Government of National Capital Territory of Delhi
Health & Family Welfare Department
9th Level, A - Wing, Room No. 910, Delhi Sectt.
I.P. Estate, New Delhi, Ph: 011-23392031

No: F.8 / (F) / (12) / DHS / HC / 2012 /478 Date: 13.06.2013

Addendum to the Notice Inviting Bids for Outsourcing of Nucleic Acid Amplification Testing (NAT) Screening of Donated Blood in Blood Banks in Delhi.

This is with reference to the Advertisement and RFP issued for Outsourcing of Nucleic Acid Amplification Testing (NAT) Screening of Donated Blood in Blood Banks in Delhi on 14th March 2013 and the pre-bid meeting held with the prospective bidders on 2 April 2013 at 11.00 AM.

The Bid Due Date (last date for receiving bids) is revised by the Authority to 27 **June, 2013 (Thursday)** upto 3.00 P.M. and the bids are to be submitted as per **Clause 2.4.** The Bids shall be opened in the Conference Room, 2nd Floor Directorate of Health Service, F-17, Karkardooma, Delhi - 32 on **27 June, 2013 at** 3.30 P.M.

In accordance with the provisions under Clause no. 13 (and sub-Clauses therein) of RFP, following modifications are made to the RFP:

ADDENDUM

1. The paragraph under "**NOTICE INVITING BIDS FOR OUTSOURCING OF NUCLEIC ACID AMPLIFICATION TESTING (NAT) SCREENING OF DONATED BLOOD IN BLOOD BANKS IN DELHI**" on page 1 of the NIT is amended as under:-
   In order to make blood safer for transfusion, Government of National Capital Territory of Delhi (GNCTD) intends to introduce Nucleic Acid Amplification Testing (NAT) screening of donated blood in Blood Banks in Delhi, and for this purpose GNCTD invites sealed bids (in single stage bid system) for 'Outsourcing of Nucleic Acid Amplification Testing (NAT) Screening of donated blood, in blood banks in Delhi'. Eligible Bidders are requested to submit their sealed Bids as per the bidding schedule mentioned in clause 2.1.2 & terms and conditions given in the prescribed Request for Proposal (RFP) Document.

2. In the **Disclaimer to the RFP document**, following is added -
   The assumptions, assessments, statements and information contained in this RFP represent the current thinking on Nucleic Acid Test (NAT) method for screening Human Immunodeficiency Virus Type I (HIV-I), Hepatitis C Virus & B Virus (HCV, HBV) from donors of human blood. These should be viewed with respect to the scope of this RFP only, unless specific regulatory or statutory requirements are cited. They do not create or confer any rights for or on any person and do not operate to bind the Authority in any manner whatsoever.

3. Following **Statement of Object & Reasons** is added in RFP before **"INTRODUCTION"**
The Authority notes that the blood banks under GNCTD shall continue Serology testing (ELISA) of donated blood for Human Immunodeficiency Virus Type I (HIV-I), Hepatitis C Virus (HCV) & B Virus (HBV), as mandatory under the law. The NAT screening tests for donated blood will supplement and not supplant ELISA tests, in order to reduce the risk of transmission.

4. The **Clause 1.1** of RFP is amended as under:
In order to make blood safer for transfusion, Health & Family Welfare Department, Govt. of NCT of Delhi (hereinafter referred to as **"Authority")** intends to introduce Nucleic Acid Testing (NAT) Screening of donated blood in 10 (ten) Blood Banks in Delhi on outsourcing basis.

5. **Clause 1.4** of RFP is amended as under:
Nucleic Acid Amplification Testing (NAT) screening of donated blood in Blood Banks in Delhi or NAT Screening means the Nucleic Acid Amplification Testing (NAT) Screening tests for HIV (at least HIV-I), Hepatitis B and Hepatitis C as per details in Schedule 1.

6. **Clause 2.1.1** of RFP is amended as under:
The purpose is screening of the donated blood in the Blood banks under GNCTD for HIV (atleast HIV I), HBV, HCV viruses.

