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 /525 Date: 24.06.2013

Subject: Response to the queries received on 20 June 2013 from a participant of pre-bid meeting in reference to the Addendum for Outsourcing of Nucleic Acid Amplification Testing (NAT) Screening of Donated Blood in Blood Banks in Delhi.

This is with reference to the RFP for Outsourcing of Nucleic Acid Amplification Testing (NAT) Screening of Donated Blood in Blood Banks in Delhi issued on 14th March 2013; pre-bid meeting held on 2 April 2013 at 11.00 AM and Addendum to the Notice inviting Bids issued on 13.06.2013

Please find enclosed the final response as above in the Annexure – 1 of this communication. *Please note that no further modifications are made to the RFP.*

The Bid Due Date (last date for receiving bids) is revised by the Authority to **02 July, 2013 (Tuesday) upto 5.00** 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 **02 July, 2013 at 5.30 P.M.**

Enclosed as above **sd/-**

Spl. Secretary (H&FW)

To,
All prospective Bidders,

Annexure 1

Outsourcing of NAT screening of donated blood in blood banks in Delhi
Response H&FW Department to additional Queries

S.No.	Query by participants of pre bid meeting	Response of H&FW Dept., GNCTD
1	Point # - I: We believe that you are allowing larger pool sizes in the tender. We wish to know whether you will allow pool sizes of 16 and 24 also	1. **No change in the terms of Addendum / RFP** 2. Please see **amended Clause 8** of the schedule I of the RFP i.e. "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] viruses 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." *Comments:* i. *It is clear that offered Assay/ system must be **commercial automated** for triplex (HIV – I, HBV, HCV) virus screening of donor blood and **approved / licensed** by the US FDA and approved for commercial use in India by Competent authority. Therefore the US FDA approved / licensed **latest commercial automated triplex** Assays/ systems will be acceptable as per minimum technical requirements under Technical Evaluation.* ii. *The offered Assay shall meet the Sensitivity criteria as*
2	Point # - II: Clause 2.1.1 - Original RFP No.F.8/(F)/(12)/DHS/HC/2012/ states that : **The purpose is mass screening of the donated blood in the Blood banks under GNCTD for reducing the window period for detection of the HIV (at least HIV I), HBV, HCV viruses.** Whereas; The addendum No.F.8/(F)/(12)/DHS/HC/2012/478 dtd 13/6/2013 states that : **The purpose is screening of the donated blood in the blood banks under GNCTD for HIV(at least HIV1), HBV, HCV Viruses.** Our Objection to the above amendment: In the addendum you have removed the objective from window period reduction to just screening. Whereas the mandatory screening is already being performed by serology, the very purpose of NAT testing is reduction of window period to the shortest possible level. By removing the 'window period' from your pupose statement, we feel it is diluting the very need for NAT screening.	
3	Point # - III: Clause # 9.d of Addendum: Specificity of tests in terms of percentage. While we shall submit the specificity data, we wish to make a point that for a screening test where the early detection and lowest possible detection limit is the major focus, you should also ask for Sensitivity of the assay for 95% LOD	

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	with 95% CI of each assay in terms of IU/ml. We wish to state that your specification covers only the HBV sensitivity in terms of IU/ml as per Addendum Point # 21 for amendment of Clause # 33.9. As per your clause # 9.1 (b) of the Addendum document, you have asked for Sensitivity data (95% LOD with 95% CI in IU/ml) but does not make any minimum criteria of sensitivity for HIV-1 and HCV. Do you mean you will accept any sensitivity without a minimum criteria for HIV-1 and HCV?	*specified in the Addendum to the Notice inviting Bids.* iii. *The clarifications on minimal use intervention for fully automated system has already been given in the pre bid meeting. It is reiterated that for the purpose of this tender a Fully Automated system is where you load the samples and obtain the results after the samples are processed by the system. The manual intervention is limited to loading the samples into the system. The processing of samples, data and results are by the system including monitoring the smooth operation and QC of the system and results.* 3. **Please see the amended Clause 33.9** of the schedule I of the RFP i.e. a) The Analytical sensitivity of the Assay for HIV I, HBV & HCV shall conform to the product inserts of the US 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 *Comments:* i. *These are among the minimum technical requirements under Technical Evaluation.* ii. *The donor screening test for HBV DNA by NAT shall have a lower limit of Detection of <100 IU/ml for HBV DNA in an individual donation (and not > 100 IU/ml as understood and quoted in the second line of query at Point # - IV)* 4. **Please see the Clause 31.1** of the Schedule 1 of the RFP i.e. *"The service provider shall procure, install and commission all*
4	Point # - IV : Your clause # 11.3 (a) (ii) The donor screening test for HBV DNA by NAT shall have a lower limit of Detection of >100 IU/ml for HBV DNA in an individual donation. **Our query:** When NAT is to screening of HIV, HBV and HCV, why only the lower limit of Detection for HBV is asked for? Why the same criteria for HIV and HCV criteria missing? Why 100 IU/ml for HBV? Why not lower? Is it that you have taken reference from US FDA for HBV sensitivity? If yes, we wish to bring to your notice that US FDA is applicable only for USA based on their circumstances. As you know that the prevalence of HBV infection in India is over 50 times that of US prevalence. Our voluntary donor rates are very low compared to US voluntary donor rates. When a country has very low prevalence and high voluntary donor population, they can afford to accept an assay with such low sensitivity. US also does 4th gen HBsAg screening and Anti HBc screening whereas in Delhi only 3rd or 4th Gen HbsAg screening is performed and Anti HBc screening is not mandatory. But in India our situation is completely different. With very high prevalence of HBV infection as well as very low levels of repeat voluntary donors, we need a more stringent and highly sensitive assay to detect early window period and Occult	

