex or cause patient to cough.*

The same swab is then used to collect the nasal specimen

Tilt patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at turbinates). Rotate swab several times against nasal wall and repeat in other nostril using same swab.

*Be aware that process may cause patient to sneeze.*

- Place the tip of swab into sterile transport media tube and break off applicator stick.

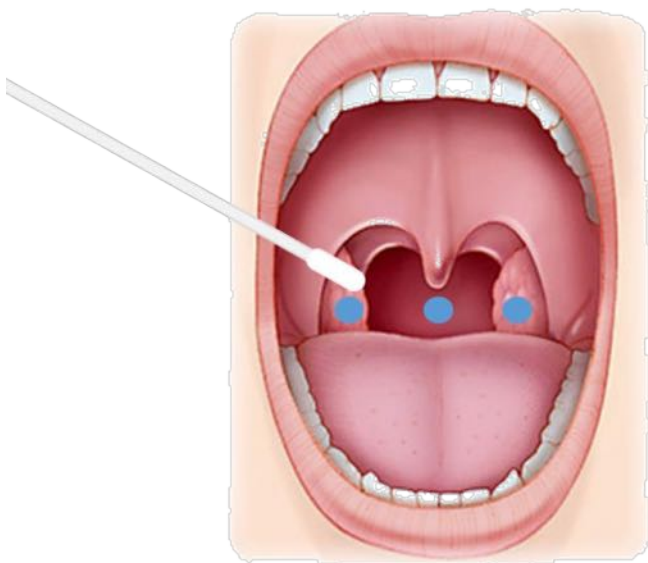


Diagram 1: Oropharyngeal swabbing

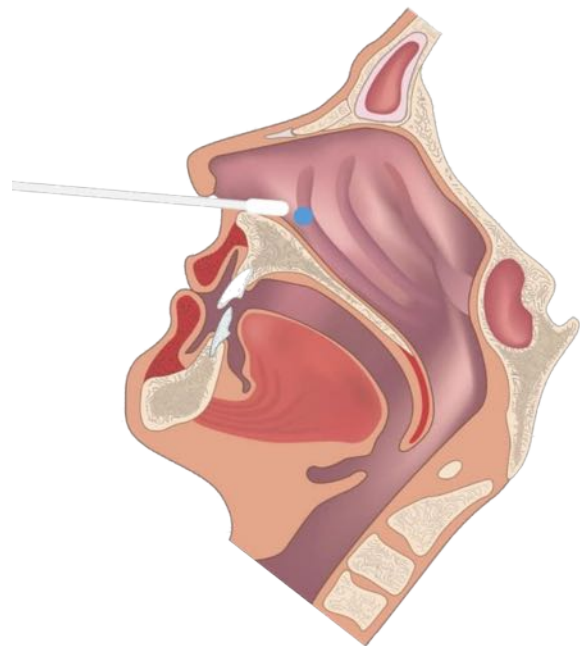


Diagram 2: Mid-turbinate nasal swabbing

## APPENDIX 4

## SAFETY GUIDANCE FOR THE USE OF CHLOR-CLEAN

### (Excerpts from Helix Solutions Safety Data Sheet)

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#### 4. FIRST AID MEASURES

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##### 4.1 Description of first aid measures

<b>Eye</b>	If in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, a doctor, or for at least 15 minutes.
<b>Inhalation</b>	If inhaled, remove from contaminated area. To protect rescuer, use a Full-face Type B-Class P1 (Inorganic and acid gas, Particulate) respirator or an Air-line respirator (in poorly ventilated areas). Apply artificial respiration if not breathing.
<b>Skin</b>	If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by a Poisons Information Centre or a doctor.
<b>Ingestion</b>	For advice, contact a Poison Information Centre on 13 11 26 (Australia Wide) or a doctor (at once). If swallowed, do not induce vomiting.
<b>First aid facilities</b>	Eye wash facilities and safety shower should be available.

##### 4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

##### 4.3 Immediate medical attention and special treatment needed

Treat symptomatically.

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#### 7. HANDLING AND STORAGE

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##### 7.1 Precautions for safe handling

Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

##### 7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, well ventilated area, removed from water or moisture, incompatible substances, heat or ignition sources and foodstuffs. Ensure containers are adequately labelled, protected from physical damage and sealed when not in use. Check regularly for leaks or spills. Large storage areas should be bunded and have appropriate fire protection and ventilation systems.

##### 7.3 Specific end use(s)

No information provided.

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#### 11. TOXICOLOGICAL INFORMATION

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##### 11.1 Information on toxicological effects

<b>Health hazard summary</b>	Irritant - slightly corrosive. This product has the potential to cause adverse health effects with over exposure. Use safe work practices to avoid eye or skin contact and inhalation. Upon contact with water, low levels of corrosive and highly irritating chlorine and hydrogen chloride vapour are released. When used in small quantities, the potential for over exposure is reduced.
<b>Eye</b>	Irritant. Contact may result in irritation, lacrimation, pain and redness. May result in burns with prolonged contact.
<b>Inhalation</b>	Slightly corrosive - irritant. Over exposure to dust or vapours may result in irritation of the nose and throat, with coughing. High level exposure may result in burning pain, inflammation and ulceration of the respiratory tract. Effects may be delayed.
<b>Skin</b>	Slightly corrosive. Contact may result in irritation, redness, pain, rash, dermatitis and possible burns.
<b>Ingestion</b>	Harmful - irritant. Ingestion may result in burns to the mouth and throat, nausea, vomiting and abdominal pain.

**APPENDIX 5**

**GRANDSTAND COVID-19 TESTING UNIT/COMMUNITY SWABBING TEAM**

**UNTOWARD INCIDENT LOG**

**TO BE USED FOR THE REPORTING OF MINOR INCIDENTS ONLY. SERIOUS INCIDENTS, OR THOSE RESULTING IN HARM, MUST BE REPORTED VIA DATIX.**

<b>DATE</b>	<b>AREA(S) INVOLVED</b>	<b>DETAILS OF INCIDENT</b>	<b>NAME(S) OF PERSON(S) INVOLVED</b>	<b>ACTION/OUTCOME</b>	<b>INCIDENT MANAGER</b>	<b>INCIDENT STATUS</b>

# GRANDSTAND COVID-19 SWABBING UNIT

## STANDARD OPERATING PROCEDURE

Amanda Phillips  
June 2020

**STANDARD OPERATING PROCEDURE FOR THE  
GRANDSTAND COVID-19 SWABBING UNIT**

<b>Title</b>	Standard Operating Procedure for the Grandstand COVID-19 Swabbing Unit
<b>Author</b>	Amanda Phillips, Care Quality & Safety Coordinator for Community Health Services
<b>Date of implementation</b>	19 <sup>th</sup> June 2020 (Version 3)
<b>Previous version(s)</b>	Version 1 (9/4/20), Version 2 (11/5/20)
<b>Changes since previous version</b>	<ul style="list-style-type: none"> <li>• Amendment of process algorithm.</li> <li>• Removal of role of Admin. 3.</li> <li>• Inclusion of Walk-in patients.</li> <li>• Removal of police role.</li> <li>• Inclusion of Covid-19 Microbiology form in appendices.</li> </ul>
<b>Ratified by</b>	<p>Due to the temporary suspension of all non-essential DHSC committees, this SOP has been agreed by: Amanda Phillips, Department of Health and Social Care (DHSC) Bernadette Devlin (DESC) Vicky Taylor (DESC) and ratified by: Cath Quilliam (Director of Nursing) Bronze Command</p>
<b>Review date</b>	Monthly (next due 19/7/20)