7. **Clause 6.1** of RFP is amended as under:
The Bidder shall furnish as part of its Bid, a Bid Security of Rs.10,00,000/- (Rupees Ten lacs only) in form of either a Demand Draft or a Fixed Deposit Receipt or a Bank Guarantee issued by a nationalized bank, or a Scheduled commercial Bank in India in favor of Director, Health Services, GNCTD payable at Delhi. For the avoidance of doubt, Scheduled Bank shall mean a bank as defined under Section 2(e) of the Reserve Bank of India Act, 1934.

8. A new **Clause 8.3** is added in the RFP as under –
A non-manufacturer bidder shall submit an authorization letter, from the manufacturer of equipment stating that the bidder is authorized to quote for their NAT Screening Assay /equipment and the manufacturer shall provide all the necessary technology, equipment, reagent and support to the bidder. The authorization letter is to be included in the Part B- Technical bid under **Clause 9.1**.

9. The following additional details / documents are also to be submitted as part of the Technical Bid under **Clause 9.1** of the RFP
a) Copies of FDA license /approval & approval from Competent authority with respect the NAT Assay / Method offered by the bidder
b) Analytical sensitivity (95% LOD with 95% CI in IU/mL) for human immunodeficiency virus Type 1 [HIV-I], hepatitis C virus [HCV], and hepatitis B virus [HBV] for testing along with a copy of the product insert in its support.
c) Acceptance and rejection criteria.
d) Specificity of test in terms of percentage.

e) Testing time (turnaround times and throughput) shall be clearly mentioned separately for samples negative and in case of positive with deconstruction and discriminatory identification of viral genome.

f) Procedure / process indicating how QA/QC/Continue quality Improvement / Quality Assessment Programme / Quality Management shall be followed as per ISO 17025 or as per equivalent standard to avoid systematic, technical and random errors and to prove accuracy, reproducibility, precision of test system.

10. **Clause 11.1** of RFP is amended as under
The evaluation of the Bids shall be done in three stages as under
Stage1- Prequalification evaluation
Stage 2- Technical evaluation and
Stage 3 – Price Bid Evaluation

11. **Clause 11.3** of RFP is amended as under
Stage -2 Technical evaluation:
Technical evaluation of only those Bids that qualify the Prequalification evaluation will be undertaken. The Technical evaluation will be done in two steps by the Technical Evaluation Committee.

(a) In the first step Technical evaluation committee constituted by the Authority will assess the Quoted NAT technology / Assay / Method / Equipment on the basis of following minimum technical requirements

(i) The Bidders shall specifically quote globally & scientifically known commercial automated Nucleic Acid Amplification Tests (NAT) Assays which are Food and Drug Administration (FDA) USA licensed, for triplex (human immunodeficiency virus Type 1 [HIV-I], hepatitis C virus [HCV], and hepatitis B virus [HBV] for use in donor blood screening. The quoted NAT Assay / method shall be the **latest version / generation** and approved for commercial use in India by Competent authority. The assay should meet the minimum requirements as per the product insert of the US FDA licensed product.

(ii) The donor screening test for HBV DNA by NAT shall have a lower limit of detection of < 100 IU/mL HBV DNA for HBV DNA detection in an individual donation

(b) The first step of technical evaluation will be done on the basis of documents submitted, technical presentation and or a demonstration at an installation site using the offered technology. The technical presentation shall include technical details on the offered NAT technology / method / Assay i.e. FDA approval, version / generation, sensitivity. In addition Technical presentation shall include acceptance criteria, rejection criteria, assay validation, testing time, through put, performance measures & upper control limits, quality control procedure, and any technical clarifications as may be required by the Technical evaluation committee.

(c) In case the Quoted NAT technology /Assay / Method / Equipment meets the minimum technical requirements, then Second step of Technical Evaluation will be done.

(d) The Second Step of technical evaluation of only those Bids that qualify the first step of Technical evaluation will be undertaken as under:

i. A Technical evaluation committee constituted by the Authority will assess the

Technical proposal submitted by the bidder. The assessment method detailing the parameters for marking, maximum marks, criteria of assessment and scale for marking are given in the table (mentioned under original clause 11.3 (i)).

ii. It is clarified that wherever it is not possible to give the marks for any parameter / criteria even at the lowest scale on account of the nature of proposal, the TEC on its own discretion may give marks lower than the minimum scale or seek clarifications, if any, and then proceed to give marks.

iii. Only those Bidders with Technical Proposals' score of 70 marks or more out of maximum of 100 marks shall qualify for Price bid evaluation. This is an output based procurement of Services; the Bidder will be selected on the basis of Price Bid evaluation only.

