Request For Proposal (RFP) for establishment of NAT testing facility at the identified Centres of State of Odisha.

Ref. no: Advt./426/BBSR Dated: 04-06-2021

Request for Proposal (RFP) invites the sealed offers in from Reputed Manufactures / any Authorised Dealer / Importers by the Principal Equipment Manufacturer for establishment of NAT testing facility at the identified centres of State of Odisha in the following goods as per terms & conditions as stipulated in the RFP documents.

Sl. No	Description of Goods & RFP Ref. No.	Date of Downloading of RFP	Last date of Submission of RFP	Date of Opening of RFP	RFP Paper Cost	EMD
01	Supply & installation of maintenance free Automated Nucleic Acid Testing (NAT) facility for screening of HIV 1&2, HBV & HCV for Maximizing the Blood Safety.	**05.06.2021**	**18.06.2021 at 12 Noon**	**18.06.2021 at 3.30 PM**	Rs.10,000/-	Rs.20,000,00/-

The filled in applications should be submitted on or before at **18.06.2021 by 12 Noon.** The non-transferable **Request for Proposal (RFP)** documents can be downloaded free of cost from websites www.orihealth.nic.in & www.orissa.gov.in. The RFP documents must be received by Speed Post/ Registered Post / Courier only at State Blood Transfusion Council, C/o- Office of the Directorate Blood Safety, Ground Floor, Heads of Department Building, Unit-V, Bhubaneswar – 751001, Odisha a wing of Department of Health & Family Welfare, Govt of Odisha.

The Director reserves the right to accept or reject in part or full any bid without assigning any reason.

Sd/-
Director,
State Blood Transfusion Council
Department of Health & Family Welfare

Points of Request For Proposal (RFP)

- Request for Proposal (RFP) paper (Non-refundable) - Rs. 10,000/- only.
- Earnest Money Deposit (Refundable) - Rs. 20, 00,000/- (Twenty lakhs only) in the form of DD in favour of President State Blood Transfusion Council Odisha payable at Bhubaneswar.
- RFP Document can be downloaded – **05-06-2021**.
- Last date for submission of RFP document - **On or before 18-06-2021 up to 12 noon**.
- Submission of RFP document – At Director, State Blood Transfusion Council, C/O-Directorate Blood Safety, Odisha Ground Floor, Heads of Department Building, Unit-V, Bhubaneswar – 751001Odisha
- Opening of RFP document date & time: **18-06-2021 at 3.30 pm.**
- Any RFP received after due date & time shall be rejected.
- Venue of opening of RFP – Deptt. Of Health & Family Welfare, (Secretariat)
- Offered RFP Validity Period – 365 Days from date of opening.
- Contract Period with the selective Organisation - Five years and can be further extended based on the satisfactory performance and with mutual consent and agreement.
- The contract of Five years and can be further extended based on the satisfactory performance and with mutual consent and agreement will be calculated only after commencement of actual NAT Screening all identified mother Blood Centres as mentioned in – **Table "A".**
- Rate shall have to be quoted in the prescribed format only otherwise it will be rejected.
- Price Bid shall have to be submitted in duplicate.
- RFP will be two bid system where technical bid and Price bid documents are to be separately enclosed in two envelops and both together put in one larger single envelope.
- Monthly Payment against bill shall be released to the selective Organisation or authorised local dealer only after receipt final bill with final valid test report duly signed by testing in-charge laboratory technician and Blood Centre Officer on or within 10-15 Working Days. Only payment will be made for valid test of blood. Discriminatory testing will not be charged by the firm.
- Only identified Blood Banks billing shall be accepted.

- RFP paper cost Rs. 10,000/- (Ten thousand only) must be in shape of DD in favour of President State Blood Transfusion Council Odisha payable at Bhubaneswar and must be attached with the RFP document during submitted time otherwise RFP will be rejected.
- No RFP will be accepted unless the full amount against respective heads has been submitted.
- The RFP submitted by the Organisation should have a minimum annual turnover of Rs 40 crores in each year for last three consecutive years proof documents should be enclosed.
- Manufacturer of NAT Equipment, or any Authorised Dealer /Importer by the Principal Equipment Manufacturer advised to submit the Product Performance Report, Service providing report and Customer views report duly signed by HOD/Medical officer or from any other user to assessment of their product performance, credential & credibility.
- Scope of supply & Specifications for Nucleic Acid Amplification Testing is attached.
- Only L1 rate offered will be taken into consideration subject to fulfilment of all RFP points.
- If the last date for receiving the RFP document is declared a holiday, the next working day will be the last date for the receipt of RFP document.