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## 1 INTRODUCTION

The Grandstand COVID-19 Swabbing Unit (GCSU) opened on the 20<sup>th</sup> March 2020, in response to the global Coronavirus pandemic; and provides a drive-through screening service for symptomatic patients who have been assessed and referred by the 111 Helpline. Results generated by this service will provide vital epidemiological information to:

- Determine the prevalence of COVID-19 on the island.
- Help predict disease patterns and subsequent health and social care needs.
- Minimise the impact on DHSC services and hospital bed availability.

The GCSU is based at the TT Grandstand. Administrative duties are undertaken in the Race Office, with screening carried out on the pit lane in front of garages 1 and 2 (see Appendix 1).

### 1.1 Scope

This Standard Operating Procedure is applicable to all IOM Government employees deployed at the GCSU and will remain effective until the unit is disbanded.

### 1.2 Policies

This SOP must be used in conjunction with current IOM Government legislation pertaining to:

- Infection Control and Prevention
- Health and Safety at Work
- Fairness at Work
- Data Protection

Registered health professionals must continue to practice in accordance with standards set by their regulatory body.

## 2 PROCEDURE

The GCSU operates four days a week, screening patients between 10:00hrs and 12:00hrs. Staff commence duty at 09:30 and finish at 12.30pm. Screening hours may be extended (or additional days covered) at short notice to accommodate demand.

The GCSU requires a minimum of 6 staff (one of whom is the Unit Manager) to function effectively:

2 sample collectors (Registered Nurses, Allied Health Professionals, senior Healthcare Assistants or student nurses).

1 information collector (RN's or Senior HCA's).

2 administration staff.

1 coordinator/runner (RN or Senior HCA).

Additional information collectors and sample collectors will be required should swabbing numbers increase.

### 2.1 Employment Prerequisites

#### 2.1.1 Declaration of health conditions

Prior to commencing employment at the GSCU, employees must first confirm that they do not suffer from any condition which places them at increased risk. An up-to-date list on such conditions can be viewed at the following Gov.UK site:

<https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19>

#### 2.1.2 Training

- PPE training (including donning and removal procedures) must be undertaken prior to carrying out any role involving close patient contact.
- Sample Collectors must also undergo training in oropharyngeal and mid-turbinate nasal swabbing techniques.

Training for the above must be delivered by a member of the Infection Prevention and Control Team (IP&C) prior to commencement of work.

### 2.2 Unit Manager

Unit Managers are responsible for the daily running of the GCSU, including student welfare, staffing and communication. The role includes:

- Unlocking the swabbing unit and preparing it for use.
- Ensuring all employees sign in.
- Allocating daily roles and ensuring employees wear the appropriate PPE.

- Facilitating meetings prior to (and following) each shift to ensure staff are confident to undertake the duties expected of them; and to discuss any problem areas.
- Overseeing stock control and cleaning duties.
- Ensuring staff adhere to infection control guidance and are competent in the use of PPE.
- Liaising with police/Department of Transport personnel based at the GCSU.
- Monitoring and safeguarding employee's mental and physical wellbeing.
- Ensuring staff act in such a way as to prevent the service from reputational harm.
- Acting as a representative for the GCSU when required (including dealing with Ministerial or press enquiries).
- Securing the premises and minimising the risk of damage to property or goods.
- Minimising unnecessary waste.
- Preparing a working rota, one week in advance, containing the appropriate skill mix to undertake all required duties.
- Safeguarding patient wellbeing.
- Liaising with Infection Prevention and Control and senior DHSC managers as necessary.
- Reporting the number of completed swabs to 111 COVID Helpline each day.
- Advising on the management of complainants or difficult patients.
- Ensuring procedural changes are promptly communicated to all staff.
- Responding to requests, from the DHSC Executive Team, to extend working hours or implement change.
- Liaising with pertinent departments at Noble's Hospital (including microbiology, catering, porters etc.).
- Ensuring any maintenance needs are promptly addressed.
- Coordinating and authorising time sheets for students and bank staff.

### 2.3 Information Collector

Information Collectors (ICs) should don PPE as stipulated in Section 3 and Appendix 2. At commencement of duty they should collect blank Covid-19 Microbiology forms (see Appendix 6), information leaflets, clipboard and pen before making their way to the awaiting vehicles.

- Starting with the vehicle nearest the canopy, the IC must:
  - Stand (at least) one metre from the side of the vehicle.
  - Instruct the vehicle occupant to lower their window.
  - If there is more than one person in the vehicle, ascertain which one requires swabbing before positioning themselves at the appropriate side of the vehicle (only one window should be lowered at a time).

- Try to maintain a safe distance from the occupants and avoid leaning against, or reaching into, the vehicle.
- Explain their role and the screening process, providing reassurance where necessary.
- Advise the patient of any potential delays.
- Ascertain if the patient is symptomatic or asymptomatic and select one of the following which best represents the reason for swabbing:
  - Symptomatic*  
For any patient or essential worker presenting with symptoms.
  - Essential Worker Post-Isolation Test*  
For EW's who have previously tested positive for Covid-19, or have been off island, and have completed their 14 days isolation period (*two consecutive swabs required*).
  - Asymptomatic Essential Worker*  
For EW's, who demonstrate no symptoms, but wish to be tested (*single swab*).
  - Asymptomatic Patient Testing*  
For patients requiring a test prior to hospital admission or transfer to a UK health facility (*single or two consecutive swabs – hospital to advise*).
- Record the following details on the Covid-19 Microbiology form:
  - Full name.*
  - Date of birth.*
  - Address.*
  - Contact number.*
  - Car registration number (to assist the sample collector in locating the patient).*
  - Date.*
  - Any Coronavirus-related symptoms.*
  - Workplace and role (for Essential Workers only).*
- Provide the patient with a self-isolation information leaflet before instructing the occupant(s) to remain in the vehicle with the windows closed.
  - If the IC is concerned that their PPE may have become contaminated whilst collecting information, they must return to Garage 1 to change their equipment before moving on to the next vehicle.
  - Depending on the volume of traffic, IC's should try to restrict the number of microbiology forms, completed at any one time, to four; and should number them to ensure they remain in car order.
  - Completed forms must be returned to the clean desk in Garage 2 and the Coordinator (Runner) informed.
  - Face masks may remain in situ for up to six hours providing there are no contamination concerns.