12. **Clause 1** of Schedule 1 of RFP is amended as under:
In order to make blood more safe for transfusion, the Authority intends to introduce NAT Screening of donated blood in 10 Blood Banks situated in various hospitals under GNCTD on outsourcing basis. The yearly collection of blood is expected to be around 1 (one) lakh units in these 10 blood banks. However the Authority does not guarantee that the yearly number of blood collections of 1 lakh units may not vary.

13. **Clause 5** of the schedule I of the RFP is amended as under
In case a newer version / generation of the NAT Method deployed by the Service provider is introduced in India, in that case Service Provider will upgrade the equipments to new latest version/generation within 3 months of introduction of newer version / generation free of any charge. Further in case NAT Screening for HIV I, HCV, and HBV becomes mandatory under Applicable law during the term of the agreement, then in that case the Service Provider shall implement the guidelines / recommendation within the same rate, without any extra cost.

14. Following is added in **Clause 6** of the schedule I of the RFP:
The term fully automatic system implies system with process control from sample preparation to result reporting with minimal end user intervention for the whole period of testing procedure.

15. **Clause 8** of the schedule I of the RFP is amended as under -
The Bidders shall specifically quote globally & scientifically known commercial automated Nucleic Acid Amplification Tests (NAT) Assays which are Food and Drug Administration (FDA) USA licensed, for triplex (human immunodeficiency virus Type 1 [HIV-I], hepatitis C virus [HCV], and hepatitis B virus [HBV] for use in donor blood screening. The quoted NAT Assay / method shall be the **latest version / generation** and approved for commercial use in India by Competent authority. The assay should meet the minimum requirements as per the product insert of the US FDA licensed product.

16. **Clause 9** of the schedule I of the RFP is amended as under:
Discriminatory test should be available on the same or additional platform specifying the type (serotype) of infection in positive cases

17. **Clause 12** of the schedule I of the RFP is amended as under:

"Continuous provision of NAT Screening services: The NAT Lab & NAT Screening equipments / machine of the Service Provider should be functional 24 x 7 in a year during the Operation Period in accordance with the Agreement generating valid NAT Screening reports with maintenance & services downtime not exceeding 3% in a year. In the instance of a failure of machine /equipment, back up created by Service Provider shall be used for NAT Screening services. But such instances should not be more than seven days per installation in 6 month period. In case the failure is more than 7 days per installation in 6 months period then a penalty of Rs 2, 00,000/- (Rs two lakhs only) shall be levied per instance of such a failure. In case the failure extends beyond one day the failure instance would be counted as another instance for each failure day till the NAT services are resumed and if the downtime exceeds 30 days (with backup) & 45 days (without backup) than the contract is liable to be terminated.

18. **Clause 23** of the schedule I of the RFP is amended as under:
The application for NABL certification/ Accreditation for each of the NAT Lab shall be made by the Service Provider within three months of issue of Development completion certificate and NABL certification/ Accreditation shall be obtained within one year of issue of Development completion certificate or any extensions granted thereof by the Authority.

19. A new **Clause 31.14** is added in Schedule 1 of RFP as under:
All personnel involved in the NAT assay and in the operation of the NAT facility shall be provided training in good laboratory procedures and the unique requirements inherent to NAT. In the case of personnel directly involved in NAT testing, training should address mechanisms to prevent cross-contamination, workflow, and careful test sample handling. Such training should include participation in periodic competency assessment, which can either be performed by evaluation of the performance of a given technician by Expert Committee or by participating in internal or external proficiency programs.

20. **Clause 32.9** of the schedule I of the RFP is deleted.

21. **Clause 33.9** of the schedule I of the RFP is amended as under:
a) The Analytical sensitivity of the assay for HIV I, HBV & HVC shall conform to the product inserts of the FDA Licensed assay.
b) The donor screening test for HBV DNA by NAT shall have a lower limit of detection of < 100 IU/mL HBV DNA for HBV DNA detection in an individual donation

22. **Clause 33.10** of the schedule I of the RFP is amended as under
Test Assay should be able to detect minimum of HIV-I Group M, Subtypes A, B, C, D, E, F, and G; and HIV-I Group O
Comment: The revised criteria allow wider participation and competition.