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	HBV infection cases. Even the recent publication from JP Allain (Ref: Transfusion. 2013 Jan 30. doi: 10.1111/trf.12096.) mention that in South east Asia, majority of both window period infection and late stage occult HBV infection, levels of circulating viral genome were very low (less than 100 IU/ML). When it is established that HBV NAT yields are associated with low viral load of less than 100 IU/ml in our region, what is the basis of keeping HBV Lower Limit of detection as 100 IU/mL? By not specifying the sensitivity criteria of HCV and HIV and allowing a very lenient sensitivity criteria of <100 IU/ml on HBV, will you therefore be willing to accept pools of 16 and 24 and risk missing early stage infections?	*NAT screening and related equipments / machinery, devices, apparatus, facilities and all other support and ancillary infrastructure as necessary for development, operations and maintenance of the NAT lab".* *Comments: It is clear that discriminatory identification of viral genome is part and parcel of the NAT Screening testing and that it has to performed in the NAT Lab setup in the premises of Authority.*
5	Point # - V: Your point no. 14. The 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. **Our query:** What is the meaning of 'minimal' end user intervention? Would you accept a bidder's definition of the fully-automated system or you have a clear definition? Would you accept a system with more than one module for test procedure based on bidders claim that it is fully automated? The general understanding is that a Fully Automated system is where you load the samples and obtain the results after the samples are processed by the system. The manual intervention is limited to loading the samples into the system and processing the data and results that are generated by the system, including monitoring the smooth operation and QC of the system and results.	
6	Point # VI - In the amendment of Clause 9 of the Schedule I of the	

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	RFP, you have stated that Discriminatory test should be available on the same or additional platform. However, you have not specified the condition that if it is an additional platform, the same should be installed in the Govt Hospital premises itself where the NAT Lab is set up. This ambiguity can easily be manipulated with performing discriminatory testing at an outside facility. In such situation, the blood banks lose the control over the quality of the results. Therefore we need a clarification about the additional platform being required to be installed at the same NAT Lab premises where the NAT screening equipment would be installed.	
7	Point # - VII: In response to the RFP 4.4 of the Original tender document, we have requested for linking the price to dollar variation. We are witnessing a huge dollar escalation these days. Just 2 weeks back One dollar was Rs 56/- and in the last two weeks it has gone up to Rs 59/-. In such volatile situation, you are requested to add a clause that the price will be reviewed if there is a substantial variation in exchange rates over 3 months period. **We have not received any response to this point raised during the Pre-bid meeting.**	**No change in the terms of Addendum / RFP** *Comments:* i. *As already clarified during pre bid meeting, there shall be no linking of the price quoted to any foreign currency fluctuation. The prospective Bidder shall bear any such risk and accordingly factor such risk in its price quote.* ii. *Please see point no. 18 of the Addendum regarding Term of the Agreement.* iii. *The hospitals will endeavor to make payment by ECS into the account of the Service Provider within 30 days of receiving the verified bills. The period of payment shall be monitored closely by the authority, to ensure timely payment to the service provider. As already clarified during pre bid meeting, the Authority will endeavor to put into place a system of centralized payment which can be tracked & monitored electronically.*
8	Point # - VIII: Page # 75 Article X of RFP document (tender document) states that: 1. 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 up to maximum of another one year on quarterly basis by way of mutual consent and at such rate which is mutually agreeable and after considering the appropriateness of technology at that point in time and subject to satisfactory performance. The Service	

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	Provider shall ensure that the Performance Security is also extended according to the extended period. We have made specific request during the pre-bid meeting that this contract period has to be extended to a minimum of 5 years so as to recover the costs. **We have not received any communication in this regard.**	
9	Point # -IX: Regarding Billing and release of payments, ref :Page # 75 Article IX of RFP document (tender document) , we have made our specific request as part of the pre-bid meeting as under : 1. The time period is too long and should be centralized. First monthly bills with signature of HOD (can take time) of each Hospital to be submitted to of each Hospital (will take time). They can respond in 15 days. Then payment will have to be collected from 10 Hospitals. **We have not got any response from you on this very important point raised.**	
10	Point # - X: The addendum was mailed to us on the evening hours of 13th June and the same was posted in your website on 14th June. Considering the next two days as weekend, practically, the document was available with us for our perusal on Monday, 17th June. With the complexities and ambiguities involved, the last date of bid acceptance of 27th June is too short for us to bid. **We kindly request you to postpone the Bid submission day to a further date so as to enable us and other participants to have an informed and well prepared bidding.**	*Comments:* i. *The Addendum was available during normal business working day / hours on 14 June which is Friday.* ii. *There is no change in the terms of RFP post issue of Addendum; however, the Bid Submission date is being advanced to 02 July 2013.*