The IC must inform the Unit Manager of any vehicle occupants who:

- Have become acutely unwell whilst waiting.

- Are being aggressive, argumentative or non-compliant.

Information Collectors must not enter the corridor, or GCSU base, until they have safely discarded used PPE and cleansed their hands using alcohol-based sanitiser (minimum 70% base) or soap and water (in the utility room).

## 2.4 Sample Collectors

Sample Collectors must work in pairs comprising of one 'clean' nurse and one 'dirty' nurse. Staff allocated the role of Sample Collectors must don PPE as stipulated in Section 3 and Appendix 2.

- After collecting the clean sample pack from the desk in Garage 2, the clean nurse must:
  - Inspect the pack to ensure it contains a labelled Sigma Virocult/VCM swab/tube (within its expiry date) and second specimen bag.
  - Check the details on the tube correlate with those on the accompanying form.
  - Check the registration number on the Microbiology form against the car at the front of the queue.
- After indicating to the driver to position his/her vehicle under the canopy, they must ask them to lower their window and switch off the engine.
- The dirty nurse will approach the vehicle and ask for confirmation of the patient's name and date of birth. The clean nurse, remaining two metres from the vehicle, will check this against the details contained in the unused sample kit. If more than one occupant requires swabbing, this should **not** be carried out simultaneously.
- The dirty nurse must explain the procedure to the patient.
- The clean nurse will pass the Sigma Virocult/VCM tube and swab to the dirty nurse whilst maintaining a safe distance.
- The dirty nurse will approach the vehicle to obtain the specimen (see Appendix 3).
- Once retrieved, the dirty nurse places the swab into the tube, snaps off the handle and tightens the lid on the tube.
- The clean nurse opens the second specimen bag for the dirty nurse to drop the tube into.
- The bag is sealed, by the clean nurse, before being placed inside the bag containing the patient's details. The outer bag is then sealed before being placed in the red specimen box in Garage 2.
- The dirty nurse must inform patients that:
  - They will be informed of their result, whether negative **or** positive, within 24 to 48 hours.
  - They must continue to self-isolate until told otherwise.\*
- Patients requesting information on COVID-19 (including isolation periods and fitness to return to work) must be advised to ring 111.
- Vehicle occupants must be asked to close their windows before leaving the unit.

- The dirty nurse and clean nurse must change their gloves and apron after each patient contact or procedure. Face masks may remain in situ for up to six hours providing there are no contamination concerns.

*\*Not applicable to asymptomatic patients being tested prior to hospital admission; or Essential Workers who have opted to have test.*

Sample Collectors must inform the Unit Manager of any vehicle occupants who:

- Have become acutely unwell whilst waiting.
- Are being aggressive, argumentative or non-compliant.

Sample Collectors must not enter the corridor, or GCSU base, until they have safely discarded used PPE and cleansed their hands using alcohol-based sanitiser (minimum 70% base) or soap and water (in the utility room).

## 2.5 Coordinator (Runner)

The staff member assigned Coordinator (or Runner) acts as the link between internal and external operations. They must wear disposable scrubs whilst undertaking their role. The Coordinator must:

- Transfer all completed Microbiology forms from Garage 2 to Admin 1 (Inputter) for processing.
- Ensure a supply of unused sample packs are available for Admin 2 (Labeller). Packs should be easily accessible and ready for use.
- Transfer labelled (clean) sample packs from the admin office to the clean desk in Garage 2 (checking to ensure the tube label matches the name on the request form).
- Inform the Sample Collectors of any additional risks or needs associated with the patient.
- Deal with telephone queries or requests from co-workers.
- Transfer specimens (dirty samples) from Garage 2 to the fridge in the Specimen Store. This should be done on a regular basis using the following process:
  - Collect the Specimen Checklist from Admin 1 and place it on the counter in the Specimen Store.
  - Wearing disposable gloves: close the lid on the red box (containing samples) in Garage 2; before transferring it to the Specimen Store (replace with a clean red box).
  - Transfer the samples from the red box to the fridge. The name and DoB on each sample must be checked and ticked off on the Specimen Checklist before being placed in the fridge (a member of the Admin team will assist).
  - Record the time the sample was placed in the fridge on the Specimen Checklist.

- Dispose of gloves, at the end of the process, and ensure hands are cleansed with soap and water or alcohol-based sanitiser (minimum 70% base).
- Ensure clean, unlabelled packs are made up ready for the following day (each containing one Sigma Virocult/VCM swab/tube and one folded specimen bag).
- Ensure appropriate resources are available for the following day (i.e. forms, Virocult/VCM tubes, labels and specimen bags)
- Coordinate refreshment breaks for administrative staff.

When the porters arrive, any samples held in the fridge, should be carefully transferred into a red box. A confirmation slip, containing the number of samples being sent to the lab, must be completed and placed in the box before securing the lid. Gloves must be worn for this procedure.

The porter will then transfer the swabs to Noble's Microbiology Department for testing. He/she should be asked to return a clean red box when next visiting the GCSU.

## 2.6 Admin 1 (Patient identification)

Admin 1 is responsible for locating patients on Medway and generating ICE labels. Before commencing their role, they must log on to the computer with the Username: **nopan21** and Password: **CallCentre111\*** and open the Medway system (using the same username and password).

Upon receiving a completed Microbiology form from the Coordinator, Admin 1 should:

- Enter the patient's date of birth and locate them from the list (if they cannot be found, search using the name instead). If the patient cannot be located by date of birth, address, or name; the form must be returned (via the Coordinator) to the Information Collector to request confirmation of details.
- Check the patient's COVID tab (on Medway) to ensure they have been referred for a test.\*
- Add the patient's Hospital Number to the Microbiology form.
- Request a COVID-19 ICE form and input details of the patient's symptoms (for asymptomatic patients input the reason for testing). Any details proving difficult to decipher should be brought to the attention of the Coordinator for clarification.
- Print the ICE form and pass it to Admin 2 - along with the original Microbiology form.
- Assist with checking in dirty samples or making up new packs.

\* Patients with no COVID tab on Medway, or those whose assessment concluded with no test being necessary; cannot be swabbed. Instead, the Microbiology form must be handed back to the Coordinator and the patient informed of the discrepancy.

## 2.7 Admin 2 (Labeller/Attendance Spreadsheet)

Upon receiving the ICE and Microbiology forms, Admin 2 must:

- Remove labels from the ICE form, placing one on the Sigma Virocult/VCM tube, one on the Specimen Checklist and one on the Microbiology form.
- Add the Hospital Number to the label on the Specimen Checklist.
- Return the labelled tube to the opened swab packet, and place back into the clean sample pack.
- Fold the ICE form and place it, along with the Microbiology form, in the sample pack sleeve (with the patient's name and date of birth visible).
- Inform the Coordinator that the pack is ready for use.

