Indian Red Cross Society
National Headquarter
Blood Centre
1-Red Cross Road,
New Delhi-110001

Notice Inviting tender

1. On behalf of Secretary General, Indian Red Cross Society, NHQ, Blood Centre invites tender from the company/firms providing fully integrated and fully automated NAT testing equipment on RT-PCR or on TMA to install the NAT equipment with lab setting free of cost and to supply the reagents on rental basis to the Blood Centre at the above address.

2. Schedule of Events:
   A. Start Date of receiving the quotation 01-10-2024.
   B. End date of last submission 30-10-2024.

3. The sealed bid/tender should reach the Director, Indian Red Cross Society, NHQ, Blood Centre, 1-Red Cross Road, New Delhi-110001 latest by 03.00 PM, on 30-10-2024. The envelope containing the tender would be sealed and superscripted as under: -

   'Tender for providing reagents for NAT equipment on rental basis from declaration of successful bidder.

4.The annual estimated quantity of reagents would be about 25,000 NAT tests.

5. Eligibility Criteria:

I. The manufacturer/Indian Agents should be licensed by the authorised Licensing Authority of Government of India, for manufacture of fully automated NAT testing on RT-PCR or TMA with the testing licensed blood centre for blood donor sample.

II. The authorized agents who submit tender and process the same further and enter into a contract against the requirement of IRCS, NHQ, Blood Centre, for the above-mentioned equipment, reagents and consumables manufactured by the firm/company, would have to produce in origin the manufacturer's authorisation letter/form on the letter head of the manufacturing firm/company signed by a person competent and having the power of attorney to legally bind the manufacturer.

III. Quoted NAT machine must have proven installations in at least 3 blood centre in India.

IV. The bidder shall comply with the policy/instructions issued by Drug Controller.

6. Terms and condition:

i. The company / firm should have a valid licence for manufacturing of NAT equipment and should furnish the notarized copies of license for manufacturing.

ii. The agreement with the selected bidder would be initially for 2(Two) years which can be extended to 5 (five) years with mutual consents.

iii. The bidder would quote the price of Kit plus GST and cost per reportable tests. However, the testing format would be decided by the user.

iv. The bidder should specify the number of free reagents to be provided annually to IRCS, NHQ.

v. The bidder shall quote the lowest price of the kit of the reagents being charged by the bidder in any part of the country. In case of proprietary items, the bidder shall certify that the rates are reasonable and would also provide proprietary article certificate.

vi. The selected bidder is to ascertain to confirm/comply the technical conditions contained in the enclosed NAT Specifications.

vii. Regarding credit policy, the IRCS, Blood Centre shall pay the amount of the supplied/accepted reagents within 30 days.

viii. The TDS @ applicable rate will be deducted.

ix. The GST @ applicable rate will be charged.

7. Tender received after the deadline or unsealed tender shall not be entertained under any circumstances whatsoever it may be. In case of postal delays tender shall not be accepted /entertained.

8. The tenderer will have to pay Earnest Money Deposit (EMD) of 2% of the bidding amount to be calculated based on multiplying the cost of per reportable test with the estimated 25000 NAT tests. The demand draft shall be drawn in favour of 'Indian Red Cross Society, Blood Centre'. The demand draft for EMD must be in the separate envelope containing the bid/tender.

9. Bids received without demand draft of Earnest Money Deposit shall not qualify for opening of bids.

10. In case of unsuccessful bidder, the Earnest Money Deposits (EMD) will be refunded back.

11. On award of the contract, the firm would have to deposit the interest free Performance Security equivalent to 5% of the agreed estimated value. The EMD so submitted by the firm will also be adjusted in the performance security.

12. The performance security will be refunded without any interest to awarded company only after completion of the formalities i.e. satisfactory execution of the contract and fulfilment of all contractual obligations.

13. Bids/tenders must be in the prescribed Performa on the letter head of the firm duly signed by the proprietor/partner or their authorized representative. In case of signing of bids /tender by the authorized representative, letter of authorization must be attached with the quotation.