23. The following sub Clauses are added under **Clause 35** of the schedule 1 of the RFP:

a) Only those lots of products / reagents / assay kits will be used which have received notification of release from a recognized agency.
b) The expiration period for the products / reagents / assay kits / components will be monitored.
c) Adverse experience reports will be submitted.
d) Service provider shall perform study to demonstrate detection of window period donations ("serologically-confirmed NAT yield cases") for human immunodeficiency virus Type I [HIV-I], hepatitis C virus [HCV], and hepatitis B virus [HBV] infection.
e) All claims must be consistent with and not contrary to FDA approved labelling.
f) The Service provider if required by the Technical Expert committee shall demonstrate the performance of the NAT methods by standard sample panels as approved by the Experts Technical committee, at its own cost.
g) Careful sample handling shall be ensured at all times. Measures, such as appropriate handling; time, temperature and selection of preservatives, shall be taken to ensure stability of pathogens and target nucleic acids. Transport and storage of test sample shall be validated to ensure stability of target sequences
h) In order to detect contamination and to monitor NAT assay performance (sensitivity and specificity), at least three types of controls shall be included in each NAT assay run: Negative assay control; Positive assay control; Reagent control. In addition, appropriate internal controls may be used to monitor the assay. Assay controls, calibrated against WHO International Standards where possible, shall be used.
i) The NAT Laboratory performance measures including initial reactive only tests; Invalid Tests (equipment invalids, operator invalids, invalid calibrators, invalid & others); Failed Runs (equipment failure, operator error failures, external run control failure, unexplained/other failures) will be measured and monitored. All these measures of performance shall be operating within the upper control limits. The upper control limits will be defined in mutual consultation with the Expert Committee.

24. **Clause 35.7** of the schedule I of the RFP is amended as under:
Accreditations: The Service Provider shall obtain NABL accreditation for each of the NAT Lab within one year of issue of Development completion certificate or any extensions thereof.

25. A new **Clause 38.20** is added in Schedule 1 of RFP as under:
Data management shall include the tracking of all relevant information from sample acquisition through final reporting of results.

26. A new **Clause 4 (i)** is added in Article IV of the agreement as under:
The Service Provider shall undertake an adequate numbers of Test runs free of charge of adequate sample size for validation of the testing protocols. The development completion certificate will be issued only upon satisfactory test run.

27. **Clause 6** of Article VII of the agreement is amended as under:

Delay in getting NABL Accreditation: In case of the Service Provider failing to get the NAT Lab NABL accredited in one year or extensions if any, from the date of issue of Development Completion Certificate, a penalty of 10% of the monthly bills of all the identified and included blood banks shall be imposed for each month delay or part thereof till the NABL accreditation is obtained. In case of failure to get the NAT lab NABL accreditation even after **12 months** of issue of Development Completion Certificate, the Agreement will be liable to be terminated and Performance Security shall be forfeited in that case. It is clarified that in case more than one NAT Lab are set up under this agreement then the penalties shall be calculated and levied for each Lab separately.

28. **Clause 1** of Article X of the agreement is amended as under:
The Term of the Agreement shall commence from the Effective Date. The Initial period of the Agreement would be for a period of two years subject to satisfactory performance. This may be extended at the sole discretion of Authority by another one year, on half yearly basis after assessing the performance, efficiency, economy and quality of Services at that point in time. The Service Provider shall ensure that the Performance Security is also extended commensurate with the extended period.

Spl. Secretary (H&FW)
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Copy to:

1. Director, Dte. of Health Services, F-17, Karkardooma, Delhi, GNCTD.
2. Technical Evaluation Committee Members/ Technical Expert Committee Members.
3. I/C SHIB through DHS: dirdhs@nic.in for publishing the clarifications/ addendum on the website http://health.delhigovt.nic.in under title "Addendum to the Notice Inviting Bids for Outsourcing of Nucleic Acid Amplification Testing (NAT) Screening of Donated Blood in Blood Banks in Delhi".
4. PS to Secretary to Hon'ble MOH, GNCTD.
5. PS to Secretary (H&FW), H&FW Department, GNCTD.
6. PS to Spl. Secretary (SBS), H&FW Department, GNCTD.