Once the sample pack has been collected by the Coordinator, Admin 2 must:

- Retrieve the USB from the locked blue box.
- Select the Daily Attendance folder and open up the excel spreadsheet (the password for which can be found in the folder name).
- Use the Specimen Checklist to populate the spreadsheet with the following information:
  - Reason for testing
  - Work place/role (for EW's only)
  - Patient name (surname first)
  - Hospital number
  - Sex
  - Date of birth
- Email the spreadsheet, at the end of the session, to [111@gov.im](mailto:111@gov.im).
- Check to ensure the email has been sent before closing the spreadsheet.
- Close the spreadsheet without saving it.\*
- Return the USB to the blue box for safekeeping at the end of the swabbing session.
- Assist with checking in dirty samples or making up new packs.

\*If there is a problem sending the email, a temporary copy of the spreadsheet may be saved (on the USB) using the date as the file name. This copy must, however, be deleted once the spreadsheet has been successfully emailed.

## 2.8 Security/Traffic Flow

Two Department of Transport employees are on duty each day. They are responsible for:

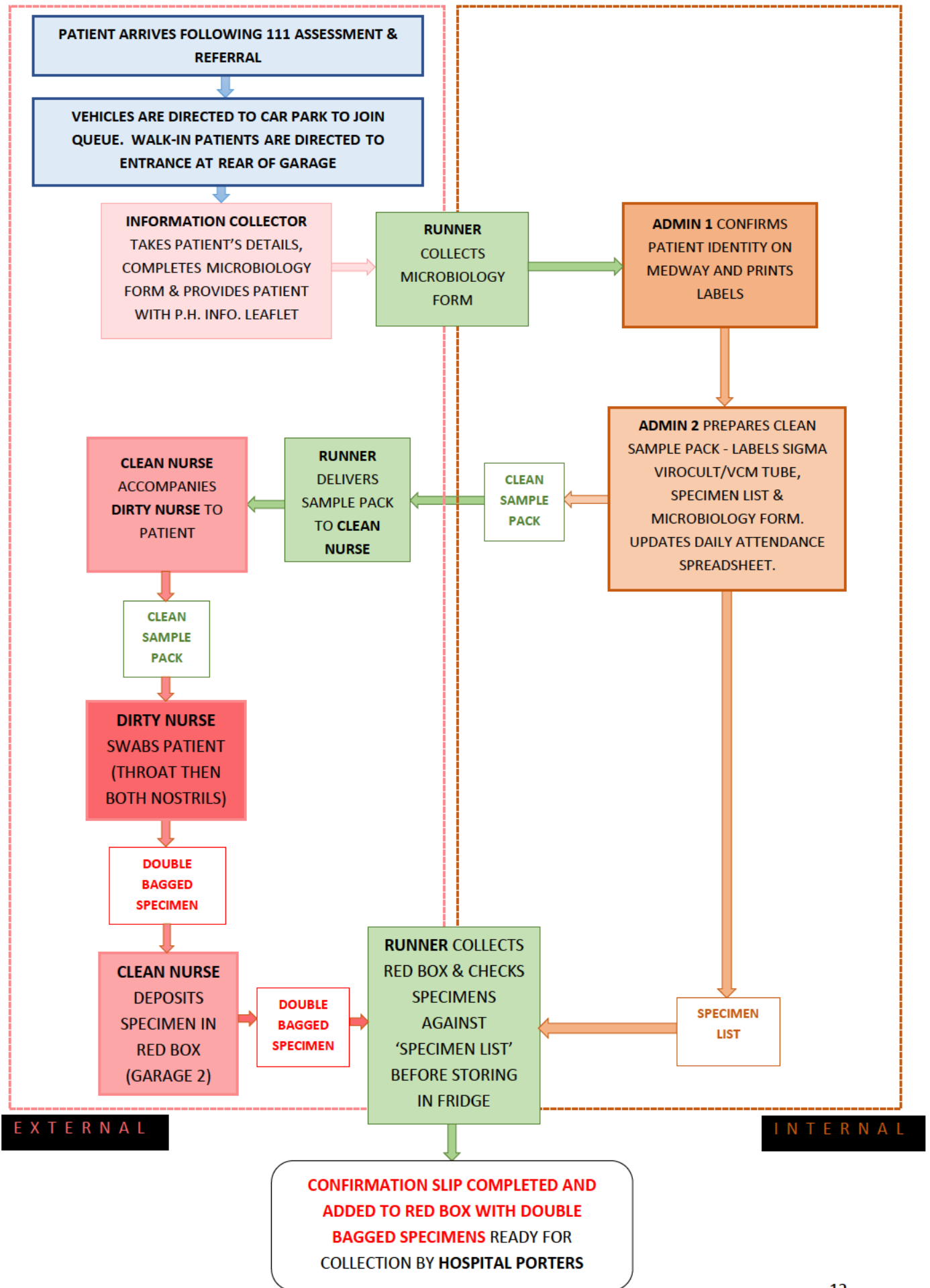
- Preventing unauthorised vehicles from entering the slip road.
- Checking with the vehicle occupants, upon arrival, to ensure they have been referred via 111.\*



- Maintaining the flow of traffic through the unit.
- Informing swabbing staff of any walk-in patients.

\*Vehicle occupants who have not been referred via 111 cannot be tested and must be politely asked to leave the premises. Those refusing to do so must be brought to the attention of the Unit Manager.

### 2.9 GCSU Process



### **2.10 Walk-in Patients**

Asymptomatic individuals, who have no means of transport, may attend the GCSU as walk-in patients. All patients must have been referred by 111.

Upon arrival at the screening car park, DOT staff will inform the team that a walk-in patient has arrived. To prevent exposure to symptomatic attendees, walk-in patients must be asked to make their way to the back of the GCSU to the external door in the Utility Room. They must not enter via the front of Garage 1.

The Information Gatherer will greet them and take them through to Garage 3 to complete the appropriate paperwork, where they will remain until the swabbing nurses arrive. If more than one walk-in patient arrives at the same time, they must be asked to remain seated. To maintain dignity, the patient must be seated behind the fixed screen whilst being swabbed.

## **3 UNTOWARD INCIDENTS AND RISK MANAGEMENT**

### **3.1 Incident Reporting**

All minor/moderate incidents must be reported to the Unit Manager and logged on the Untoward Incident log (Appendix 5) as soon as possible. Serious incidents (or those resulting in harm) must be immediately reported to the Unit Manager who will then record the event on Datix and inform the Director of Nursing.

### **3.2 Risk Register**

The GCSU's Risk Register is maintained by the Unit Manager. Staff must inform the Unit Manager if:

- The severity of a risk (already on the register) increases.
- A new risk is identified within the department.

The Untoward Incident log and GCSU Risk Register can be found on the black USB.

## **4 PERSONAL PROTECTIVE EQUIPMENT (PPE)**

The level of PPE required by staff is dictated by exposure to risk. The following guidelines indicate the level of protection required to undertake each role. Additional duties may require increased protection and must be risk assessed beforehand.

