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

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Dated: 22/10/2020

Advisory on CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) technology-based SARS-COV-2 test

1. CRISPR SARS CoV-2 test is a new diagnostic method based on CRISPR-Cas9 technology to identify and target the genetic material of SARS-CoV-2 virus.
2. The test has been developed by Council of Scientific & Industrial Research (CSIR)-Institute of Genomics and Integrative Biology (IGIB), Delhi and has been validated by Department of Atomic Energy (DAE) – National Center for Biological Sciences, Tata Institute of Fundamental Research, Bengaluru.
3. The test has been approved by DCGI for use in India.
4. The test works by identifying SARS-CoV-2 virus strain and uses a Thermal Cycler instead of a qPCR machine for conducting the test.
5. As claimed by the manufacturer, no further RT-PCR based confirmation is required for samples that are confirmed as positives or negatives by the CRISPR SARS-CoV-2 test.
6. ICMR advises that specimen collection and transfer of sample for CRISPR SARS-CoV-2 test must be performed using appropriate PPE.
7. It is further advised that testing with CRISPR SARS-CoV-2 test be carried out under appropriate biosafety (BSL2 level) precautions, following the standard RTPCR guidelines laid down by ICMR.
8. Existing Govt/Private laboratories already approved by ICMR for SARS-CoV-2 RT-PCR based testing may use this new CRISPR test if the laboratory desires to do so. No further approval is required from ICMR for existing laboratories. The option of “TataMD CHECK CRISPR Test (TATA Medical and Diagnostics Ltd.)” has been added in the drop-down kit selection menu of the COVID-19 web portal of ICMR and may be selected by the concerned laboratory while entering the results.
9. New laboratories intending to initiate molecular testing of SARS-CoV-2 testing by any method will be required to seek approvals as per the standard process laid down by ICMR and NABL before initiating any kind of molecular testing.
10. Any prescription for RT-PCR, CRISPR, TRUENAT, CBNAAT may be considered equivalent.
11. All testing data should be essentially entered into the ICMR COVID-19 web portal on a real time basis. The laboratories may use the existing login credentials provided by ICMR to enter these results. Other reporting mechanisms to the state and IDSP should also be ensured as per the laid down protocols of COVID-19 case reporting.
12. The assay should be used as per the standard operating procedure provided by the manufacturer.