General Terms & Conditions:

For the supply & installation of required numbers of good performing Automated Nucleic Acid Testing (NAT) facility for screening of HIV, HBV & HCV for maximizing the Blood Safety programme against the per valid test of blood unit basis in which only the final test report against the unit will be considered and no payment will be made by Govt. of Odisha against any erroneous result or any duplicate or repeat test or for further confirmation and discrimination testing.

On behalf of Department of Health & Family Welfare Government Of Odisha, Director, State Blood Transfusion Council, Odisha (SBTC) invites the sealed RFP against per test basis (Only on Final Valid test Report) for the supply & installation of maintenance free & good performing Automated Nucleic Acid Testing (NAT) facility for screening of HIV, HBV & HCV for maximizing the Blood Safety in State against per test basis on the following terms & conditions: -

Who can participate In Request For Proposal (RFP)

a) Manufacturer of NAT Equipment (Original Equipment Manufacturer).
b) Or any Authorised Dealer/Importer by the Principal Equipment Manufacturer) should have sufficient experience screening for HIV 1&2 / Hepatitis B & C by NAT having installed NAT Screening equipments in India.
c) Should be capable to develop a robust Operational Model for the proposed services network including transportation of sample reporting of results and resolution of disputed test results at Odisha.

Indicative Scope Of Work & Service Level:

- In order to make blood safer for transfusion, Govt of Odisha intends to introduce NAT Screening of collected blood in Blood Centres situated in various hospitals per valid test of blood basis. The details of the annual blood collections and addresses of these Blood Centres are as under **Table "A".**
- The mentioned annual collection units may either increase 20 % or decreases 20 % from mentioned quantity.

Table – "A"

Sr. No.	Blood Centre Name	Approx. Collections	Total Collections	Proposed site
1	Odisha Blood Centre, Capital Hospital, Bhubaneswar	23000	31000	Capital Hospital, Bhubaneswar
2	Odisha Blood Centre, BMC Hospital, Bhubaneswar	8000		
3	Odisha Blood Centre, SCB Medical College, Cuttack	28000	76000	SCB MCH, Cuttack
4	Central Red Cross Blood Centre, Cuttack	48000		
5	Odisha Blood Centre, VIMSAR, Burla	22000		VIMSAR, Burla
6	Odisha Blood Centre, MKCG Medical College, Berhamapur	28000		MKCH MCH, Berhamapur
7	Odisha Blood Centre, Fakir Mohan Medical College and Hospital, Balasore	23000	33000	FM MCH, Balasore (DHH, Blood Bank)
8	Odisha Blood Centre, Pandit Raghunath Murmu Medical College and Hospital, Baripada	10000		
9	Odisha Blood Centre, Santha Bhima Bhoi Medical College and Hospital, Bolangir	10000		SBB MCH, Bolangir (DHH, Blood Bank)
10	Odisha Blood Centre, SLN Medical College and Hospital, Koraput	10000	15500	SLN MCH, Koraput (DHH, Blood Bank)
11	Odisha Blood Centre, Jeypore	5500		
	Total	215500	215500	7 sites

- In addition to above Blood Centres, Govt of Odisha at any stage may include any other Blood Centres for such NAT screening on the same terms and conditions.
- The NAT screening should be able to screen the donated blood sample for HIV 1&2, Hepatitis B and Hepatitis C and communicate the validated NAT screening test results to the concerned Blood Centre through the IT based Information Management, by SMS and by hard copy by the stipulated time mentioned by the award contracted.
- The NAT Lab & NAT Screening Equipments / Machine of the Service Provider should be functional round the clock i.e., 24 hours and 365 (366) days in a year. Back up arrangement of same model and fully automated equipment at Cuttack centre shall be made by Service Provider.
- NAT Lab shall be open to all educational activities, undergraduate and Post Graduate teaching purpose.

Role and Responsibility of Govt of Odisha.

- Will be responsible to provide only required amount of space as per requirement of the service provider at the identified centres.
- The Director, SBTC shall have right to Inspect /Audit the NAT Lab regularly particularly with respect to the staff training and competency requirements, proficiency testing, performance improvement and quality control requirements.
- Will pay only per valid test of blood unit charge basis which include HIV 1&2, Hep-B, Hep-C. Further, it is clarified that Govt. will not bear any charge towards repeat test, further confirmation / discrimination test or for erroneous test result.
- Will make payment to the service provider or its authorised dealer within first 10-15 working days after receiving of the bill along with required documents which should be duly signed by LT and Counter signed by the Blood Centre Officer (BBO) of the NAT established Blood Centres.