	SCRUBS	GOWN	SURGICAL FACE MASK	GOGGLES OR VISOR	GLOVES	APRON
UNIT MANAGER	✓*					
INFORMATION COLLECTOR	✓		✓	✓	✓	✓
SAMPLE COLLECTOR - DIRTY	✓		✓	✓	✓	✓
SAMPLE COLLECTOR - CLEAN	✓		✓		✓	✓
COORDINATOR (RUNNER)	✓				✓**	
ADMIN 1						
ADMIN 2						
ADMIN 3						
SECURITY/TRAFFIC FLOW			✓		✓	

\*Minimum requirement

\*\*When handling used sample packs

To promote safety, and minimise cross-contamination, staff must:

- Always select the correct sized scrubs and gloves prior to use.
- Ensure they are familiar with PPE donning and doffing techniques.
- Regularly check each other's PPE use and highlight any discrepancies to colleagues.
- Promptly raise any concerns, involving PPE use, with the Unit Manager.

#### 4.1 Frequency of PPE Changes

PPE must be changed at the soonest opportunity if:

- It becomes contaminated.
- It is damaged during a procedure.
- It shows signs of deterioration (e.g. dampening of face masks).

In the absence of any of the above, PPE should be changed as follows:

	FOLLOWING EACH PATIENT CONTACT	AT THE END OF EACH SESSION (2 - 4hrs)	DAILY
GLOVES	✓		
APRON	✓		
SURGICAL FACE MASK		✓*	
GOGGLES OR VISOR		✓	
SCRUBS			✓

\*May be worn for up to 6hrs if no signs of deterioration

## 4.2 Scrubs

Reusable scrubs should be donned at the start of duty and removed prior to leaving the unit. Dirty scrubs should be placed inside a red soluble bag which should then be placed in a clear plastic bag (both bags must be tied). This must be placed into a red, material, laundry bag (labelled 'Grandstand') and returned to Noble's for laundering. Under no circumstances must staff take scrubs home with them.



## 5 EMERGENCIES

### 5.1 Potential Threats to Personal Safety

Patients (or other vehicle occupants) who are hostile or engaging in inappropriate behaviour (including photographing or recording events) must be reported to the Unit Manager.

The Unit Manager will do his/her best to de-escalate the situation and (if pertinent) should consider the following options:

- Moving the patient's position in the queue to expedite the process or to delay swabbing (i.e. to allow a 'cooling off' period).
- Offer a home visit by the Community Screening Team.

If the patient is accompanied, they may be asked if they would prefer another person (in the vehicle) to carry out the screening process. Patients must, however, be informed of the risks; and the person swabbing must be supervised/instructed throughout.

If the UM is unable to de-escalate the situation, the incident will be referred to the police. The police must also be asked to attend if a patient (or vehicle occupant):

- Attempts to grab or assault any member of staff.
- Makes threats towards the staff member.
- Threatens to leave the car.

Vehicle occupants who continue to act in an aggressive manner may be asked to leave the unit, and return the following day; if the Unit Manager feels their behaviour poses a threat to staff.

## **5.2 Physical Assault or Reckless Behaviour**

To ensure the wellbeing of employees, the GCSU service will be suspended if any member of staff:

- Is intentionally grabbed or restrained.
- Is physically assaulted (including being spat at or deliberately coughed on).
- Has his or her PPE deliberately removed or destroyed.

Staff who have experienced any of the above are at high risk of contamination and must (along with any colleagues coming to their aid) immediately withdraw to the Decontamination Room in Garage 1 (see Section 5.3). The Coordinator/Runner should be instructed to call the police for assistance.

In the event of a patient (or other vehicle occupant) stepping out of their car, staff must:

- Move to a safe distance (a minimum of two meters).
- Demand that the person gets back into the car.

If they refuse to get back into their vehicle, all staff must withdraw to Garage 2 and lower the shutters. If time allows, the occupants of other vehicles should be visually instructed to lock their doors; however, this act must not delay staff from seeking safety themselves.

If there is insufficient time to lower the shutters, staff should assemble at the bottom of the corridor behind the first lockable door (they must not, however, enter the race office until all PPE has been removed). The Coordinator/Runner should be instructed to call the police.

## **5.3 Contamination**

Staff who have (or are concerned they may have) become contaminated must immediately relocate to the Decontamination Room in Garage 1.

Should this occur:

- Screening may be halted if necessary.
- The staff member should be accompanied by a colleague, wearing protective equipment, who will collect and dispose of the contaminated PPE.

- The affected staff member must wash themselves using soap and water. Jay cloths and white paper cloths (for drying) can be found in the Decontamination Pack along with a clean set of scrubs.
- If personal clothing has become contaminated, it should be sealed in a red (soluble) bag and placed inside a clear plastic bag. Arrangements must then be made for it to be laundered at Noble's Hospital. Staff must be mindful of the fact that the hospital laundering process is not suitable for all clothing types.
- Advice must be sought from Occupational Health and/or Public Health on the need to undergo COVID-19 testing and commence isolation.
- The wash basin and surrounding areas must be thoroughly cleansed using Chlor-Clean solution\* following use.
- The affected staff member must be given emotional support and checked on later by the Unit Manager.

*\*Made up of one Chlor-Clean tablet per litre of cold water.*

#### 5.4 Medical Emergencies

GCSU staff should take great care when dealing with medical emergencies involving vehicle occupants and must wear full PPE before approaching the casualty.

In the event of a vehicle occupant suffering a cardiac arrest, staff must:

- Call for an emergency ambulance, informing them that the patient is a high risk for COVID-19.
- Retrieve the defibrillator from the Grandstand (the call handler will supply the access code).
- Utilise the defibrillator to deliver a shock (if indicated by the AED).

Contrary to standard practice (and AED instructions) chest compressions must **not** be initiated due to the potential for contaminated air being expelled from the casualty's nose and mouth. Should occupants (from the same vehicle) wish to commence CPR, staff must retreat to a safe distance to observe and provide guidance where necessary.

If cardiopulmonary circulation is restored (following use of the defibrillator, for example) the casualty may be placed in the recovery position whilst awaiting the ambulance.

#### 5.5 Fire

In the event of fire staff must:

- Raise the alarm.
- Dial 999, informing the call handler of the fire and additional COVID-19 risk.

GCSU admin staff must leave the building via the back entrance and assemble on the grassed area near the car park. Staff working in the garage should exit, via the garage doors, and make their way around to the assembly point at the rear. The Unit Manager must use the daily attendance sheet to ensure all staff are safely accounted for.

Should a patient's vehicle catch fire whilst awaiting screening, staff should:

- Instruct the occupants to exit the vehicle and to stand in a specified area, away from the hazard and staff.
- Place an emergency call to the fire service, informing them that the vehicle occupants are being screened for COVID-19.
- Summon the police (in an emergency, police based at GCSU, should be contacted using a 999 call).
- Instruct other drivers to move their vehicles away from the hazard. Occupants must be discouraged from exiting their vehicles unless life is at risk. In such instances, they must be instructed to stand in a designated area away from others.

