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:
3. ICMR In-house validation protocols