Role and Responsibility of Service Provider.

- The service provider should provide totally free of cost automated NAT equipments with one standby at one centre of same model same type equipment. And the following centres are as per **Table "A"** proposed sites.
- The service provider has to collect sample from nearby centre as mentioned in **Table "A"**
- The collection and transportation of sample from connected or satellite centre is the sole responsibility of the service provider.
- The service provider has to provide Sample Collection Vial as per Standard Operating Procedure (SOP) or recommendation by Manufacturer along with centre wise proper barcode stickers, Barcode printers and reader with cold chain box.
- The service provider has to provide the detail diagram of round the clock service with time effective manner so that blood can be released for transfusion purpose within 48 hours which includes sample collection to reporting of the NAT screening blood units.
- The Service Provider shall set up a NAT Screening laboratory at identified Blood Centres.
- The NAT Lab & NAT Screening Equipments / Machine of the Service Provider should be functional round the clock i.e., 24 hours and 365 (366) days in a year.
- Procurement, installation, testing, commissioning, operation and day to day maintenance of NAT Screening and all related equipment and machinery like freezers,

Computers, Bar code Reader, Bar code printer, other related articles shall be responsibility of the Service Provider.

- All essentials' items like consumables, diagnostics, spares etc. shall be responsibility of the Service Provider.
- The Service Provider should establish a system of Collection and transportation of samples to the NAT Lab, towards conducting the NAT Screening tests and delivery of the testing reports to the concerned Blood Centres.
- The Service Provider shall make all necessary arrangements for bar coding and labelling of samples provided by the identified Blood Centres. This will include printout of bar code labels and capture of Unique Identification Number Donor (UID) against each valid test of blood unit into IT System.
- The Service Provider shall develop and provide the necessary information technology (IT) system including hardware / software / peripheral and other equipments / consumables etc. The IT system will be used to capture all the data related to tracking of status of each donated blood sample. The Service Provider shall provide all other support services that are ancillary to the NAT services.
- The Service Provider shall prepare and develop Operation and Maintenance Manual ("O&M Manual") and Standard Operating Procedures and Protocols (SOP) will be part of the manual.
- Service Provider shall Setup the NAT Lab, commence the NAT Services and run the valid NAT Screening tests within 4 to 6 months from date of signing of the contract and the contract shall be valid from the date of commencement of NAT testing.
- The NAT Lab / NAT Services will be running under supervision of the respective identified Head of Blood Centres in the respective hospitals and Director, SBTC, Odisha.
- The Service Provider shall be responsible to provide UPS systems at its own cost.
- The Bio Medical waste has to be disposed as per the BMW rules should be ensured by the service provider.
- Adequate required number of qualified and experienced technologist, IT professionals, Supervisor and all other manpower required for NAT Lab / Lab services shall be given 24 Hrs X 7 Days by the service provider.
- The Service Provider shall ensure that equipment's are maintained and quality checks are undertaken on a regular basis to ensure optimal quality outputs.
- The Service Provider ensure availability of all necessary consumables, reagents, supplies and materials are of standard or good quality which should be certified by a nationally or internationally recognized organization and are not to be used beyond their expiry dates.
- Regular maintenance and quality checks shall be undertaken by the Service Provider to ensure that good quality NAT Screening Services and accurate and Reliable NAT screening test results / reports are provided as per the SOP / Protocols for quality assurance and quality control as approved by competent authority.
- The Service Provider has to include manufacturer prescribed calibrators/control samples in each run of the fully automatic NAT Screening equipments / machines.
- The Service Provider shall document and maintain accurate records, database and reports as per applicable laws and as specified under the Agreement in a comprehensive and planned manner.
- The service provider should calibrate the equipment at their cost or replace the necessary parts as per the parameter of the manufacture or as and when required.
- The service provider 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 the respective sites without fail as per requirement under normal circumstances.

- Waiver should be taken into consideration in case of force majeure laid down under OGFR and any pandemic times etc.
- Service provider / company need to replace the model of the offered equipment if there is any complete change in reagents or kits or the offer / quoted equipment with similar or better specifications and with same price of the contract entered.

