Specifications

Viral RNA Extraction

- Kit should work with silica membrane column / magnetic bead-based technology allowing extraction of Viral RNA From Human Samples (Plasma, CSF, Urine, Other cell-free body fluids and Cell-culture supernatants.
- The Viral RNA extracted using this kit should be used for downstream applications like PCR, qPCR, real-time PCR
- Kit should extract Viral RNA using sample volume between 100µl - 200µl and Elution volume between 40 µl - 80 µl
- The process of extraction using the kit should be either centrifugation/vacuum based/magnetic bead based.
- Carrier RNA should be used in the kit to capture maximum amount of the Viral RNA from sample and carrier RNA Should help viral RNA to escape from degradation by RNases
- Time per extraction should be 30-60Min
- Yield of the Viral RNA should be >90% recovery
- The Elution buffer should have necessary components to prevent microbial growth and contamination with Rnases.
- Should be optimized for use with biological fluids and cell-free samples such as serum, plasma, swabs, and cell culture medium.
- The extraction kit should be able to work on manual as well as automated platform both.

RT-PCR Kits for COVID-19

- Should be approved by European CE-IVD or US-FDA
- If not approved by CE-IVD/US-FDA, validation by ICMR Institutes such as NIV Pune is mandatory.
- Company should have obtained marketing licence for RT PCR test kits from Drug Controller General India.
- Real time PCR test protocol with fluorescent probe based chemistry.
- Compatible for multiple RT- PCR platforms
- Compatible with different viral RNA extraction kits available in the market.
- Test should be based on at least two viral gene targets along with internal control which validates sample quality, RNA extraction and RT PCR reaction.
    a. Screening Assay : Gene specific for sub genus Sarbeco + Internal Control
    b. Confirmatory assay : One or more gene targets specific to SARS CoV-2

Antibody IgM and IgG Rapid Test Kit for COVID-19

- Should be approved by European CE-IVD or US-FDA
- If not approved by CE-IVD/US-FDA, validation by ICMR Institutes such as NIV Pune is mandatory.

- Company should have obtained marketing licence for Rapid test kits from Drug Controller General India.
- The kits should be able to differentiate IgM and IgG separately for COVID-19.

Viral Transport Medium

- 10-15 ml volume screw-cap, leak-proof tube
- Two sterile synthetic fiber swabs (polyester, rayon, or dacron) with plastic shafts or Wire shaft (flexible shaft): In general ICMR recommends two swabs i.e. NP and OP specimens should be combined at collection into a single vial.
- Should contains 3 ml of viral transport media
- 1 Ziplock specimen bag containing absorbent pad
- Labeling stickers
- It should be in the volume of 3ml viral transport medium in 10-15 ml centrifuge tube.
- It should contain a protective protein antibiotics to control microbial contamination and buffers to control the pH.
- The medium also contains a cryoprotectant which helps in preserving the viruses, if specimens are frozen for prolonged storage.
- The medium should be stable at room temperature.
- pH 7.3 +- 0.3.
- Osmolality in mOsm/Kg H2O 500.00 - 600.00