28th Oct 2024

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

Subject: Date extension,Tender pre-bid clarification and submission for modification in tender specs for published tender for Fully Integrated and Fully Automated NAT Testing equipment on RT-PCR or on TMA on reagent rental basis to the Blood Centre,IRCS,NHQ,New Delhi.

Dear Sir,

Roche Diagnostics Headquartered in Basel, Switzerland is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology, and neuroscience. Roche is also the world leader in in-vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management and blood screening.

In India we are leading suppliers of blood screening NAT systems and currently we have more than 75 installations, with satisfied users of our fully automated nucleic acid test system across the country. Our NAT system are running successfully in various esteemed government institutes such as AIIMS-Kalyani ,AIIMS-NCI Jhajjar,AIIMS-Patna, SMS-Jaipur, KGMU & SGPGI Lucknow, BHU-Varanasi, IMA Blood Bank- Bareilly & Dehradun. We are also running State NAT projects for Orissa State Govt, Madhya Pradesh State Govt,Uttarakhand State Govt and J&K State Govt.

Moreover, to the best of our knowledge only two companies,Roche using PCR and Grifols using TMA,are offering NAT globally for blood screening.

In the published Tender dated 01/10/2024 for Fully Integrated and Fully Automated NAT testing equipment on RT-PCR or on TMA on reagent rental basis for the Blood Centre, IRCS-NHQ,New Delhi, we need more clarification on certain points before we participate. Also as there was no mention of a Pre-Bid meeting, we sincerely request your clarification for the points raised by us in the letter

We also would like to apprise you that most of the Government tenders including a few recent NAT tenders for blood banks had been published with neutral tender specifications such as HITES-AIIMS-NCI Jhajjar, SGPGIMS-Lucknow, BHU Varanasi, Orissa State Gov. Project, MPPHSCL MP State Government, Telangana State Govt. etc.

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN - U85195MH1988PTC141417

Regional office :
3rd Floor Office Block
MGF Corporate Park
Metropolitan mall, Plot No. A2
Didtrict Centre, Saket
New Delhi - 110017

Tel.: +91 (11) 46034500
Fax: +91 (11) 46034528

Regd. Office :
501 B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai - 400069

Tel.: +91 (22) 66974900
Fax: +91 (22) 66974909
www.roche-diagnostics.co.in

Roche

We request your kind consideration for a Date extension and Pre Bid meeting such that all points for clarification can be put up for discussion, thereby allowing us to participate through an open & neutral Competition Bidding process.This will also provide you with more than one option to select the best techno-commercial bid for the procurement.

Tender Sr. No.	Tender Technical Specification	Amendment requested in Tender / Technical Specs	Remarks
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 labeled on the machine having the feature of an 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 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 labeled on the machine having the feature of an in-built system of Barcode reading with the capacity to analyze 140 samples in 8 hrs and 240 samples in 12 hrs(detection and discrimination).	Considering the existing workload of IRCS approx. 25000 donations annually and estimated growth in future the minimum 140 donation per day results (42,000 Donation annually) which can be conveniently delivered with our system. Since our instruments are capable of testing continuously which will take care of any occasional spike in the sample load.
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		Need clarity on which format to be quoted as its mention in Terms & Conditions that testing format would be decided by the user. Testing format should be cleared in the specs only for level ground playing.

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN - U85195MH1988PTC141417

Regional office :
3rd Floor Office Block
MGF Corporate Park
Metropolitan mall, Plot No. A2
Didtrict Centre, Saket
New Delhi - 110017

Tel.: +91 (11) 46034500
Fax: +91 (11) 46034528

Regd. Office :
501 B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai - 400069

Tel.: +91 (22) 66974900
Fax: +91 (22) 66974909
www.roche-diagnostics.co.in

	consists of ID or pooling or both systems, if pooling the vendor should specify the validated pool size of blood samples. Pt.No.6 Terms & Condition: 3.The bidder would quote the price of the kit plus GST and cost per reportable tests. However, the testing format would be decided by the user.		
3	The system must perform all steps of sample processing and viral nucleic acid extraction to target amplification and detection automatically in a single tube.	The system must perform all steps of sample processing from viral nucleic acid extraction to target amplification and detection automatically in a single tube/ Individual Well	As tender allow,PCR & TMA to participate,both has a different format of testing in case of PCR,sealed multi well plates are used to perform extraction,amplification & detection.Moreover in PCR, highly specific Taqman chemistry is used and Amperase enzyme is used to prevent any carryover contamination.Globally available NAT systems are closed systems, specific consumables are used for Extraction, Amplification, and detection processes in both the technologies. Single Tube testing is vendor/system specific. Whereas RT- PCR uses multi well plate as a standard consumable for extraction and amplification detection with separate tips for samples and reagents handling to remove any chances of contamination.

