Annexure I

Fully Automated Nucleic Acid Amplification Testing (NAT) facility

(Pre-transfusion molecular screening)

Sl. No.	Technical Specifications (Revised)
1.	The system must be fully automated system with process control from sample pipetting to interpretation of final results with minimal end-user interface for the whole period of testing procedure
2	The Principle of the assay shall be based either on RT– PCR (Real Time-PCR) or on TMA (Transcription Mediated amplification).
3	The system shall be able to detect the viral targets either in single sample or in mini-pool samples.
4	The system must perform all steps from sample loading & processing and viral nucleic acid extraction to target amplification and detection automatically.
5	The automation system provided must have the following features and must provide documentary evidence that it can be achieved. a. Positive sample identification with barcode scanning b. Manually entered samples IDs possible c. Disposable filtered tips must be used to prevent any carry over and cross contamination of samples d. Leaks, fibrin clots and bubble during aspiration and dispense cycles, and samples and reagent can be detected and documented e. True level sensing or insufficient volume detection for sample and reagent can be detected and documented
6	Selected company must supply appropriate and adequate units of air conditioning, other required accessories including UPS, tables, Hepafilter etc. as per instrument requirement.
7	Selected company must provide 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 qualified personnel to assist validation process and acceptance evaluation.
8	The system should support multiplexed nucleic acid amplification testing feature for use in blood screening either in single unit blood donation or in mini pools of serum / plasma for the presence of hepatitis B virus deoxyribonucleic acids (HBV DNA), human immunodeficiency virus ribonucleic acids (HIV-1 RNA) & (HIV-2 RNA) and hepatitis C virus ribonucleic acids (HCV RNA) in human plasma or serum
9	Reagents should be ready to use reagents and stable either at room temperature or 2 to 8 °C to avoid any unnecessary delay or inconvenience.
10	Barcode facility should be provided for identification of the proper reagent for verification and cross check for correct reagent placement as well as to ensure the expiry and lot of the reagents and consumables
11	The equipment should have computer interface facility with Blood Bank Interface System to reduce any chances of error.
12	Selected Company must guarantee the system or any part there of commencing from the date of acceptance certificate are in good working condition. They shall also replace faulty parts and provide both scheduled and breakdown maintenance service by qualified maintenance personnel.
13	The rate contract awarded firm must ensure that due to want of reagents and other consumables the testing procedure should not be hampered even for one day and the firm shall maintain sufficient buffer stock of reagents and consumables in Imphal without fail as per requirement
14	Discriminatory test should be available on the same platform and must provide discriminated result within 24 hours from starting of testing. Company should submit a SOP of complete procedure to the institute.

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15	As Blood Bank have limited space, the NAT system must support single room operation and Reagents should be ready to use and 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 Test procedure.
16	Assay Performance – they should be able to detect accurately the following viral markers of a. HIV 1 & 2 (All HIV variants including subtypes) b. HCV genotype 1,2,3,4,5 and 6 c. HBV genotype A,B,,C,D,E,F,G,H
17	The selected company must provide proven data with details showing assay performance of the reagents for the detection of the requirements listed as above. Wider spectrums of viral genotypes detection will be advantageous in assessment
18	Analytical sensitivity of the complete assay performed on system(with 95% detection probability) should be at least a. HIV; 55 copies /ml b. HCV; 10 IU/ml c. HBV; 10 IU/ml
19	The service provider shall specifically quote globally and scientifically known commercial automated NAT Testing system and Assays which should be approved by United States Food and Drugs Administration (US FDA),or European Standard(CE) and Competent Indian Authority for use in donor blood screening. The NAT assay/method shall be of the latest version/generation.
20	User will only pay Cost Per Valid donated blood unit test which include HIV,HBV and HCV for one unit. This remain valid irrespective of Assay, method (ID/ Mini pool), Discriminatory tests, control and calibrator used. Institute will not pay anything extra for any repeat test, run fail, use of control, calibrator or any other relevant test.
21	The selected company must deploy Protocol for accurate identification, labelling and reporting of samples in mutual consultation and agreement with the authority
22	The service provider should provide free of cost maintenance of instruments for entire contract period. The system must have throughout of minimum 250 samples in 8 hrs and 400 samples in 12 hrs (including detection and discrimination)
23	All reagents supplied shall be within 1/3rd of their shelf life (calculated from the printed dates of manufacture and expiry) at the time of delivery. Any expired and used reagents shall be replaced by the company free of cost.
24	Equipment shall be a newly manufactured one and not a refurbished system,with the latest software for operation.
25	The tenderer has to provide the test kits and consumables needed to run 1000 (One thousand) tests for validation and trial run
26	Provision for upgradation,the technology of which is approved by USFDA or European Standard(CE) and Competent Indian Authority should be available without any increase in the agreed rate.

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Annex. II

Terms and Conditions for Fully Automated NAT facility

(Pre-transfusion Molecular Screening)

Sl. No.	Terms and Conditions
1	The institute wants to install fully automated NAT system (Pre-transfusion molecular screening) under reagent rental contract with 5 years validity. Validity may increase further depending on performance of the selected company. Under this model, the institue will not pay any money for the instrument, its maintenance and will only pay for the cost per valid donation of the Blood Bank.
2	Role of the institue will be limited to providing space, tap water connection, security, electricity and power backup for the instrument. All other arragement including air conditioner, UPS, furniture,room modification etc. will be responsibility of the selected company.
3	Company must provide man power for running of the instrument and role of this man power will be limited to collection of sample tube from blood bank personnel, performing test in the instrument and supply result to the blood bank concerned person within defined time frame.
4	System should have facility to provide consolidated report on month end. Selected Company should submit seal and signed monthly report along with monthly invoice to the institute to release payment. Institute will make payment within 7-10 working days after receiving of the invoice (as per agreement).
5	If any other blood bank's(other than RIMS) sample is run in this instrument, company must have facility to segregate separate report for all concerned blood banks. Such software should be provided free of cost to the institute.
6	The institute will pay per valid donation only irrespective of reagent, control, calibrator, consumables used by the instruemnt. If any rerun require by the instrument and extra reagents need to be put in the instrument for this purpose, company should absorb that cost and should not pass any extra cost other than agreed rate to the institute e.g. If institute perform 1000 test and agreed rate is Rs.X, instute will pay 1000 x Rs. X = Rs. 1000X only. This is irrespective of assay, protocol used by the compay and amount of reagents consumed for the test. Under any circumstances, company is not allowed to charge anything extra, other than agreed rate.
7	Institute will float an "Expression of Interest", where company need to quote their product details as per technical specification provided by the institute, along with a technical compliance sheet and price of the kits in the format provided by the institute.
8	After proper scrutiny of the documents, institute will issue 'Letter of Intent(LoI)' and based on LoI selected company need to provide draft agreement to the institute and once agreement get signed by the authority, company should develop infrastructure and place instrument within 45-60 days at the most and start performing test immediately after that.
9	Although, the company will deploy instrument, manpower and run test under their custody, but everything will be performed under supervision of HOD, Transfusion Medicine RIMS, Imphal and he will have every right to take decision for successful running of the instrument.
10	NAT lab will be used by Transfusion Medicine students for education purpose and company must provide all required data as and when required.
11	The service provider is to conduct Specialised training of blood bank in-house staff to perform NAT testing independently

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