Research Institute for Tropical Medicine - Department of Health
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Tel Nos.: (632) 8809-7599 / 8807-2631/32/37 • Website: www.ritm.gov.ph

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Undersecretary of Health
Health Facilities and Infrastructure Development Team
Department of Health

SUBJECT: RESPONSE TO THE FREEDOM OF INFORMATION (FOI) REQUEST OF A PRIVATE CITIZEN

Dear Usec David:

Greetings from the Institute.

This is to respectfully provide you with our response regarding the request for the Freedom of Information (FOI) from a private citizen (Mr. Nicanor Perlas) dated May 31, 2021 and August 10, 2021. Below is the summary of our comments, for your reference:

1ST BATCH OF FOI REQUESTS (May 31, 2021)	RITM COMMENTS
I. Cycle Threshold from March 15,2020 to present	There is no single database of all Ct values of all PCR tests done from the start of the pandemic to present. It must be noted that Ct value interpretation is dependent on the PCR kits that are used. These are NOT comparable across brands.
II. Models/Brands of RT-PCR tests used	RITM may provide the list of models/brands of RT-PCR tests used based on information generated from the RITM QA Programme for the COVID-19 Lab Network. We have attached this as Annex 1.
III. All DOH communications regarding the RT-PCR tests whether from DOH or to DOH	The request is very broad and is not very clear. RITM defers the request to DOH as to what communications are referred to in this request. For additional reference, the DOH issues public guidelines and advisories on the response to COVID-19, including laboratory testing. The requesting party is directed to the DOH website: https://doh.gov.ph/COVID-19-policies
IV. All communications from and to the World Health Organization (WHO) regarding the use of RT-PCR tests	The request is very broad and is not very clear. RITM defers the request to DOH as to what communications are referred to. For additional reference, the WHO has been releasing technical guidance on the laboratory testing of COVID-19, which includes PCR tests: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications?publicationtypes=f85a3610-b102-4287-a6df-f3bc0b2e9f7c

2ND BATCH OF FOI REQUESTS (August 10, 2021)	RITM COMMENTS
I. Documents and/or communications regarding the Certified Reference Material (CRM) being used by DOH and its authorized testing centers to determine whether a person is positively infected with SARS-CoV-2.	Real-time PCR technology is reliant on the ability of the thermocycling machine's camera to correctly detect successive exponential increases in the fluorescence intensity against erratic fluorescence signals that behave as background noise. As such, the primary determinant whether a person is classified as positive is the presence of the viral RNA target in their sample. In the context of the PCR procedure, the "CRM" referred here may pertain to the "positive" control that is incorporated as part of the components of the real-time PCR kit. The primary function of a positive template control is to serve as a validity checkpoint to detect general failures or errors assumed to be related to all samples belonging to the same run; that is to say that if a positive control fails, then all samples belonging to the same run are retested. The final outcome of each tested sample is tied to the performance of the positive control.
II. Documents, lab results, and/or communications including but not limited to scientific articles demonstrating, using procedures that satisfy Koch's Postulates, that this Certified Reference Material is the successfully isolated SARS-CoV-2 virus	The real-time RT-PCR test for SARS-CoV-2 does not "isolate" the virus but rather detects short target sequences of the virus in clinical samples. If these target sequences are detected in clinical samples, these can be amplified and detected through the test. The positive control material included in the PCR kit is likewise not a whole virus but rather nucleic acid fragments taken from the virus or synthesized, and that which serve as the basis for (1) comparing if a clinical sample that is tested is positive for the virus; and (2) provide supporting information that the assay is working. As originally stated, the four criteria known as "Koch's postulates" are: (1) The microorganism must be found in diseased but not healthy individuals; (2) The microorganism must be cultured from the diseased individual; (3) Inoculation of a healthy individual with the cultured microorganism must recapitulated the disease; and finally (4) The microorganism must be re-isolated from the inoculated, diseased individual and matched to the original microorganism. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3775492/). Ethically, it is not appropriate or acceptable to inoculate a healthy individual with a virus such as SARS-CoV-2 and check for development of COVID-19, to satisfy Koch's postulates. Therefore, it is probably impossible to get any actual data on experiments that involve this. At the outset of the pandemic, clusters of cases in Wuhan exhibited similar symptoms, and, subsequently on conduct of various diagnostic techniques to include virus isolation and sequencing, it was determined that a novel coronavirus, was present among the affected as the causative agent of the disease. We do not have any additional information requested as we do not perform Virus Isolation for SARS-CoV-2 in RITM.

III. Documents, lab results, and/or scientific and other communications, demonstrating that said isolate, that has now become the Certified Reference Material (CRM) for the RT-PCR tests, is the isolate of a complete SARS-CoV-2 virus	We do not have such information as we do not perform Virus Isolation for SARS-CoV-2 in RITM.
IV. Documents showing the source of the CRM that DOH and authorized testing centers have been using and are using for its/their RT-PCR tests	COVID-19 laboratories use various brands of commercial PCR detection kits for SARS-CoV-2. The positive controls are included as part of the components of the PCR kit. Manufacturers may be contacted as to the source of their positive controls, subject to their policies on the confidentiality of their product information.