14. No overwriting or cutting will be permitted in the rate. If found, the quotation will be summarily rejected.

15. The rate quoted must be valid for 180 days from the last date receiving the bids. Silence on this issue by the bidder shall be treated as agreed with the condition.

16. The technically qualified Bidder who submits the minimum cost per reportable test in the price bid format and maximum number of free reagents i.e. percentage to the total estimated number of NAT tests shall be considered as successful bidder and communication to that effect shall be made as approved/decided by the Competent Authority.

17. If the price of any item is reduced due to any reason during the validity of the rate contract the contractor will forthwith notify IRCS, NHQ, Blood Centre regarding price reduction and will charge reduced rates instead of existing rates in the rate contract.

18. The awarded company/firm would depute a qualified full time laboratory technician in IRCS, NHQ, Blood Centre to work in NAT lab at their own cost.

19. IRCS, NHQ, reserve the right to increase or decrease quantity of NAT tests. Decision of the IRCS, NHQ, regarding the quantity of material will be final.

20. Secretary General, IRCS reserves the right to reject any bids/tender with or without assigning any reason. In this regard the decision of the Secretary General, IRCS, NHQ will be final.

21. The selected firm shall enter into an agreement with IRCS, NHQ, Blood Centre on stamp paper worth Rupees 100 (One hundred), duly notarized, which will be drawn after final selection of the bidder.

22. After successful of the contract, Performance Security would be refunded to firm by Indian Red Cross Society, NHQ, Blood Centre.

23. In case of any dispute, the decision of the Secretary General of IRCS, NHQ would be final.

Encl. Annex 1 (Format of Price bid)
2 NAT Specifications

(on the letter Head of firm) Annex- I

Price Bid Form

To
The Secretary General,
Indian Red Cross Society,
National Headquarter
Blood Centre,
1-Red Cross Road,
New Delhi-110001
Dear Sir,

I/We submit the quotation for enquiry No. QUOTATION FOR THE cost per reportable test in the Format of price bid along with the number of reagents to be offered annually by the bidder for the supply of reagents to the Indian Red Cross Society, NHQ, Blood Centre, 1-Red Cross Road, New Delhi.

1. I/we thoroughly examined, understood, and accept the terms and conditions given in NAT Technical Specifications.
2. I/we hereby offer the rates as mentioned in the following Price Bid Format.
3. I/we offer the number of free reagents to be offered annually, in the following Price Bid Format.

Format of Price Bid

Sl. No.	Name of the Kit /particular	Net Rates of one kit of reagents after discount (with lab setting/ consumable)	Amount of GST	Total cost including GST(A)	Kit size (B)	Cost per reportable test(A/B)	Number of free reagents to be offered by the bidder

Above mentioned rates are inclusive of cost of the technician who shall be deputed by the firm at IRCS, NHQ, Blood Centre.
The above-mentioned price of kit is the lowest being charged by the firm in any part of the country.

(Signature of Authorized Person)
Name----------
Name of Firm----------
Phone No. ----------
Email----------

Date:
Place:

Annex-2

Indian Red Cross Society
National Headquarters
Blood Centre
Technical Specifications for NAT (PCR/TMA)

Sl. No.	Technical Specifications
1	The system must be fully automated & True Walk away, NAT screening system for blood donors screening only, with process control from sample pipetting to interpretation of final results. The vendor should specify the size, weight with model and serial number labelled on machine having the feature of in built system of Barcode reading with the capacity to analyze minimum 400 samples in 12 hrs including deduction and discriminatory test of pool samples. The vendor should also specify whether our requirement of testing is possible in one machine or required more than one machine. • The machine should be fitted in the provided area of IRCS, NHQ, Blood Centre.
2	The Principle of the assay shall be based either on RT-PCR (Real Time-PCR) or on TMA (Transcription Mediated amplification) with the testing licensed blood for blood donor sample. The vendor should provide information on the following points: • Whether the testing platform is consisting of ID or pooling or both systems, if pooling the vendor should specify the validated pool size of blood sample. • customizable testing configuration, • on- board sample capacity, • continuous feed of sample, • continuous operator access for an interrupted operation (e.g. allow the ability to change the reagents/consumable while in operation, • What will be operational temperature /humidity requirement/ limitations, • STAT processing and specify their minimum time for result, • Audible and visual alarms (to alert for system faults).
3	The system must perform all steps from sample processing and viral nucleic acid extraction to target amplification and detection automatically in a single tube.
4	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 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 detection 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. F. The selected vendor/firm would supply EDTA test tube for specimen collection.

