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

Date: 10/11/2020

Evidence based ICMR advisory on molecular testing of COVID-19: Availability of testing platforms and their recommended use

- Molecular diagnosis of SARS-CoV-2 is considered to be the best diagnostic modality for early detection of infection (1).
- Amongst molecular diagnostics, open system real-time reverse transcriptase polymerase chain reaction (rRT-PCR) was the first approach to be adopted globally (2).
- Given the need for rapidly implementing large scale testing for SARS-CoV-2, the field of molecular diagnostics for SARS-CoV-2 has evolved rapidly. Now other technologies like closed system RT-PCR i.e., CBNAAT platforms, RT-LAMP assays and CRISPR-based diagnostics have also become available.
- All these platforms are validated with open system rRT-PCR test as gold standard and are approved for use only if they have sensitivity and specificity comparable to the open system rRT-PCR (3).
- In view of this, the closed system RT-PCR i.e., CBNAAT platforms like TrueNat, GeneXpert, US-FDA approved cartridge based systems like Abbott ID Now and other platforms like RT-LAMP assay, CRISPR based tests etc. are considered equivalent to the open system rRT-PCR.
- The available newer molecular assays as well as other evolving molecular technologies, if validated and found comparable to open system rRT-PCR, can be equally considered for use.

References:

1. Chu DKW et al. Molecular Diagnosis of a Novel Coronavirus (2019-nCoV) Causing an Outbreak of Pneumonia. Clin Chem. 2020;66(4):549-555. doi:10.1093/clinchem/hvaa029
2. Diagnostic detection of 2019-nCoV by real-time RT-PCR. 2020. Available at: https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf (Accessed on 09 November, 2020)
3. ICMR In-house validation protocols