Eligibility: Pre-requisite Qualifications:

1. The Request for Proposal (RFP) are invited from the Vendor i.e., Reputed Manufacturers or any Authorised Dealer/ Importers (i.e., Manufacturer of NAT Equipment, or any Authorised Dealer /Importer by the Principal Equipment Manufacturer). The firms who are intending to participate in the RFP should first ensure that they should fulfil all the eligibility criteria as prescribed in the general terms & conditions of the RFP document.
2. The participated Vendor submitting their RFP documents would be deemed to have thoroughly read, considered and accepted all the terms and conditions.
3. The participated Vendor should have minimum turnover of Rs 40 crores in a year for last three consecutive financial years or more, proof of the same may be enclosed & should have a good track record for the supplies in government / tertiary care institutions in India within last three years.
4. The participated Vendor is advised to submit the Product Performance Report, Service providing report and Customer views report duly signed by any authorised technical expert from any other user institute as assessment of their product performance, credential & credibility.
5. No enquiries, verbal or written shall be entertained in respect to acceptance or rejection of the RFP. If found in any action deemed to be fit will be applicable.

Procedure for submitting RFP:

1. The Single Vendor should submit RFP document only for a Single Company.
2. A single RFP document will contain all the required parameters of RFP.
3. The Vendor should clearly State whether they are Manufacturers or any Authorised Dealer/ Importers of NAT Equipment to the Institute under the sealed cover. The sealed RFPs should reach on or before the date and time as specified in the RFP inviting notice.
4. Each and every page of the RFP document will be submitted duly signed & stamped by the authorized signatory stating his / her name & position / Designation.
5. The Participator shall submit the pre-requisite information as per attached prescribed format. The Participator should take care that the rates and amounts are written in such a way that interpolation is not possible. No blank space should be left, which would otherwise make the RFP liable for rejection. Vendor should quote in figures as well as in words the rates and amount quoted.
6. Alteration, if any, unless legibly attested by Vendor, with their full signature, shall invalidate the RFP. For any error in rates, the manufacturer & importer would be responsible.
7. The terms and conditions should be clearly typed giving the full name and address of the proposal shall include as follows
   a) Pre-condition of supply, delivery, packaging & shipment should be clearly defined.
   b) Storage condition of consumables etc.
   c) Each & every page of the RFP should be serially numbered.

Technical Documents for RFP:

1. Copies of proof / supporting documents or related material should be enclosed in support of original documents submitted by Vendor must be highlighted and compliance to the related document should be serialised against the sl. number of the technical Specification and a table must be prepared related to the same for easy verification purpose.
2. Product catalogue.
3. GST Registration certificate and copy of latest return of GST should be enclosed.
4. DCG (I) along with CE-IVD or US FDA approval certificate should be enclosed.
5. Documentary evidence of sales turnover.
6. Audit Statement of last three years with audit certificate duly certified by CA.
7. Non-black listing / conviction certificate duly notarized.
8. Letter of authority or authorization certificate from the company giving reference of this RFP advertised number.

Price related Documents for RFP:

1. Rate shall have to be quoted in the given format.
2. Original financial form duly filled-in, stamped and signed with printed product price list in support of RFP.
3. Original Financial format should also contain notarized self-declaration on non-judicial stamp paper. If any discrepancy observed the rates quoted in the RFP in question are then the lowest & most competitive with given similar commercial terms and conditions.
4. Self-declaration shall also mention "any downward revision during the period of rate contract will be passed on to the same.
5. Self-declaration is an essential document of price bid.
6. Price format shall have to be submitted in duplicate.
7. If a bidder performs 1000 valid donation screening and reagent rates is X plus taxes, then Govt. will pay 1000 x X plus taxes only. No payment will be made for any repeat tests, control, calibrators or any other purpose.

Rate / Price related documents for RFP:

Shall mean the rates quoted by Vendor shall remain firm and fixed until the completion of the contract

- All rates quoted should be for One Unit per valid test in which it includes HIV 1 & 2, Hep-B & HCV (figures & words both). If discrepancy arises then words mentioned that will be taken into consideration.
- Format should be neatly typed.
- All rates quoted should be F.O.R. destination basis.
- The Institute will not own responsibilities for clearance of consignment.
- No escalation in rates except Govt. levy / tax would be permissible.
- No blank space should be left.
- Should take care that the rate and amount are written in such a way that interpolation is not possible.
- Alteration if any should be attested by Vendor.