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5	Selected vendor/firm to ensure that the machine with NAT Lab work properly and is not affected by any deficiency/lack of harmony in the cooling system etc. for this purpose selected vendor/firm for other required accessories including UPS with three hours back up, furniture (Vibration Free Granite top table to keep the instrument working table set etc). In addition computer with latest configuration having software, network, antivirus software/security, backup system, storage of data and laser printer with scanner, civil work etc as per instrument requirement. The selected company shall provide and shall be responsible for providing the infrastructure required to make the equipment and lab functional. The machine and all required software will be provided /installed free of cost which would be available for entire period of contract.
6	Selected vendor/firm must provide a complete protocol for validation of the system in relation to Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). The selected Company shall provide certificate for installation, evaluation, validation and calibration of the equipment. The company shall also provide one Technical Personnel to operate the equipment during the entire period of enforcement of agreement. The company shall also provide **5000 test** regents and consumables free of cost for validation, trial run and training which will be in addition to free reagents annually. The supplier would provide the documentation and training, Instrument operator manual describing all procedure including maintenance and cleaning of the machine, product inserts for assays, reagents and consumables, control and calibrators with MSDS.
7	Assay Performance- they should be able to detect accurately the following viral markers of (a) HIV-1 (all HIV variants including subtypes), HIV-2 (all HIV variants including subtypes) and HIV-1: Dual target detection, (b) HCV genotype 1,2,3,4,5 and 6, (c) HBV genotype A,B,C,D,E,F,G,H and pre core mutants. The system should be stable capable of detecting hepatitis B virus deoxyribonucleic acid (HBV DNA), human immunodeficiency virus ribonucleic acid (HIV-1 RNA) & (HIV-2 RNA) and hepatitis C virus ribonucleic acids (HCV RNA) in human plasma or serum in single unit blood Donation.
8	The reagents should be stable & ready to use at any Temp prescribed by manufacturer to avoid any unnecessary delay or inconvenience. The selected company must provide storage system with the storage capacity of 6,000 reagents at a time i.e. refrigerator and deep freezer for storage of reagents. The refrigerator and deep freezer must have temperature monitoring chart and alarm system.
9	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 the lot of the reagents and consumables. Instrument should not allow use of expired reagents.
10	The equipment should have computer interface facility with Blood Bank Interface- system to reduce any chances of error. In addition there should be configuration in the system that the data of NAT testing should automatically be transferred to the e-Raktkosh Application which IRCS, NHQ is using.
11	The equipment must be able to run on the existing electrical provision which is single phase. Any additional electrical requirement for the equipment must be arranged by the selected

