Tender under sealed cover are invited from reputed companies for Fully Automated Nucleic Acid Amplification Testing (NAT) with following specifications.

**Specification** –

- Fully Automated system and integrated (walk way) system.
- Target amplification by polymerase chain reaction / transcription mediated amplification..
- The system must perform all steps from sample processing and viral nucleic acid extraction to target amplification and detection automatically
- All equipment/components of the system supplied shall be of the latest version, consisting of all compatible equipment, hardware and software designated and set up to perform the offered NAT assay.
- The automation system provided must have the following features and must provide documentary evidence that it can be achieved.
  - Positive sample identification with barcode scanning.
  - Manually entered samples IDs shall be possible.
  - Disposable filtered tips must be used to prevent carry over and cross contamination of samples.
  - Leaks, fibrin clots and bubble during aspiration and dispense cycles and samples and reagent can be detected and documented.
  - True level sensing or insufficient volume detection for sample and reagent can be detected and documented.
- The instrument must display on board the temperature for all temperature control functions wherever applicable.
- Reagent dispensing process shall be monitored to ensure that the accurate amount of fluid (sample, reagents, washing solutions etc are dispensed.
- The vendor shall supply appropriate and adequate units of decapper, if required for decapping of samples tubes for routine operation.
- The vendor shall supply appropriate and adequate units of air conditioning and humidification, as required, to be installed in the laboratory where the instrument is located. Any modification room partition, roof flooring civil and electrical work related to the functioning of the NAT Lab is the responsibility of the service provider.
- All essential accessories like electronic pipettes, bar code scanners, bar code printers, centrifuge machine, vacutainers (EDTA & plain) and other essential equipments may be provided by the vendor.
- The equipment/components of the system shall be provided with uninterrupted power supply (UPS) devices, which keep the system running for at least 30 minutes from the time of power failure without loss of any data.
- In the event that specific reagent preparation is required prior to loading onto the system, the manufacturer shall provide sufficient sets of automated reagent preparation instrument as part of the system to meet the throughput mention above and allow for back up.
• All automation system(s) should come with on-board laser printer(s) and supply of ink cartridges for hard copy printouts of the NAT testing results that is water proof for the period of whole tender contract.

• Reagent identification via barcode shall verify that correct reagent placement, lot match and expiration information.

• Untested samples shall be able to be loaded onto and tested samples shall be able to remove from the system when in operation to ensure continuous processing.

• Should have stat testing facility with priority samples can be loaded processed and reported on priority basis out of queue.

• The manufacturer shall provide the latest software to operate the system and the data backup solution as part of the software to enable the staffs to interface it with hospital infrastructure.

• Report information generated from the software shall include but shall not be limited to the following

  a) Instrument identification
  b) Assay name (type)
  c) Operator identification
  d) Date and time of batch started and completed
  e) Lot number of reagents including verification of expiration dates.
  f) Date and status of calibrators and controls (internal and external)
  g) Recognize duplicate or faulty barcode unit number
  h) Flagging of reactive test for follow up testing
  i) Reasons of invalid results

• Should provide both visual and audio assistance through intuitive task driven interface

• The system must have throughput of minimum 275 samples in 8 hours and 500 samples in 12 hours (including detection & discrimination)

• The tenderer shall supply a complete protocol for validation of the system in relation to Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). The tenderer shall provide sufficient number of suitably qualified personnel and make available support to assist the validation processes and acceptance evaluation. Also should include comprehensive training programme for staffs. The tenderer is to provide the NAT test kit and consumables needed for screening of 1,000 tests for validation and trial run.

• The vendor shall guarantee the system, or any part thereof commencing from the date of acceptance certificate are in good working condition. The vendor shall also replace faulty parts and provide both scheduled and breakdown maintenance service by qualified maintenance personnel.

• The system should support multiplexed in-vitro nucleic acid amplification testing for use in screening either single unit blood donation or in pools of serum / plasma for the presence of hepatitis B virus deoxyribonucleic acids (HBV DNA), human immunodeficiency virus ribonucleic acids (HIV RNA) and hepatitis C virus ribonucleic acids (HCV RNA) in human plasma or serum.

• Able to detect all the three viral markers on primary screening (multiplexed test for HIV RNA, HCV RNA and HBV-DNA), and discriminatory steps on the same platform.
• Bidder should provide start-up regents with consumables for 1000 tests along with the equipment. The price quoted for regents should be on cost per valid kit / test basis. Invalid tests kits will not be charged. Any expired and un-used regents shall be replaced.

• Discrimination test for individual detection of HIV-RNA, HCV-RNA and HBV-DNA should be available.

• Test kit should consist of ready to use reagents. Each kit should contain positive and negative controls, calibrators, internal controls and external control samples and all other necessary chemicals for the completion of the whole NAT procedure.

• Assay Performance. They should be able to detect accurately the following viral markers
  o HIV. All HIV variants including subtypes
  o HCV genotype 1, 2, 3, 4, 5, and 6
  o HBV genotype A, B, C, D, E, F and G

• Analytical sensitivity of the complete assay performed on system (with a 95% detection probability) will be atleast
  o HIV: 50 copies/mL
  o HCV: 10 IU/mL
  o HBV: 10 IU/mL

Tenderers are required to provide proven data on analytical sensitivity, specificity, reproducibility / repeatability and other relevant parameters of assay performance.

• The NAT test kit, test protocol and automated system should be approved by United States Food and Drug Administration (US-FDA) or conform to European Standard (CE) and the competent Indian Authority for use in blood screening. Tenderers shall submit relevant supporting document evidence for the above requirements.

• The tenderer shall maintain stock of one month’s supply of reagents.

• Vendor shall provide onsite free installation and comprehension training to the laboratory staff and support service till familiar and confident of using the system.

• Vendor shall make necessary backup arrangements for testing samples in case of breakdown of equipment.

• Equipment shall be a newly manufactured one and not a refurbished system.

• System must offer 24 hours calibration stability.

Tender should reach the office of Incharge Blood Bank, J.N Medical College & Hospital, AMU Aligarh by 20 June, 2018

Thanking you.

(Prof. S.H. Arif)
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