

Indian Council of Medical Research  
Department of Health Research  
Government of India  
New Delhi

Dated: 11<sup>th</sup> April, 2020

Indian Council of Medical Research, New Delhi invites techno-commercial offer for procurement of following items related to COVID-19 testing.

S.No.	Item Description #	Quantity required (Approx.)
1.	Viral Transmission Media (VTM)	52.25 lakh tests
2.	Real Time PCR Combo Kit	25 lakh tests
3.	RNA Extraction Kit	30 lakh tests
4.	Antibody IgG/IgM COVID-19 Rapid Test Kit	45 lakh tests

# Detailed Generic Specification for each item is attached.

- 1) The item offered must have either US-FDA or EU's CE-IVD or ICMR-NIV Pune approval/certification.
- 2) The bidder should have certificate/License from the Drugs Controller General of India (DCGI) for import of the intended item.
- 3) The bidder is required to submit a separate bid for each item as mentioned in the table above, in case it qualifies for supply of more than one item.
- 4) If the item is proposed to be imported from China, NMPA (National Medical Product Administration), China approval for the said item/company is **mandatory**. Compliance to any other conditions imposed by the "source-country" will remain the responsibility of the bidder and ICMR will remain indemnified from any liabilities on such account.
- 5) ICMR reserves the right to ensure random "**Lot-testing**" or "**Pre-shipment testing**" of supplied items for quality. On negative findings, the consignment will be rejected outrightly. Any supply not found acceptable shall be returned and the supplier needs to replace them in a timely manner. Bidder should take into consideration this fact while pricing for their supplies.
- 6) ICMR reserves the right to distribute the purchase to more than one vendor following Multiple Vendor System to ensure timely supply.

- 7) The bids will be evaluated on the basis of “Rate Quoted”, “Timely Schedule of Supply”, “Desired Quantities”, “Capability of the supplier to supply the desired quantity” and “Quality of the offered product”. In case the quoted rate is not FOB New Delhi, it will be calculated for FOB New Delhi for comparison purpose. **However, during evaluation first such bids will be evaluated and decided which are either FOB, New Delhi or have clear indication about factors as mentioned at point 8 (iv) below.**
- 8) Prospective bidders (Manufacturer or their authorized distributors in India) can submit the offer giving complete detail on the following four aspects:
- i) Complete techno-commercial specification including Catalogue No. Of the product along with certification for the product offered;
  - ii) Maximum quantity which it can supply up to 31st of May, 2020 by giving their firm delivery schedule starting from 1<sup>st</sup> May, 2020 or before;
  - iii) Price of the offered item (preferably FOR/FOB New Delhi in Indian Rupees) per test. The rates quoted should mention duties and taxes separately.
  - iv) In case the quoted price is **not FOB New Delhi**, conditions and associated cost of logistics, insurance, clearances and other related activities to ensure delivery at ICMR, New Delhi depots may also be clearly indicated with clear indication of party responsible for the same.
  - v) Other Terms and Conditions of supply and payment.
  - vi) Bidders are requested to regularly visit the website of ICMR, New Delhi for further clarifications, amendments, etc. DG, ICMR reserves all the rights to accept or reject any/all bids without assigning any reason. Bids not complying to the above tender formalities, shall summarily be rejected.
  - vii) If there is difference of the amount in figure and words, the lesser one will be considered.
  - viii) Taxes, duties, levies, etc. shall be as per actuals paid/due.

Interested suppliers may submit their quotations through the email [head.rbmh@gmail.com](mailto:head.rbmh@gmail.com) **AND** [sharmav1.del.cca@gov.in](mailto:sharmav1.del.cca@gov.in) by 14<sup>th</sup> April, 2020 not later than 02:30 PM Indian Standard Time.

# 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 H<sub>2</sub>O 500.00 - 600.00

With reference to EOI dated 11.4.2020 regarding techno commercial offer for different items relating to Covid-19 testing, it is requested to read as under:-

- 1. DCGI permission is not a precondition and may be submitted before delivery.**
- 2. The certification of US-FDA, CE-IVD is desirable. However the CE from the country of origin will also be considered subject to approval by ICMR.**

Other terms and conditions will remain same.