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN - U85195MH1988PTC141417

Regional office :
3rd Floor Office Block
MGF Corporate Park
Metropolitan mall, Plot No. A2
Didtrict Centre, Saket
New Delhi - 110017

Tel.: +91 (11) 46034500
Fax: +91 (11) 46034528

Regd. Office :
501 B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai - 400069

Tel.: +91 (22) 66974900
Fax: +91 (22) 66974909
www.roche-diagnostics.co.in

6	The Company shall also provide 5000 test reagents and consumables FOC for validation,trial run and training which will be in addition to free reagents annually	5000 tests reagents & consumables FOC for validation , Trial run & Training in addition to free reagents provided annually - Need more clarity5	In many open tenders,There is quantity mentioned for FOC.So requesting authority to quantify number as an FOC and for testing.There should not be any ambiguity for level ground playing for all the bidders.
13	Discriminatory test should be available on the same platform and must provide discriminated results within 1 week from starting of testing/as when required by user	Discriminatory test should be available on the same platform using the same Test Kit. Company should submit a SOP of the complete procedure to the institute.	As per point no.19,The system must have throughput of minimum 400 samples in 12 hrs including detection and discriminatory tests, creating a confusion as one side you are asking for detection & discrimination of 400 samples in 12 hrs in specs no.01 and in the specs no.13 you are asking to provide discriminated results in a week. To eliminate the possibility of ambiguous or non- discriminated results, it is important that the same Test kit with the same sensitivity should be used for virus identification as well as for viral discrimination Nowadays latest reagents available which can give discrimination in 24 hrs and which helps blood banker to council donors within 24 hrs of testing

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN - U85195MH1988PTC141417

Regional office :
3rd Floor Office Block
MGF Corporate Park
Metropolitan mall, Plot No. A2
Didtrict Centre, Saket
New Delhi - 110017

Tel.: +91 (11) 46034500
Fax: +91 (11) 46034528

Regd. Office :
501 B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai - 400069

Tel.: +91 (22) 66974900
Fax: +91 (22) 66974909
www.roche-diagnostics.co.in

27	The sensitivity of assay at 95% LOD must be at least : HIV – 30 IU/ml HIV – 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 intendent evidence to support performance claims	The sensitivity of assay at 95% LOD must be at least : HIV – 1 : 30 IU/ml HIV – 2 : 15 IU/ml HCV : 8 IU/ml HBV : 1.3 – 2 IU/ml The above mentioned sensitivity of assay is applicable for ID and MP - NAT. The system must offer 24 hrs calibrator/control stability. The supplier should provide analytical and clinical sensitivity of the assay including intendent evidence to support performance claims	Since HIV & HCV replication/doubling time is very fast and getting double in couple of hours so the range can be increased for both but for HBV being a slow replicating virus with a high prevalence in general as well as donor population of our country, HBV sensitivity quoted should be the best & highest. This point needs to be modified as per companies protocol and Prescribing iInformation(PI).In PCR,we don't use calibrators, we use controls and internal controls.
29	Selected vendor/firm shall supply the relevant calibration certificate for the equipment from NABL accredited Lab in India.	Need to Remove this point	NAT systems and reagents are tested in NIB for validation so in such cases CDSCO certificate will suffice the requirement. And NAT systems are already CE/IVD/FDA/CDSCO approved Therefore no calibration certificate for the equipment from NABL accredited Lab is required
33	Quoted NAT machine must have proven installation in at least 3 blood banks in India	Quoted or Equivalent NAT machine must have proven installation in at least 3 blood banks in India	There are firms which are offering 10 year old systems however the latest systems are available. Modification helps the bidder to offer the latest system.

ROCHE DIAGNOSTICS INDIA PVT. LTD.
CIN - U85195MH1988PTC141417

Regional office :
3rd Floor Office Block
MGF Corporate Park
Metropolitan mall, Plot No. A2
Didtrict Centre, Saket
New Delhi - 110017

Tel.: +91 (11) 46034500
Fax: +91 (11) 46034528

Regd. Office :
501 B, Silver Utopia
Cardinal Gracious Road
Chakala, Andheri (East)
Mumbai – 400069

Tel.: +91 (22) 66974900
Fax: +91 (22) 66974909
www.roche-diagnostics.co.in

We appreciate the tendering authority, and call for a Pre Bid Meeting to discuss the specifications and Terms & conditions in detail which will help to clear in ambiguity which could arise. The Pre Bid Meeting will also bring more clarity to the table and allow us a chance to participate and submit our tender bid for the supply of our fully automated Nucleic Acid amplification testing system for screening of blood donation.

Thank you for your kind consideration.

