Notice Inviting e-Tender

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SUPPLY AND INSTALLATION OF 2 UNITS OF REAL TIME PCR MACHINE ON REAGENT RENTAL BASIS IN THE HOSPITALS AND MEDICAL COLLEGES OF THE GOVERNMENT OF WEST BENGAL.

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-108/2026	**Dated-03.02.2026**

AMENDMENT-I

Revised Technical Specification

REAL TIME PCR MACHINE

Technical specification for quantitative viral load estimating platform for HBV & HCV:

Assay Parameter		Specification
1	**Type of PCR & specimen used**	**CLOSED** HCV and HBV nucleic acid extraction and viral load testing (Automated and Integrated) Quantitative Real-time PCR platform using human whole blood derived **plasma & serum**
2	**Assay technology**	Technology of platform should be based on real time PCR chemistry like TaqMan, molecular beacon probes, SYBR Green

		and all other fluorescent dye based chemistries and should be calibrated for multiple dyes.
3	**Approval required**	The Assay should be FDA-approved and CE-IVD marked. The quoted test shall be licensed to bidder in India by DCGI (I)
4	**Limit of detection (LoD)**	**HCV RNA: 15 IU/mL or lower for 0.5 mL input** **HBV DNA: 10.5 IU/mL or lower for 0.5 mL input**
5	**Dynamic range of assay**	**HCV: 15 - 1 × 10^8 IU/mL or better** **HBV: 10 - 1 × 10^9 IU/mL or better**
6	**Assay Sensitivity**	**95% or above, subject to the LoD specified above for HCV RNA and HBV DNA**
7	**Assay specificity**	**100%**
8	**Genotype coverage**	Assay shall cover HCV genotypes 1 to 6 & HBV genotype A to H plus Pre-Core Mutants
9	**Inclusion of reagents/enzymes**	The assay shall have inclusion of reagents/enzymes (either built in or external addition) to remove the carry over contamination by degrading of Nucleic Acid templates amplified in previous runs.
10	**Sample size per 8 hr cycle**	Capable of completing extraction and testing of **120 samples within 8 hours**
11	**Turn around time for 1st batch** (urgent samples)	First 24 or more results in ≤5 hrs
12	**Throughput**	Automated sample extraction & testing should have a throughput of up to 96 specimens in batches of 24 to 96.
13	**Specimen identifier**	Platform shall have barcode system for specimen tube identification.

2.0. General specifications:

1. The bidder will provide installation qualification, operational qualification and performance qualification at the time of installation with all certificates and log book for maintenance of the equipment at no extra cost.
2. The agency shall provide an EQAS on a 6-monthly basis provided by any ISO 17043 approved provider which should be part of the package with two sets of proficiency testing panels for HBV DNA and HCV RNA.
3. Yearly preventive maintenance and calibration shall be the responsibility of the bidder as per requirement of quoted system/assay. Timely upgradation of the facility with respect to hardware/ software/reagent/workflow shall be provided free of cost along with orientation of the concerned lab personnel.
4. The manufacturer should provide at least 95% uptime of the HCV & HBV viral load testing facility.

5. The bidder shall provide free of cost replacement of the viral load platform in case new model or upgraded version is released by the manufacturer.
6. The bidder shall submit the details of Engineer and Application Support Team.
7. The bidder will be responsible for training of laboratory staff on operation of equipment at the time of installation and subsequently every year for optimal utilization of the equipment. The cost of refresher trainings will be borne by the government but the technical aspects will have to be dealt with by the vendor.
8. The bidder shall set up the operational facility as per the requirement of proposed system and assay such as refrigeration (4 / -20 / -80 degree Celsius), centrifuge, HEPA filters, pipettes or any other equipment/consumables required for running of Quoted assay. The same shall be calibrated by the bidder as per requirements of NABL.
9. Compatible (5 to 10 KVA) UPS will be provided by bidder for nucleic acid extraction and testing equipment with back-up to complete one cycle at least.
10. Electrical requirement:
    a) Output voltage: 220 volts +/- 10% volts. Input voltmeter and ampere meter. Protection: High-low voltage cut-off, overload and short circuit protection.
    b) Electrical safety: Equipment meets electrical safety specifications such as that of IEC (Class I)
11. Down-time commitment to be restricted to a maximum period of 48 hours in the cities and 96 hours in other areas, if any (working days) and provide alternative to ensure uninterrupted testing services. Punitive actions (pro-rata) shall be taken in case of failure to maintain the desirable downtime.
12. Satisfactory report from at least 3 Govt./Private (atleast 1 Govt. installation) sites which have the equipment installed in last 3 years.
13. All ancillary parts required for functioning of the PCR platform such as the dedicated UPS, barcode reader, barcode printer etc. are to be provided afresh with the extraction & PCR platform. Maintenance and support related to the dedicated UPS must be borne by the bidder.
14. The time limit from the site of installation being ready and the platform being ready for sample testing (including installation & training) should be not exceeding 2 weeks.

The bidder should submit valid CDSCO Certificate / Registration / License for both the manufacturer(s) and importer(s) as applicable.

Wherever possible, the reagent rental models, for the viral load platforms, will be preferred.

The committee approved the technical specifications of the quantitative viral load testing platform for HBV and HCV and agreed for procurement of the same under reagent rental model wherein the kits procured for HBV DNA and HCV RNA would be compatible with the platform.

Sl. No.	Number of test per year for each parameter as committed
1	Hepatitis B: 21600 tests for 2 equipment Hepatitis C: 8400 for 2 equipment