

आई सी एम आर - राष्ट्रीय विषाणु विज्ञान संस्थान

भारतीय आयुर्विज्ञान अनुसंधान परिषद स्वास्थ्य अनुसंधान विभाग स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

I C M R - NATIONAL INSTITUTE OF VIROLOGY

Indian Council of Medical Research

Ministry of Health & Family Welfare, Govt. of India

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No. 1/8/2005/RTI/Admn./XVII- 669

28th June 2021

To

Sh. Trinayan Das Kamarchuburi, NT Road, Tezpur, Sonitpur, Assam - 784001

Sub.: Online Application under Right to Information Act 2005 Ref.: Registration No. NIOVP/R/E/21/00038 dated 16/06/2021

Sir,

This is in reference to your above online application no. NIOVP/R/E/21/00038 dated 16th June 2021, seeking information under Right to Information Act 2005. The information sought by you is furnished below.

1. Any proof of isolation/purification of SARS-CoV-2 (COVID-19) virus?

Please find the below mentioned publications for the SARS-CoV-2 isolations by ICMR-National Institute of Virology.

- a. Sarkale P., Patil, S., Yadav, P.D., Nyayanit, D.A., Sapkal, G., Baradkar, S., Lakra, R., Shete-Aich, A., Prasad, S., Basu, A. and Dar, L., 2020. First isolation of SARS-CoV-2 form clinical samples in India. The Indian Journal of Medical Research, 11(2-3), p.244.
- b. Yadav, P., Sarkale, P., Razdan, A., Gupta, N., Nyayanit, D., Sahay, R., Potdar, V., Patil, D., Baradkar, S., Kumar, A. and Aggarwal, N., 2021. Isolation and characterization of SARS-CoV-2 VOC, 20H/501Y. V2, from UAE travelers, bioRxiv.
- c. Yadav, P.D., Nyayanit, D.A., Sahay, R.R., Sarkale, P., Pethani, J., Patil, S., Baradkar, S., Potdar, V. and Patil, D.Y., 2021. Isolation and characterization of the new SARS-CoV-2 variant in travelers from the United Kingdom to India: VUI-202012/01 of the B. 1.1. 7 lieage. Journal of Travel Medicine, 28(2),

विश्व स्वास्थ्य संघटन

उभरते वायरल संक्रमणों का सहयोग केन्द्र राष्ट्रीय शीतज्वर केन्द्र पोलिओ, खसरा एवं रुबेला के लिए रेफरल प्रयोगशाला



WORLD HEALTH ORGANIZATION

Collaborating Centre for Emerging Viral Infections National Influenza Centre Referral Lab for Polio, Measles and Rubella

	p.taab009. d. Yadav, P.D., Nyayanit, D.A., Sahay, R.R., Shete, A.M., Majumdar, T., Patil, S., Patil, D.Y., Gupta, N., Kaur, H., Aggarwal, N. and Vijay, N., 2021. Imported SARS-CoV-2 V501Y. V2 variant (B. 1.351) detected in travelers from South Africa and Tanzania to India. Travel Medicine and Infectious Disease.
2. What are the methods used for isolation/purification of SARS-CoV-2 virus?	Virus isolation is being performed in Vero cell lines using the tissue culture techniques.
Is the RT-PCR test approved for diagnostic of infectious disease like SARS-CoV-2 (COVID-19) virus?	Yes, Real Time Reverse Transcription Polymerase Chain Reaction (Real Time RT-PCR) is the gold standard test for detection of SARS-CoV-2. For more details on molecular testing of SARS-CoV-2 please refer to ICMR advisory available at https://www.icmr.gov.in/pdf/covid/labs/ICMR Advisory Testing System v 10112 020.pdf and the WHO guidelines available at https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf
4. Was the RT-PCR test used earlier to diagnose any infectious disease? What is the accuracy of the test?	Yes, RT-PCR test is a widely used test to detect many infectious diseases such as Influenza viruses, Hepatitis viruses, HIV, Dengue chikungunya etc. it is widely used in biomedical science research. The test is highly sensitive and detects specific targets very accurately.
5. How does the PCR test help in diagnosing SARS-CoV-2 virus genetic sequence?	Real-Time PCR offers sensitivity, specificity and wide dynamic range for detecting target nucleic acids. For the SARS-CoV-2 detection variety of RT-PCR kits are available. The RT-PCR of SARS-CoV-2 detects more than two genes of SARS-CoV-2 such as E, N, ORF, S, RDRP along with human housekeeping genes as sample quality targets. The positive results in RT PCR are confirming the presence of SARS-CoV-2 virus infection.
6. What is the false positive rate of PCR test on CT-35?	The RT-PCR kit has a cut off range to determine positivity in tests. Majority kits have the set Cut off values ranging from 35 to 40 ct value. As mentioned above SARS-CoV-2 kits use multiple targets for detection and the decision of the sample as positive is dependent on the targets used in the test. If a single gene showed ct value 35 then the sample is inconclusive and recommended to