## **6 STAFF SICKNESS**

Due to the highly infectious nature of COVID-19, staff must inform one of the Unit Managers if:

- They develop symptoms associated with Coronavirus infection.
- A member of their household has symptoms of (or has tested positive for) COVID-19.

Staff who develop symptoms whilst on duty must immediately inform the Unit Manager and leave the premises as soon as possible. Advice must be sought from Occupational Health and/or Public Health on the need to undergo COVID-19 testing and commence isolation. The DHSC Executive Team must also be made aware of the potential disruption to service.

Screening may need to be suspended to allow for cleaning of the GCSU.

## **7 MISCELLANEOUS**

### **7.1 Patient Identifiable Information**

Surplus paperwork containing patient identifiable information must be placed in the 'Confidential Shredding' folder. The contents of the folder will be taken to Crookall House (or Keyll Darree) where they will be shredded.



## 7.2 Cleaning Rota

The Unit Manager is responsible for ensuring the department is cleaned at the end of every shift.

- Clinical and domestic waste bags must be sealed and placed in the bins in Garage 1.
- Chlor-Clean solution\* or Sani-Cloth(Chlor) should be used to wipe down all surfaces including desks, chairs, telephones, computer keyboards/mouse and worktops.
- Door handles must also be wiped.

\*Information on the use of Chlor-Clean (including first aid measures, handling, storage, and toxicological details) can be found in Appendix 4.

## 7.3 Specimen Refrigerator

The specimen fridge must be cleaned at the end of each shift (or more frequently if there is increased risk of contamination) using a Chlor-Clean solution or Sani-Cloth(Chlor). This should then be recorded on the fridge daily log.

The fridge must only be cleaned when completely empty. If samples are held overnight, cleaning should be carried out the following morning once the specimens have been transferred to hospital.

### 7.3.1 Temperature Checks



The refrigerator must be checked to ensure the appropriate temperature has been maintained (+2 - +8°). The following must be recorded daily:

- Maximum temperature
- Minimum temperature
- Current temperature

To check max/min temperature:

- Press the Hi/Lo button  once. The highest temperature will be displayed first, followed by the lowest.

After recording the temperatures, the unit must be reset as follows:

- Press and hold the Hi/Lo button  until it beeps.
- Press and hold the tick button  until it beeps.

The Microbiology Department must be contacted for advice in the event of refrigerator malfunction.

#### 7.4 General Household Duties

General cleaning duties must be shared between members of the GCSU. The general waste and clinical waste bins, located in Garage 1, are emptied daily by the porters (access is via the rear door/shutter in Garage 1). This process is overseen by the DoT Traffic Flow Officers to ensure that porters are not exposed to awaiting symptomatic patients.

### 8 STOCK CONTROL/SUPPLIES

Due to the ongoing review of services, stock should be requested twice weekly and must not be ordered in bulk.

Goods	Supplier	Distribution
PPE	Noble's Radiology Dept.	Ask porters to collect and deliver
Sigma Virocult/VCM swab/tubes and specimen bags	Microbiology Dept/Specimen Reception.	As above
All other hospital supplies	Stores	As above
Stationery	Crookall House/Keyll Darree	Arranged by staff

Refreshments are provided by Noble's Catering Department and delivered daily by the porters. The Catering Dept. must be given a day's notice should requirements change.

### 9 PREMISES

#### 9.1 Maintenance

Although the building remains the property of the Department for Enterprise, any maintenance work or alterations must be requested through the Estates Department at Noble's Hospital.

#### 9.2 Security

Three keys have been issued by the DoE. Before leaving the building at the end of a shift, the Unit Manager must ensure:

- All windows are closed and secured.
- Portable heaters are unplugged.
- Garage shutters are down.
- All doors are locked.
- All lights are turned off.

## 10 FURTHER RESOURCES

The following IOM Government resources are available:

Infection Prevention and Control:

<https://www.gov.im/about-the-government/departments/health-and-social-care/guidance-centre/disease-control/>

Coronavirus: COVID-19

<https://covid19.gov.im/>

Health and Safety at Work Inspectorate:

<https://www.gov.im/about-the-government/departments/environment-food-and-agriculture/environment-safety-and-health-directorate/health-and-safety-at-work-inspectorate/>

Data Protection and GDPR on the Isle of Man:

<https://www.gov.im/about-the-government/data-protection-gdpr-on-the-isle-of-man/>

Fairness at Work:

<https://hr.gov.im/fairness-at-work/>

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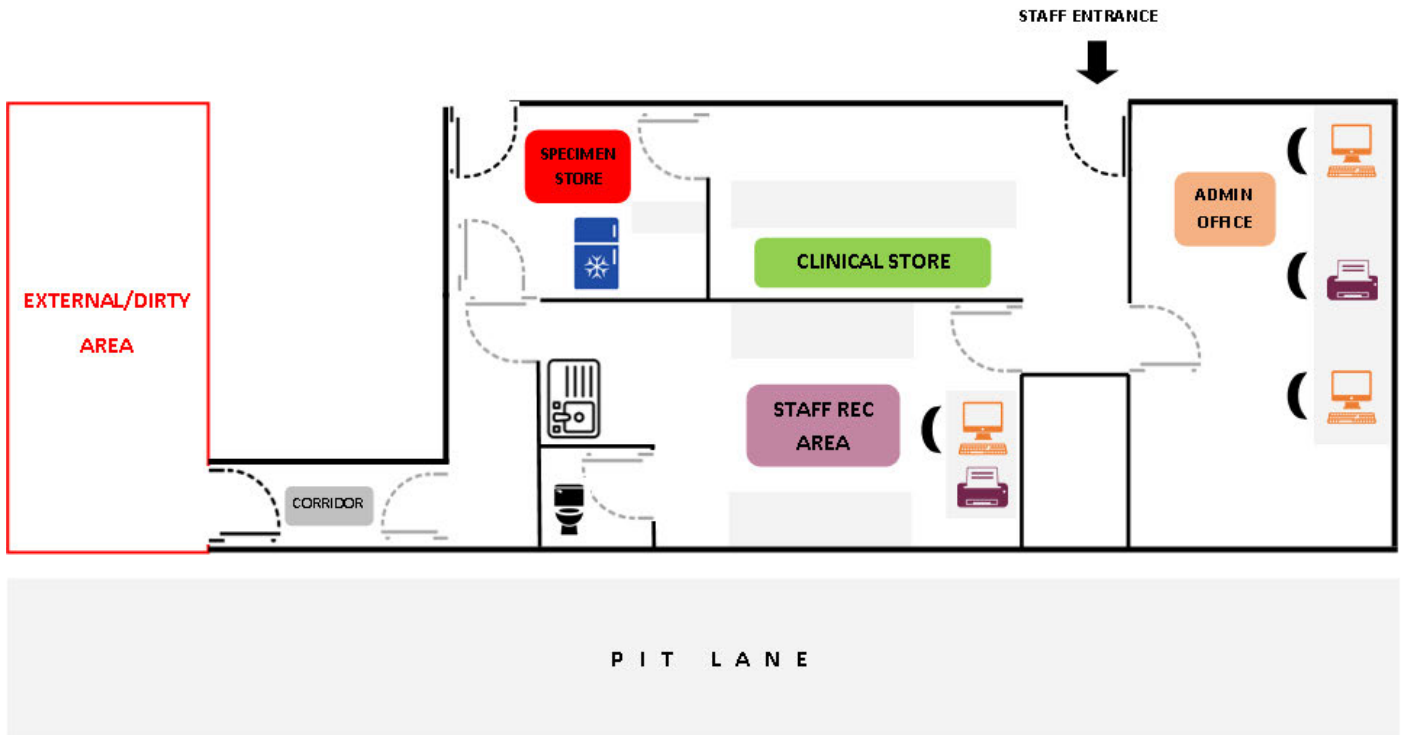
<https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-non-aerosol-generating-procedures>