	company. There should not be single second interruption.
12	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 1000 buffer stock of reagents and consumables in IRCS, Blood Centre, New Delhi without fail as per requirement.
13	Discriminatory test should be available on the same platform and must provide discriminated result within 1 week from starting of testing / as when required by user
14	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.
15	The selected vendor/firm must provide proven data with details showing assay performance of the reagents for the detection of the requirements listed above. Wider spectrum of viral genotypes detection will be advantageous in assessment; Bidder must submit sufficient scientific publication regarding the sensitivity, specificity, reproducibility, repeatability and accuracy of test result.
16	Analytical sensitivity of the complete assay performed on system should be provided by the vendor for the given format.
17	The selected vendor/firm shall specifically quote the latest model available globally & scientifically known fully automated NAT testing system and Assays which should be approved by US FDA/CE and BIS (Bureau of Indian Standards) as well CDCSO (both).
18	The selected vendor/firm must deploy Protocol for accurate identification, labelling and reporting of samples in mutual consultation and agreement with the IRCS,NHQ, Blood Centre.
19	The selected vendor/firm shall provide free of cost maintenance of instrument for entire period of enforcement of agreement. The system must have throughput of minimum 400 samples in 12 hrs including detection and discriminatory tests.
20	All reagents and required consumable such as pipette Tips, MTUs supplied shall be within 2/3rd 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. The selected vendor/firm would supply chemicals required for cleaning/decontamination and manage waste disposals. The selected vendor/firm would supply chemicals required for cleaning/decontamination and manage waste disposals. The selected vendor/firm may also confirm the supply of additional reagents other than testing reagents, if needed free of cost.
21	Selected vendor/firm shall provide complete testing protocol and Algorithm for testing and confirmation of test results as approved by CDSCO.
22	Equipment shall be a newly manufactured one and not a refurbished system.
23	The selected vendor/firm shall update and provide free of cost any up gradations on the testing platform or the testing kits to the IRCS, NHQ, Blood Centre.
24	STAT feature must be there, and facility for the priority sample testing to avoid any delay in emergency sample or rare blood group testing.

25	The selected vendor/firm shall be responsible for transport of equipments and accessories to the IRCS, NHQ, Blood Centre, at his own expanses.
26	The Selected vendor/firm shall provide seamless backup for the instruments or alternative arrangement would be made by the company and any breakdown would be penalized at the rate of Rs. 5000/- per day.
27	The sensitivity of assay at 95% LOD must be at least: HIV1- 30 IU/ml HIV2- 15 IU/ML HCV- 8 IU/ml HBV- 5 IU/ml The above mentioned sensitivity of assay is applicable for ID and MP-NAT. The system must offer 24 hrs calibrator stability. The supplier should provide analytical and clinical sensitivity of the assay including independent evidence to support performance claims.
28	The specificity of the test must be 100% also supplier to provide specificity definition, specificity of each assay and independent evidence to support performance claims.
29	Selected vendor/firm shall supply the relevant calibration certificate for the equipment from NABL accredited Lab in India.
30	Required test calibrators, control, invalid and discriminatory tests will not be charged by the firm and in such case the selected vendor/firm has to supply additional reagents and consumables for these testes free of cost.
31	In case the technical committee of IRCS, NHQ wish to do so for better clarity on features of the equipment, the Selected vendor/firm shall arrange free of cost demonstration of performance of equipment.
32	During Machine downtimes/breakdown, the test should be performed at other place or the machine should be repaired/functional within 24 hours failing which the penalty of the breakdown as decided in item No. 26 would be Rs. 5000/- per day. Samples transportation to another facility would have to be taken care by the selected vendor/firm.
33	Quoted NAT machine must have proven installations in at least 3 blood banks in India.
34	The bidder shall offer/disclose the maximum discount on rate of regents to IRCS, NHQ.
35	The bidders would specify the numbers of free reagents to be provided annually to IRCS, NHQ.
36	Consumable like gloves, masks, shoe cover etc. would be given by IRCS, NHQ directly to operator.

Format of Price Bid

S. No	Name of the Kit / particulars	Net Rate of one kit of reagents after discount (with Lab consumable)	Amount of GST	Total cost including GST (A)	Kit Size (B)	Cost per reportable test (A/B)	Number of free reagents to be offered annually by the bidder
1							

REMARKS:

1. The bidder would quote the price of kit plus GST and per reportable test. However the testing format would be decided by the user.

2. The bidder, considering that IRCS is a humanitarian organisation and not commercial organisation and having the limited resources and doing the humanitarian and social services, would quote the lowest price of the kit being charged by the bidder in any part of the country.

3. The bidder would also mention the number of free reagents i.e percentage to the total estimated number of NAT tests, to be provided by him on annual basis. The estimated total number of annual NAT tests in IRCS, NHQ is likely to above 25000 tests.

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