repeat after four days. The main reason for this kind of report may be improper timing of specimen collection e.g. early phase of infection or recovery phase of infection. Any specimen that has a Ct below the cut off for the test is most likely a true positive. Ct values can differ immensely between a poorly collected specimen to a wellcollected specimen. Other factors than can improper include values impact Ct storage specimen transport, specimen many times temperatures, how the been frozen, and specimen has instrument on which testing is performed. Each test is different, with different sensitivities based on things like how the test was designed. An N95 mask is a respiratory protective 7. Can a N95 face mask prevent the device designed to achieve a very close transmission of SARS-CoV-2 virus? facial fit and very efficient filtration of airborne particles. N95 masks without gaps can filter 99.9 percent particles larger than 0.3um and 85 percent particles smaller than 0.3um. 8. Any proof of isolation/purification of the Please find the below mentioned Delta variant or any other variants of publications for the SARS-CoV-2 SARS-CoV-2? isolations by ICMR-National Institute of Virology. a. Sarkale P., Patil, S., Yadav, P.D., Nyayanit, D.A., Sapkal, Baradkar, S., Lakra, R., Shete-Aich, A., Prasad, S., Basu, A. and Dar, L., 2020. First isolation of SARS-CoV-2 form clinical samples in India. The Indian Journal of Medical Research, 11(2-3), p.244. b. Yadav, P., Sarkale, P., Razdan, A., Gupta, N., Nyayanit, D., Sahay, R., Potdar, V., Patil, D., Baradkar, S., Kumar, A. and Aggarwal, N., 2021. Isolation and characterization of SARS-CoV-2 VOC, 20H/501Y. V2, from UAE travelers, bioRxiv. c. Yadav, P.D., Nyayanit, D.A., Sahay, R.R., Sarkale, P., Pethani, J., Patil, S., Baradkar, S., Potdar, V. and Patil, D.Y., 2021. Isolation characterization of the new SARS-CoV-2 variant in travelers from the United Kingdom to India: VUI-202012/01 of the B. 1.1. 7 lieage. Journal of Travel Medicine, 28(2),

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	Imported SARS-CoV-2 V501Y. V2
	variant (B. 1.351) detected in
	travelers from South Africa and
	Tanzania to India. Travel Medicine
	and Infectious Disease.
9. Was there any tissue culture done on the	Yes, virus was cultured for development of
SARS-CoV-2 virus?	indigenous inactivated vaccine and for
SARO-COV-2 VII uo	development of ELISA and neutralization
	assays.

The Appellate Authority in respect of the information furnished above is, Prof. Priya Abraham, Director, ICMR-National Institute of Virology, Pune. If you are not satisfied with this reply, you may appeal within 30 days of receipt of this letter.

Thanking you,

Yours sincerely,

Dr. Paresh Shah CPIO & Scientist-E