[Accessed 9/5/20]

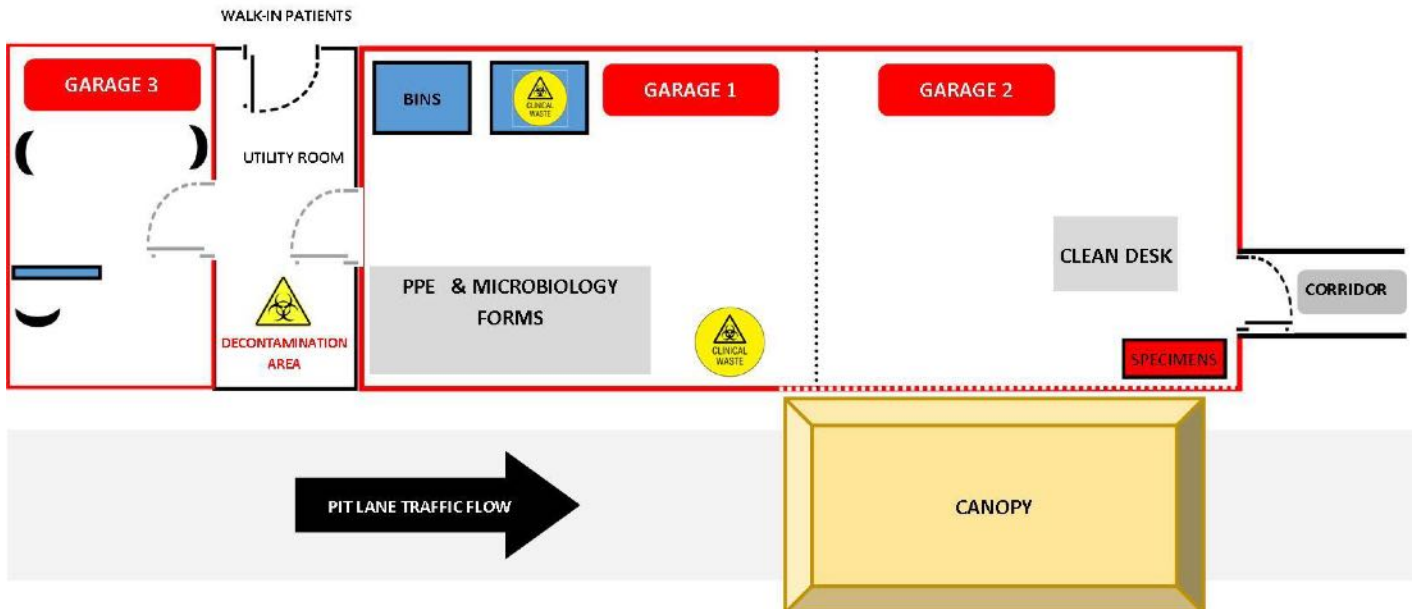
APPENDIX 1

GRANDSTAND COVID-19 SCREENING UNIT LAYOUT

Internal



External



## APPENDIX 2

\*\*\*This is for reference only and does **not** replace the need for training in PPE use\*\*\*



# Putting on personal protective equipment (PPE) for non-aerosol generating procedures (AGPs)\*

Please see donning and doffing video to support this guidance: [https://youtu.be/-GncQ\\_ed-9w](https://youtu.be/-GncQ_ed-9w)

## Pre-donning instructions:

- Ensure healthcare worker hydrated
- Remove jewellery
- Tie hair back
- Check PPE in the correct size is available

- 1** Perform hand hygiene before putting on PPE.



- 2** Put on apron and tie at waist.



- 3** Put on facemask – position upper straps on the crown of your head, lower strap at nape of neck.



- 4** With both hands, mould the metal strap over the bridge of your nose.



- 5** Don eye protection if required.



- 6** Put on gloves.



\*For the PPE guide for AGPS please see: [www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures](https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures)

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Public Health  
England

# Taking off personal protective equipment (PPE) for non-aerosol generating procedures (AGPs)\*

Please see donning and doffing video to support this guidance: [https://youtu.be/-GncQ\\_ed-9w](https://youtu.be/-GncQ_ed-9w)

• PPE should be removed in an order that minimises the risk of self-contamination

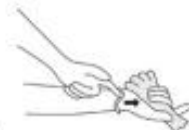
• Gloves, aprons (and eye protection if used) should be taken off in the patient's room or cohort area

**1** Remove gloves. Grasp the outside of glove with the opposite gloved hand; peel off. Hold the removed glove in the remaining gloved hand.



Slide the fingers of the un-gloved hand under the remaining glove at the wrist.

Peel the remaining glove off over the first glove and discard.



**2** Clean hands.



**3** Apron. Unfasten or break apron ties at the neck and let the apron fold down on itself.



Break ties at waist and fold apron in on itself – do not touch the outside – **this will be contaminated**. Discard.



**4** Remove eye protection if worn. Use both hands to handle the straps by pulling away from face and discard.



**5** Clean hands.



**6** Remove facemask once your clinical work is completed.



Untie or break bottom ties, followed by top ties or elastic, and remove by handling the ties only. Lean forward slightly. Discard. DO NOT reuse once removed.

**7** Clean hands with soap and water.



\*For the PPE guide for AGPS please see:

[www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures](https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures)

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## APPENDIX 3

## OROPHARYNGEAL AND MID-TURBINATE NASAL SWABBING FOR COVID-19

\*\*\*This is for reference only and does **not** replace the need for training prior to undertaking throat and nasal swabbing\*\*\*

- Don PPE as per Appendix 2.
- Confirm patient's identity, ensure details match labelled tubes, and check tube expiry date.
- Explain procedure to patient.
- Swab using the following procedure:

Oropharyngeal swab collection

Remove swab from packaging and insert into patient's mouth, swabbing the posterior pharynx and tonsillar areas. Avoid the tongue and cheek (see diagram 1).