For Roche Diagnostics India Pvt Ltd

ROCHE DIAGNOSTICS INDIA PVT. LTD. NEW DELHI Roche

Authorized Signatory

Parvesh Sachdeva

Zonal Manager-Molecular Lab

parvesh.sachdeva.ps1@roche.com

09599840057

Clarification to the points raised by ROCHE on the NAT specifications in their letter dated 28.10.2024.

Sl.No.	Amendment requested in Tender/ Technical Specification by Roche	IRCS Remarks	Panel of Experts committee remarks given in the meeting held on 19.11.24 for clarifications
1 Roche	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 labeled on the machine having the feature of an in built system of Barcode reading with the capacity to analyze 140 samples in 8 hours and 240 samples in 12 hrs (detection and discrimination)	Most of the time IRCS Blood Center is holding 2-3 blood donation camps every week, where we are getting good response of blood donation. Approximately blood collection in these camps is around 350-400 units in a day. Keeping in view of this company shall specify that one equipment is sufficient to cope-up this load within 12 hrs. or additional equipment will provide by the company, without adding any additional cost.	The capacity to analyze blood samples for NAT testing should be in the range of 300 to 400 samples in 12 hours.
2 Roche	Need clarity on which format to be quoted as its mention in Terms and conditions that testing format would be decided by the user. Testing format should be cleared in the spaces only for level ground playing.	The company shall provide information about the ability of Equipment's whether testing platform carry only ID, only Pooled OR both testing mode.	The company shall provide information about the testing ability of the equipment whether the testing platform being carried only ID, only Pooled OR both testing mode. In addition to this, the rates should be specified based on the rates of the kits and overall consumables to be provided by the company.

3 Roche	The system must perform all steps of sample processing from nucleic acid extraction to target amplification and detection automatically in a single tube/individual well.	The system must perform all steps of sample processing from viral nucleic acid extraction to target amplification and detection automatically in single tube/Individual well, subject to the condition that no manual intervention will be involve during the process. The system must be fully automated &True Walk away NAT screening system.	No change in IRCS remarks.
6 Roche	5000 tests reagents &consumables FOC for validation, trial run & training in addition to free reagents provided annually- need more clarity.	For initial Startup 5000 tests reagent with consumable would provide by the company for trial run and training of the staff purpose only. However as far as annual Free of Cost (FOC) is concerning company shall separately disclose quantity of test reagent &consumables will be provided by them.	The cost of invalid tests including run failure tests, (like control part failure, hardware unit control failure) would be replaced free of cost by the company. It is also clarified that the cost of only validated test would be paid by the IRCS, NHQ. over and above 5000 test reagents and consumables provided FOC for Validation trial run and training.

13 Roche	Discriminatory test should be available on the same test kit. Company should submit a SOP of the complete procedure to the institute.	This column is specifically mean to which type of infectious markers detected in the blood donors' samples, for the counselling of blood donor.	Discriminatory tests should be available on the same platform and must provide discriminatory result within 1 week and screening on the same day, from the start of testing, as and when required by the user.
27 Roche	The sensitivity of assay at 95% LOD must be at least: HIV – 1:30 IU/ml HIV – 2:15 IU/ml HCV – 08 IU/ml HBV – 1.3-05 IU/ml The above-mentioned sensitivity of assay is applicable for ID and MP–NAT. The system must offer 24 hrs. calibrator/control stability. The supplier should provide analytical and clinical sensitivity of the assay including intendent evidence to support performance claims.	No change is in IU/ml of each test required with reference to the sensitivity of assay. As for as the stability of calibrators/ control/ internal control, should be maximum for 24 hrs.	The sensitivity of assay at 95% LOD must be at least: HIV ≤ 30 IU/ml HIV ≤ 15 IU/ml HCV ≤ 08 IU/ml HBV ≤ 05 IU/ml
29 Roche	Need to remove this point	The ID NAT assay /kits must have necessary approvals from NIB or any of Center which is approved by Govt. Of India. The tender shall submit relevant specific documentary evidence in support to the requirements.	(A)Calibration certificate of the equipment shall be provided by the company free of cost frequently on every six months. (B) The NAT assay /kits must have necessary approvals from NIB or any of Center which is approved by Govt. Of India. The company/firm shall submit relevant specific documentary evidence in support to this requirement.

26			During the Machine down times /break down the company will perform the test at an alternative site. The machine should be repaired / functional/replaced within 48 hours, while the test in the meantime are performed at alternative site, failing which the penalty of the breakdown as decided in items No-26 would be Rs 5000/- per day. In case of machine downtimes/breakdown continues for more than a week backup equipment as an alternative arrangement of testing shall be provided by the company at IRCS (NHQ), Blood Centre.
33 Roche	Quoted or equipment NAT machine must have proven installation in at least 3 blood banks in India.	If the company is offering latest version of the equipment and that has not been installed in India or in the process of installation, then the company shall submit satisfactory reports from USA as a document or any developed country	The physical technical demonstration in person would be done by the company, if required.