- Conditional price bids would not be entertained. For example,
  a) Ten percent discount if all quoted products are procured.
  b) Ten percent discount on items 'A' if item 'B' is also procured from this firm.
  c) Ten percent discount on item 'A' if total qty. purchased exceeds a Particular Amount.
- The prices quoted by Vendor shall not in any case exceed the controlled price, if any, fixed by Central / State Government and Maximum Retail Price (MRP).
- Must ensure that the quoted rates inclusive of Central Excise Duty, Entry Tax, Central Sales Tax etc as applicable. All rates quoted should be excluding GST as applicable.
- Vendor cannot quote any conditional price or any alternative suggestion in related to unit rate, equipment or in terms of alternative arrangement etc. If so the RFP will be rejected and Vendor cannot claim further.
- Delivery schedule with definite date of delivery at destination must be indicated. This contractual delivery date and / or period should be inclusive of all the lead-time.
- The EMD of the successor will be returned after commissioning and successfully running of the NAT screening at the identified centres.

Disqualification of RFP:

1. Late receipt or submission of RFP document will not be accepted & considered.
2. Any action on the part of the bidder to influence anybody of the Institute will make his RFP liable for rejection.
3. Non-compliance of the single RFP submission for one company would be liable for cancellation.

Awarding Rate Contract:

1. Annual supply rate contract will be awarded to the selected firm only. Supplies can be accepted through their authorized Institutional dealer or distributor against their authority letter. However, it will be the sole responsibility of the principal company to ensure the supplies well within the delivery period.
2. The contracting authority shall enter into rate contract with the successful bidder for a period of five years or more and can be further extended based on the satisfactory performance and with mutual consent and agreement.
3. Govt. of Odisha reserves the right to accept or reject the bid in part or full without assigning any reason.

Contract Award:

- The sole award criterion will be the price. The contract will be awarded to the cheapest priced RFP satisfying the administrative and technical criteria.
- Right of the government to accept or reject any RFP.

Situations in which actions can be taken against the Service Provider:

Unless and otherwise specified in the supply order, award of the contract, the ordered price shall remain firm and will not be subjected to escalation. The Institute reserves the right to cancel the supply order or any part and shall be entitled to revise the contract wholly or in part by a written notice to Vendor, if: -

- Vendor fails to comply with the terms & conditions of the supply order.
- Vendor becomes bankrupt or goes into liquidation.

- Vendor fails to deliver the goods in time. Vendor does not replace the rejected goods.
- A receiver is appointed for any of the property owned by Vendor.
- Any prayer of the bidder, which does not serve the purpose of the Institute.

- Upon receipt of the said cancellation notice, Vendor shall discontinue all work of the purchase order and matters connected with it.
- In the event of delay in making delivery, it will be purchaser's discretion to receive delivery or otherwise.
- Bidder will insure all goods or material against all transit risks.
- Delivery time as mentioned in supply order shall be the essence of the order or contract. No variation shall be permitted except with prior authorization in writing from the Institute.
- In the event that the materials supplied do not meet the specifications and / or are not in accordance with the requirement or the terms & conditions of order and replacement is required, the Institute shall notify to the seller giving full details of the discrepancies. The seller shall attend the complaint, within seven days of receipt of such notice to correct the deficiency. If Vendor fails to attend the complaint within the prescribed time, the Institute shall immediately get the same work / material at cost and risk for removing such trouble or defects.

Key terms & conditions for the installation of maintenance free Equipment

- The firm should offer their scientifically proven equipment at no cost basis to the Institute.
- Period of Installation should be minimum five years and can be further extended based on the satisfactory performance and with mutual consent and agreement.
- Maintenance & timely Calibration of the equipment will be the sole responsibility of the firm.
- Terms of payment would be a written agreement i.e. as per MoU of both the parties.
- Up time guarantee 95% of 365 days including hospital and other government holidays.
- Frequent revision in the model of the offered equipment is discouraged. However, if there is any complete change in reagents or kits on the offer / quoted equipment better specifications and with same price of the contract entered.
- Quoted NAT machine must have proven installation base in India & must have installations in at least five licensed Government Blood Centres in Health institute in India with satisfactory report of last three years and also need to submit user list for the quoted model in India.
- The successful bidder should keep the installation free from all conditional purchasing.
- Pre-installation requirement &conditions should be highlighted.
- Cost per valid test of blood unit should be quoted as accurately as possible in the financial bid.
- It is a fixed term rate contract for equipment and consumables to be used in.
- Rate per valid test will be frozen for agreed period, which include HIV 1 & 2, Hepatitis – B & C.
- All equipments and reagents should be as per specifications.
- Backup UPS facility / arrangement should be clear to all stake holders.
- Ranking of the equipment will be carried out as under.
    - ✓ Cost per valid test of blood unit payable will be the final factor for arriving at L1 firm's offer.

- ✓ The exchange rate prevails on the date of opening of Price bid will be applicable.
- ✓ In case, equipment performing more tests including viral discrimination at the same cost will be preferred.

