



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: 24/09/2020

## Revised Guidelines for TrueNat testing for COVID-19

The TrueNat system is now a comprehensive assay for screening and confirmation of COVID-19 cases.

- Sample is collected in viral lysis buffer and hence biosafety and biosecurity requirements for use of TrueNat are minimal.
- **Types of assays:**

**There are three different types of TrueNat assays available now:**

1. Assay 1\*: TrueNat Beta CoV E gene Screening assay.
2. Assay 2: TrueNat SARS CoV2 RdRp gene confirmatory assay.

*\*Assay 1 needs to be followed by Assay 2 for confirmation of the results.*

3. Assay 3: TrueNat Covid-19 Multiplex assay.

**Detailed guidance on use of the assays is as follows:**

### 1. Two step singleplex assay-

- A) Step 1:** This is E gene screening assay. All samples of suspect COVID-19 should be first tested by this assay. All negatives are to be considered as **true negatives**. All positive samples should be subjected to confirmation by step 2 assay.
- B) Step 2:** RdRp gene confirmatory assay. All samples that test positive by this assay must be considered as **true positives**.

### 2. Multiplex assay-

TrueNat system is also now a multiplexed point of care test that includes a single assay comprising of both the **screening (E gene)** and **confirmatory (Orf1a)** targets in a single test. All samples of suspected COVID-19 cases can also be tested by this assay. All negatives are to be considered as **true negatives**. All samples that test positive by this assay must be considered as **true positives**.

- No further RT-PCR based confirmation is required for samples that are confirmed as true positives by the TrueNat assays.
- All positive and negative results must be reported to ICMR portal on real time basis.