Let us know if there are any additional queries.

Sincerely yours,

CELIA C. CARLOS, MD, CESO III, FPPS, FPIDSP, FPSMID
Director IV
Research Institute for Tropical Medicine

CC: **NESTOR F. SANTIAGO, JR., MD, MPHC, MHSA, CESO II**
Assistant Secretary of Health
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ANNEX 1 – LIST OF MODELS/BRANDS OF RT-PCR TESTS
used in the COVID-19 Laboratory Network
(as of August 17, 2021)

1	DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit. Manufactured by Solgent Co., Ltd.
2	GenAmplify™ Corona Virus Disease-2019 (COVID-19) rRT-PCR Detection Kit. Manufactured by Manila HealthTek Inc.
3	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing). Manufactured by Sansure Biotech Inc.
4	TibMolbiol LightMix® by Roche Diagnostics
5	genesig Real-Time PCR Coronavirus (COVID-19) CE IVD kit. Manufactured by Primerdesign Ltd.
6	STANDARD M nCoV Real-Time Detection kit. Manufactured by SD Biosensor, Inc.
7	A*STAR FORTITUDE KIT 2.0. Manufactured by MiRXES Pte Ltd.
8	A*STAR FORTITUDE KIT 2.1. Manufactured by MiRXES Pte Ltd.
9	LightCycler® Multiplex RNA Virus Master Manufactured by Roche Molecular Systems, Inc.
10	LightMix® Modular SARS-CoV-2 (COVID19) RdRP by Roche Diagnostics
11	Real-Time Fluorescent RT-PCR kit for detecting 2019-nCoV(SARS-CoV-2). Manufactured by BGI Biotechnology Co., Ltd.
12	TaqPath™ COVID-19 Combo Kit. Manufactured by Thermo Fisher Scientific, Inc.
13	Logix Smart Coronavirus Disease 2019 (COVID-19) kit. Manufactured by Co-Diagnostics, Inc.
14	GeneFinder™ COVID-19 Plus RealAmp Kit. Manufactured by OSANG Healthcare Co., Ltd.
15	Allplex™ 2019-nCoV Assay. Manufactured by Seegene Inc.
16	FTD SARS-CoV-2. Manufactured by Fast Track Diagnostics Luxembourg S.à.r.l.
17	abTES™ COVID-19 qPCR I Kit. Manufactured by AITbiotech Pte Ltd.
18	PerkinElmer® New Coronavirus Nucleic Acid Detection Kit. Manufactured by PerkinElmer, Inc.
19	PerkinElmer® SARS-CoV-2 Real-time RT-PCR assay. Manufactured by PerkinElmer Inc, SYM-BIO LiveScience Co., Ltd
20	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing) manufactured by Da An Gene Co., Ltd. of Sun Yat-sen University
21	Fosun COVID-19 RT-PCR Detection Kit. Manufactured by Shanghai Fosun Long March Medical Science Co., Ltd.
22	xABT Multiple Real-Time PCR Kit for Detection of 2019-nCoV. Manufactured by Genecraft Labs.
23	OPTI SARS-CoV-2 RT-PCR Test. Manufactured by OPTI Medical Systems, Inc.
24	GenePro SARS-CoV-2 Test. Manufactured by Gencurix Inc.

25	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR). Manufactured by Wuhan Easy Diagnosis Biomedicine Co., Ltd.
26	SARS-CoV-2 Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method). Manufactured by ZYBIO INC.
27	Diagnostic Kit for Novel - Coronavirus (2019-nCoV) RNA - EasyNat. Manufactured by Ustar Biotechnologies (Hangzhou) Ltd.
28	cobas® SARS-CoV-2 & Influenza A/B assay. Manufactured by Roche Diagnostics GmbH.
29	DirectDetect™ SARS-CoV-2 qPCR Kit. Manufactured by Coyote Bioscience Co., Ltd .
30	BioFire® Respiratory 2.1 (RP2.1) Panel. Manufactured by BioFire Diagnostics.
31	1copy™ COVID-19 qPCR Multi Kit. Manufactured by 1drop Inc.
32	Total Solution of Novel Coronavirus 2019-nCoV Nucleic Acid Detection. Manufactured by Shenzhen Uni-Medica Technology Co., Ltd. (Uni-medica)
33	STAT-NAT® COVID-19 MULTI. Manufactured by SENTINEL CH. SpA
34	SARS-CoV-2 Fluorescent PCR Kit. Manufactured by Maccura Biotechnology Co., Ltd.
35	BD SARS-CoV-2 Reagents for BD MAX™ System. Manufactured by Becton, Dickinson and Company
36	GeneXpert Xpert Xpress SARS-CoV-2. Manufactured by Cepheid.