- Rate of consumables is fixed except the GST payable on goods under rate contract. In case, any new tax or tax liability comes under any rule of state / central govt. will be borne by the service provider against such installations like service tax against the cost of manpower or GST payable against the installation cost and so on, if any.
- That equipment that is approved from US FDA or CE-IVD along with DCG (I) will be only considered for RC.
- Manufacturers / importers may provide their equipment through their dealer / distributor or agent but the sole responsibility would be of the manufacturer / importers for all supports.
- Options are opened for operational conditions depending upon the point of care services. In other words, there are some locations where the point of care services required with technical support staff of the service provides, so the service provider should quote their rate with manpower for smooth & effective performance of the respective tests & investigations.
- Govt will only provide space in identified centre in setting of the lab. All the incidental charges including machinery, equipment and manpower will be borne by the service provider.
- On behalf of Govt of Odisha Director, State Blood Transfusion Council will organize the installation of point of care services.
- There are several parameters on which a technical evaluation process takes place viz. operational conditions, cost of consumables, cost of the test, quality, reliability, dependability, processing & reporting time, inter-departmental support, volume of the tests, state of art technology, pre-installation conditions, terms of payment, prior experience etc.

Technical Specifications for Nucleic Acid Amplification Testing:

1. The system must be automated 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 samples or in pool samples.
4. The system must perform all steps from sample processing and viral nucleic acid extraction to target amplification and detection automatically.
5. All equipment/components of the system supplied shall be approved by US FDA or CE IVD along with DCG (I) approved version, consist of all compatible equipment, hardware and software design and set up to perform the protocol as per instructions by the manufacturer for NAT assay Purpose.
6. 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 tips with technology to prevent carry over and cross contamination of samples Ids shall be possible.

- 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.

7. 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.
8. After handing over the required space by Govt. of Odisha any modification and renovation like Air-Conditioning, roof, flooring, electrical work related to functioning of the NAT lab and walling is the responsibility of the service provider.
9. 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.
10. Interface as part of the software and shall enable the system to
    - Send test results through a serial port or network connection.
    - The interface shall be compatible with Blood Centre information system.
11. Service provider shall supply a complete protocol for validation of the system in relation to Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). Vendor shall provide sufficient number of suitably qualified personnel and make available support to assist the validation processes and acceptance evaluation and should include a comprehensive training programme for staff. Vendor is to provide all together the NAT test kit and consumables needed for screening of 1,000 tests of blood unit for validation and trial run.
12. 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.
13. 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 high throughput requirements of Odisha State.
14. 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.
15. NAT screening system must have minimum facility to detect HIV (all variants) and all known genotypes of HBV and HCV.
16. The equipment should have a computer interface facility for transfer of the results to the dedicated Blood Centre to reduce turnaround time and timely release of the blood units. In exceptional circumstances such as mass causality or disaster etc., the sample collection and NAT screening will be done at the earliest on top priority.
17. Service provider shall guarantee the system, or any part thereof 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 and selected firm should make provision for standby equipment of same make and same model at the sites where workload is more like NAT centre at Cuttack

18. 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 the respective sites without fail as per requirement under normal circumstances. Waiver can be given in case of natural calamities like, cyclones, floods, earthquakes, pandemic times etc.
19. Discriminatory test should be available on the same platform with the same assay to avoid any ambiguity in the final results. Discriminatory test result should be available within 24 hours from the start of testing. Company should submit a SOP of complete procedure.
20. The kit should consist of ready to use reagents. The vendor should provide positive and negative controls / calibrators, chemicals for the completion of the whole NAT procedure.
21. Assay Performance – they should be able to accurately detect maximum and all prevalent genotypes of HIV, HBV and HCV.
22. Analytical sensitivity of the complete assay performed on system (with a 95% detection probability) will be at least
    a) HIV-1 : < 55 IU/ml.
    b) HCV : <7 IU/ml.
    c) HBV : <5 IU/ml.
    d) HIV-2 : <8 IU/ml.

