

ICMR validates indigenous assays for COVID-19 diagnosis

By ISW

New Delhi, May 21 (India Science Wire): Indian researchers and authorities have prioritized to reduce dependence on other countries by developing and validating indigenous diagnostic assays for COVID-19 testing. A total of 11 RT-PCR-based indigenous assays were validated and recommended for the testing of COVID-19. This has been revealed by the Indian Council of Medical Research (ICMR).

As COVID-19 cases are increasing; the limited supply of diagnostic kits required for its diagnosis remains a concern. To meet the demand for diagnostic devices, indigenous production and rapid validation have become necessary. Indigenous production of diagnostic material to ensure its uninterrupted availability could be a game changer especially in India, a country with a population load of more than 130 crore.

ICMR had earlier validated the indigenous TrueNat assay for Tuberculosis (TB). The test is WHO pre-qualified and is included as a reliable and accurate method for quick screening of TB patients. The TrueNat assay has also been validated by ICMR-National Institute of Virology (NIV) as a point of care test for Nipah virus disease.

In April 2020, an indigenous manufacturer developed TrueNat assay for screening of SARS-CoV-2 that causes COVID-19. ICMR undertook successful validation of the E-gene screening assay, following which TrueNat-based testing has been initiated by the states for SARS-CoV-2 detection. From April 2020 till date, more than 1.3 lakh screening tests have been conducted by states. However, the rate-limiting step has been the lack of TrueNat confirmatory assay. All the TrueNat positive samples had to be confirmed by RT-PCR-based tests either located in the same or different laboratory.

Recently, the indigenous manufacturer has also developed an RdRp gene-based confirmatory assay of TrueNat, which has been successfully validated again by ICMR and has been found to have high sensitivity and specificity. Both the validations have been stringently conducted by Department of Health Research (DHR)/ICMR Virus Research and Diagnostic Laboratory (VRDL) at Bangalore Medical College and Research Institute, Bengaluru.

ICMR has now recommended the TrueNat COVID-19 test as a two-step test: step one, i.e., E-gene screening assay for all COVID-19 suspect samples to be followed by step two for the RdRp-based confirmatory test in all E-gene positives.

This fully indigenous diagnostic platform offers a reliable and affordable option to augment the SARS-CoV-2 testing capacity in India. The platform comprises a TrueNat machine, inbuilt RNA extraction system, RT-PCR chips, collection swabs and viral lysis medium (VLM). Single assay has a turnaround time of 35-50 minutes for 1-4 samples with a total of 12-48 samples being tested per day, depending upon the type of machine. The biosafety and biosecurity requirements are minimal in view of the sample being collected in VLM, which inactivates the virus. The test can be used at the level of district hospital/primary health centres also. (India Science Wire)

Keywords: COVID-19, ICMR, MoHFW, Coronavirus, Diagnosis, Testing