*Be aware that process may initiate gag reflex or cause patient to cough.*

The same swab is then used to collect the nasal specimen

Tilt patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at turbinates). Rotate swab several times against nasal wall and repeat in other nostril using same swab.

*Be aware that process may cause patient to sneeze.*

- Place the tip of swab into sterile transport media tube and break off applicator stick.

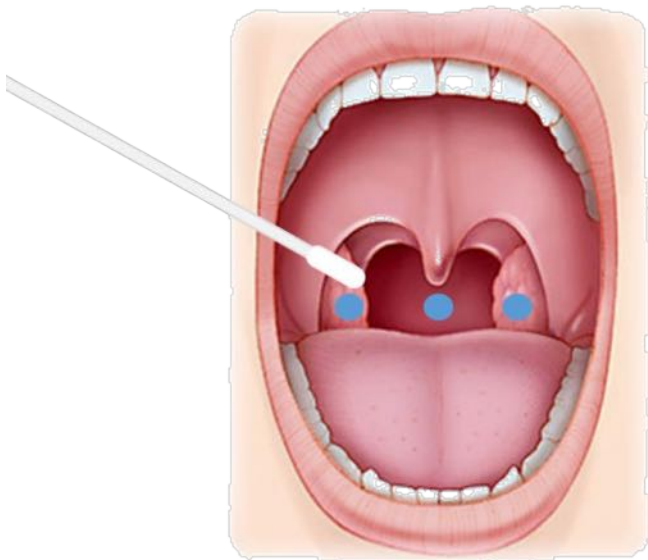


Diagram 1: Oropharyngeal swabbing

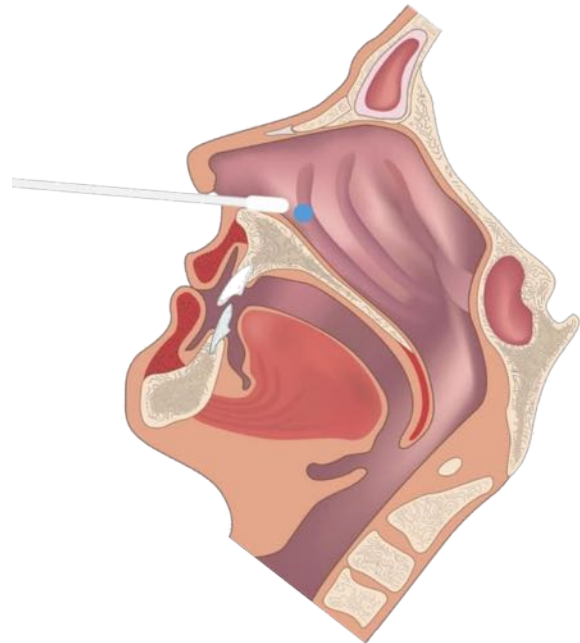


Diagram 2: Mid-turbinate nasal swabbing

## APPENDIX 4

## SAFETY GUIDANCE FOR THE USE OF CHLOR-CLEAN

### (Excerpts from Helix Solutions Safety Data Sheet)

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#### 4. FIRST AID MEASURES

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##### 4.1 Description of first aid measures

<b>Eye</b>	If in eyes, hold eyelids apart and flush continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre, a doctor, or for at least 15 minutes.
<b>Inhalation</b>	If inhaled, remove from contaminated area. To protect rescuer, use a Full-face Type B-Class P1 (Inorganic and acid gas, Particulate) respirator or an Air-line respirator (in poorly ventilated areas). Apply artificial respiration if not breathing.
<b>Skin</b>	If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised to stop by a Poisons Information Centre or a doctor.
<b>Ingestion</b>	For advice, contact a Poison Information Centre on 13 11 26 (Australia Wide) or a doctor (at once). If swallowed, do not induce vomiting.
<b>First aid facilities</b>	Eye wash facilities and safety shower should be available.

##### 4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

##### 4.3 Immediate medical attention and special treatment needed

Treat symptomatically.

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#### 7. HANDLING AND STORAGE

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##### 7.1 Precautions for safe handling

Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

##### 7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, well ventilated area, removed from water or moisture, incompatible substances, heat or ignition sources and foodstuffs. Ensure containers are adequately labelled, protected from physical damage and sealed when not in use. Check regularly for leaks or spills. Large storage areas should be bunded and have appropriate fire protection and ventilation systems.

##### 7.3 Specific end use(s)

No information provided.

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#### 11. TOXICOLOGICAL INFORMATION

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##### 11.1 Information on toxicological effects

<b>Health hazard summary</b>	Irritant - slightly corrosive. This product has the potential to cause adverse health effects with over exposure. Use safe work practices to avoid eye or skin contact and inhalation. Upon contact with water, low levels of corrosive and highly irritating chlorine and hydrogen chloride vapour are released. When used in small quantities, the potential for over exposure is reduced.
<b>Eye</b>	Irritant. Contact may result in irritation, lacrimation, pain and redness. May result in burns with prolonged contact.
<b>Inhalation</b>	Slightly corrosive - irritant. Over exposure to dust or vapours may result in irritation of the nose and throat, with coughing. High level exposure may result in burning pain, inflammation and ulceration of the respiratory tract. Effects may be delayed.
<b>Skin</b>	Slightly corrosive. Contact may result in irritation, redness, pain, rash, dermatitis and possible burns.
<b>Ingestion</b>	Harmful - irritant. Ingestion may result in burns to the mouth and throat, nausea, vomiting and abdominal pain.





APPENDIX 6

COVID-19 MICROBIOLOGY FORM

	CAR REG.	TEL. NO.
<b>Noble's Hospital</b>	<b>Microbiology (Covid-19)</b>	<b>01624 650000</b>
Surname _____	Mr Mrs Miss	DOB _____
		Folder No. _____
Forenames _____		Prev. names _____
Address _____		
_____	Postcode	IM _____
<input type="checkbox"/> <b>SYMPTOMATIC STAFF OR PUBLIC</b> <i>(List symptoms below)</i>		
<input type="checkbox"/> <b>ESSENTIAL WORKER <u>POST-ISOLATION</u> TEST</b>		
WORKPLACE _____		
ROLE _____		
<input type="checkbox"/> <b>ASYMPTOMATIC ESSENTIAL WORKER (SCREENING)</b>		
WORKPLACE _____		
ROLE _____		
<input type="checkbox"/> <b>ASYMPTOMATIC PATIENT TESTING (PRE-OP/TRANSFERS)</b>		
Date ____/____/____	Time taken _____	NHS <input checked="" type="checkbox"/>
Specimen type <u>SWAB</u>	Spec. site <u>THROAT/NASAL</u>	Request <u>COVID-19</u>
<i>Relevant details of clinical history/diagnosis</i>		
Signature _____		