    Service provider is required to provide proven data on analytical Sensitivity, Specificity, Reproducibility/ Repeatability and other relevant parameter of assay performance.
23. The service provider shall specifically quote globally and scientifically known commercial automated Nucleic Acid Amplification Test (NAT) Assays which should be approved by United States Food and Drugs Administration (US FDA) or CE IVD along with Drugs Controller General (India) for use in donor blood screening.
    - The quoted NAT assay/method shall be the approved version /generation by along with DCG (I). The assay should meet the minimum requirements as per the product insert of the US FDA or CE licensed product. In other word the NAT test kit, test protocol and automated system should be approved by United States Food and Drug Administration (US-FDA) or CE IVD and the competent Indian Authority ie.; Drugs Controller General (India) for use in blood screening. The service provider shall submit relevant supporting document as evidence for the above requirements.
24. The service provider has to include manufacturer prescribed calibrators /control / internal control samples in each run of the fully automatic NAT Screening equipment / machines. The number and frequency of running of such controls should be same as prescribed in the manufacturer's kit literature and as agreed by the Authority in the approved Standard Operating Procedures. Any subsequent change required as per technological changes would be carried out and with approval of Authority. The final valid test cost per test of collected blood unit must include all these requirements (i.e., cost of consumables, accessories, controls, and reagents required to run the test).
25. The service provider shall deploy Protocol for accurate identification, labelling and reporting of samples in mutual consultation and agreement with the authority.
26. The service provider should provide free of cost calibration facility as per the company protocol and as and when required.

27. 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 service provider in free of cost.
28. The service provider is to conduct specialized training of the Blood Centre in-house staff for end-users to perform the NAT testing independently.
29. System should be compatible with anticoagulants routinely used on the Blood Centre such as EDTA, SAGM and CPDA.
30. As Blood Centre have limited space, the NAT system must support single room operation and must have throughput of minimum 250 donations in 8hrs and 500 donations in 12 hrs. (Detection and Discrimination)
31. Quoted NAT machine must have proven installation base in India & must have installations in at least five licensed Government Blood Centres in Health Institutions in INDIA with satisfactory report of last three years. The Bidders have to provide details of its supply to the Government Blood Centres with contact details also need to submit user list for the quoted model in India.
32. Govt. of Odisha will pay Cost per Valid test. This remains valid irrespective of Assay, method (Individual Donation / 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 test.

Pre-qualification Form - I

(Pre-qualification for the supply of items)

This information will be furnished with RFP

General Information to be furnished by Vendor **in the given format**

1. Name of the Vendor.
2. Full Postal Address.
3. Telephone No:

   Fax No:

   E-mail address:
4. Status of (Whether Proprietorship/Partnership/Company or Consortium).
5. State whether is small scale, medium scale, organized sector (Indian or multinational company or firm).
6. Name of the persons who are responsible for conduct of business as explained under Section 34 of the Drugs & Cosmetics Act, 1940.

Sl. No.	Name	Father's Name	Age	Residential Address

7. Particulars of licenses held under the Drugs & Cosmetics rules including date of grant of license and its renewal date.
   a) Attach attested copy of Drug License along with list of items permitted.
   b) If the licenses are under renewal, a certificate from the State Drugs Controller, in whose jurisdiction the factory is located stating that the licenses are under renewal and the same are deemed in force, should be attached with this RFP form.
   c) If the item is manufactured under any loan license/marketing arrangements full details should be provided.
8. Particulars of business experience.
   a) Names of procurement agencies with whom the Vendor is registered.
   b) Names of procurement agencies to who item have been supplied during last 12months.
      (Copy of supply orders to be enclosed)
   c) Has the ever been black listed/debarred by any procurement agency? If yes, give details

(Authorized Signatory of the firm)
Name &Signature:
Date:

Designation & Stamp:

Pre-qualification Form – II

This information will be furnished with RFP

(Financial Aspects)

1. Turnover for the firm in last three financial years (year wise) as mentioned below. Please furnish the attested copies of Audited Balance Sheets / Profit & Loss Account of the Firm.

   2017-2018

   2018-2019

   2019-2020

2. Facilities available from Bank Overdraft facilities in lacs

   Overdraft facilities against hypothecation

   Other facilities, if any

3. Name & full address of your bankers
4. Furnish the following information or documents

   Income Tax PAN no.

   GSTN Registration

5. No. of Service Engineers / skilled & trained personnel.
6. Dealer or distributor available at Odisha:

(Authorized Signatory of the firm)

Name &Signature:

Designation & Stamp
Date:
Place:

Pre-qualification Form - III

(Pre-qualification of the Vendor)

1. All necessary support for Accreditation of Lab as per NABH norms.
2. Whether USFDA or CEIVD along with DGC (I) approved reagents shall be used in the machines installed in Lab or not?
3. Whether maintenance charges to be taken by the company for the equipments installed in Lab throughout the contract period or not?
4. Whether Capable to maintain 100% up time of machines in the Lab?
5. Whether Capable to attending to break down and setting things right in given time?
6. Whether the firm is willing to modernize or upgrade the equipment free of cost?

(Authorized Signatory of the firm)

Name & Signature:
Designation & Stamp:
Date:
Place:

Form – IV
(Self-declaration)

(This form will be attached with the technical bid duly filled in by the)

I, _____Prop. / Partner / Director of M/s _____ hereby declare that the Information given in IRF Form- I, II and III are true and correct to the best of my knowledge and belief.

Name & full address:

Designation:

Date:

Place:

Warning:

1) Subsequently, if information furnished in this form is found incorrect, this may also be black listed by the Institute.

   And / or

2) This may also be debarred from participation from Institute's business.

   And / or

3) The Institute may also forfeit the earnest money deposit.

   And / or

4) The Institute on the may also impose any embargo.

   And / or

5) Any other action as deemed fit against the Vendor or Principal Company.

Form – V

Acceptance for general terms & conditions of the RFP

I / We have gone through the terms & conditions as laid down in the RFP documents and are acceptance to me / us.

I / We, am / are submitting the pre requisite documents and the details of the same are given therein.

I / We hereby accept all the terms and conditions of the proposed in RFP of the Govt. of Odisha Health & Family Welfare Deptt. In case it is awarded to me / us or to my / our principal company / manufacturer against quoted rates.

(Authorized Signatory of the firm)

Name & Signature:
Designation & Stamp:
Date:
Place:

Checklist

Please ensure whether the documents attached with RFP

1) Whether the RFP Paper cost of non-transferable document paid. Yes /No
2) Whether Earnest Money Deposit (Refundable) attached. Yes /No
3) Whether all Forms are attached. Yes /No
4) Whether audited statements of each of the last three Financial Years enclosed. Yes /No
5) Whether Sales Tax & Income Tax assessment certificate is attached. Yes /No
6) Whether Authorisation letter of principal manufacturer is attached. Yes /No
7) Whether Non-black listing affidavit, duly notarized, is attached. Yes /No
8) Whether copy of documents is attached in support of your turnover. Yes /No
9) Whether each & every page of the RFP document is serially numbered. Yes /No
10) Whether each & every page signed and stamped stating the name of authority. Yes /No
11) Whether envelop is properly sealed. Yes /No
12) Whether Self-declaration Form duly filled in is attached. Yes /No
13) Whether the validity of the offer is mentioned. Yes /No
14) Whether Applicable taxes clearly mentioned is in%. Yes /No
15) Whether the Sample / Product catalogue is provided. Yes /No
16) Whether all US FDA, DCG (I) documents are provided. Yes /No
17) Whether in support of document submitted has highlighted against the technical Specification or not and a table in this light has prepared and against the sl. no of Technical Specification is enclosed. Yes/No

Signature and Seal

FORMAT FOR QUOTE or OFFER PRICE
PRICE BIDS FOR NUCLEIC ACID TESTING (NAT)
SCREENING OF DONATED BLOOD IN BLOOD CENTERS at ODISHA

Sl. No.	Details of the Items	Name of Item to be mentioned in as Schedule of Supply Brand name / Catalogue no. / Model No.)	*Rate in Indian Rupees exclusive of GST	
1.	NAT Screening Rate per sample of valid donated blood.		(In Figures)	(In Words)
2.	Total rate per valid donation need to mentioned to carry out NAT test of total 2,15,500 unit of valid donation			

* The rate quoted should include all applicable taxes except GST which would be paid as applicable.
* In point no 2 need to mention the rate to carried out NAT test for 2,15,500 valid donated blood tested X price per valid donated blood tested=_____ total amount (excluding GST)
* No discrepancy should be in Word and Figure in the Format For Quote or Offer Price document.

NB:

1. During evaluation the base price of the offered rate will be taken in to consideration by excluding the GST and other Taxes.
2. Govt. of Odisha will pay GST as per Financial Rule.
3. No discrepancy should be their during rate quotation in between Sl. No. 1&2, if found such case then the bid of the bidder will not be taken in to consideration for final evaluation.
4. Conditional Price bids would not be entertained. For example,
    a) Ten percent discount if all quoted products are procured.
    b) Ten percent discount on items “A” if item “B” is also procured from this firm.
    c) Ten percent discount on item “A” if total qty. Purchased exceeds a Particular Amount.
5. A second copy of Price FORMAT FOR QUOTE or OFFER PRICE may prepare and submitted in separate envelop with proper tamperproof seal and signature by addressing to the President, GB, SBTC & Addl. Chief Secretary to Govt. of Odisha H & FW Deptt.

(Signature of Authorised Signatory)
With rubber stamp of the firm in Letter Head