STATE BLOOD TRANSFUSION COUNCIL, ODISHA

Health & Family Welfare Department, Govt. of Odisha

1st Floor, Oil Orissa Building, Nayapalli, Bhubaneswar-12

Letter No 402 **/Bhubaneswar** **Dated** 19 **/05/2021**

Revised Corrigendum / Amendment / Clarification to the Pre-Bid Queries raised by prospective bidders in response to RFP No-318/SBTC dated 08-04-2021

In response to advertisement no- **318/ SBTC** dated-08-04-2021 published in the Newspapers i.e. "The Samaja, The Sambad, The Times of India and Hindustan Times" as well as website **www.odisha.gov.in** on 9th April 2021towards establishment of NAT testing facility at the identified centers of State of Odisha. Pre-Bid meeting for this tender was held on 11-05-2021 at 11.30 am under the Chairmanship of Special Secretary (MS) to Govt, Health & Family Welfare Department Govt. of Odisha on virtual platform. The queries received from Three (3) nos. of prospective bidders i.e., M/s Roche Diagnostics India Pvt. Ltd., M/s Mylab Discovery solutions and M/s Hemogenomics Pvt. Ltd. respectively through office email on the above mentioned RFP.

In response to the corrigendum / amendment / Clarification to the Pre-Bid Queries raised by prospective bidders vide letter No-386 dated. 15.05.2021, the following revised Corrigendum / Amendment / Clarification in response to queries raised by prospective bidders are enclosed at **Annexure-A**.

Hereby, this to notify that this Directorate has decided to extend the **last date of receipt of the bid till 28th May 2021 at 12 noon** and the receive **bids will be opened at 3.30 pm on the same day** due to upsurge of 2nd wave of COVID-19 cases in the State.

19/5/2021

Director Blood Safety cum
Ex-Officio Director SBTC

19/5/21

Special Secretary (MS) to Govt
Health & Family Welfare Department

Annexure-A				
Sl. No	**Item Name/Particulars**	**Details as mentioned in the tender document**	**Queries raised by the prospective bidders**	**Clarification / Amendments in response to the queries**
1	RFP Page # 5 : Roles & responsibility of Govt of Odisha, bullet point 3	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.	Clarification for the term 'Per Valid Test'. If the service provider pools 10 samples together and performs only 1 test, it should be considered as one valid test and not 10 valid tests. The Govt of Odisha will pay to the service provider according to the actual tests performed.	No change
2	RFP Page # 7: Roles & responsibilities of Service Provider, bullet point - 1	The service provider should provide totally free of cost automated NAT equipment's with one stand by at one centre of same model same type equipment.	The service provider should provide totally free of cost automated and brand-new NAT equipment's with one stand by at one centre of same model same type equipment which is of the latest model.	No change
3	RFP Page # 7: Roles & responsibilities of Service Provider	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	Service provider / company must quote their globally latest model; and further the 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.	No change
4	RFP Page # 7: Eligibility Pre-requisite qualification, point # 5	Vendors must specify the pack size & MRP of the regents supplied	Presently there is no provision given in any of the bid formats to include the MRP and pack size. The price bid format must be amended to include the MRP and pack size of the reagents supplied. A suggested price bid format is included at the end of this document as Annex I.	No change
5	RFP Page # 9	The EMD of the successor will be returned after	Please remove 'PCR' from the above sentence, since	NAT-PCR is modified to NAT Screening in the same

		commissioning and successfully running of the NAT- PCR screening at the identified centres	your tender specifications are accepting both PCR and TMA	clause.
6	RFP Page # 10, Key terms & conditions for the installation of maintenance free equipment, bullet point # 6	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.	Frequent revision in the model of the offered equipment is discouraged. Therefore, the service provider must quote their globally latest model to reduce the need for frequent revision of the model. 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.	No change
7	RFP Page 10	Cost per valid test of blood unit payable will be the final factor for arriving at L1 firm's offer	Clarification needed: Please confirm that Cost per valid test is arrived based on actual test performed by the service provider, so as to avoid any chance of manipulation and over charging by service provider.	No change
8	RFP Page # 11 – 1st line	In case, equipment performing more tests including viral discrimination at the same cost will be preferred.	the said sentence may be removed as it is indirectly favouring Pooling.	No change
9	RFP Page # 13, under Technical Specifications, point # 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.	Discriminatory test should be available on the same platform 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.	No change
10	RFP Page # 13, under Technical Specifications, point # 20	The kit should consist of ready to use reagents. Cassette format and stable either inconvenience. The vendor should provide positive and negative controls, chemicals for the completion of the whole NAT procedure	The sentence "Cassette format and stable either inconvenience." is not clear. As such specifying cassette format is favouring one particular company. It doesn't matter whether reagents come in cassette format, cartridge format, bottle format etc; as long as the performance parameters according to screening the	Amended as "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".

			samples are satisfied. We therefore request you to remove that particular sentence. The vendor should provide positive and negative controls, chemicals forthe completion of the whole NAT procedure." Here you have not mentioned the word Calibrators. Different companies use the words either Control or Calibrator used for the same purpose. Therefore, we request you to amend the said sentence as below: The vendor should provide positive and negative controls/calibrators, chemicals for the completion of the whole NAT procedure.	
11	RFP Page # 13, under Technical Specifications, point # 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 : <8 IU/ml. Service provider is required to provide proven data on Analytical Sensitivity, Specificity, Reproducibility/Repeatability and other relevant parameter of assay performance.	We are not clear about the basis of arriving at this Analytical Sensitivity threshold. Usually, the Analytical Sensitivity threshold for HIV 1 and HIV-2 are kept as the same. Therefore, we request you to amend the said clause as below: Analytical sensitivity of the complete assay performed on system (with a 95% detection probability) will be at least: a) HIV-1 : < 30 IU/ml. b) HIV-2 : <30 IU/ml c) HCV : <7 IU/ml. d) HBV : <5 IU/ml. Service provider is required to provide proven data on Analytical Sensitivity, Specificity, Reproducibility/Repeatability and other relevant parameter of assay performance in the method quoted by them (Pool / ID). There should not be any compromise in the	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.

			Analytical sensitivity as a result of pooling method offered to Govt of Odisha.	
12	RFP Page No : 14, Technical Specification , No.29	System should be compatible with anticoagulants routinely used on the Blood Centre such as EDTA, SAGM and CPDA.	We request you to add one more routinely used anticoagulant to this list i.e, Heparin. We request to modify the said clause as: System should be compatible with anticoagulants routinely used on the Blood Centre such as EDTA, SAGM, CPDA and Heparin. There should not be any interference with these anti-coagulants in the testing process or results.	No change
13	RFP Page No : 14, Technical Specification , No.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 donation in 12 hrs. (Detection and Discrimination)	The same to be modified as below: As Blood Centre have limited space, the NAT system must support single room operation and must have throughput of minimum 250 tests in 8hrs and 500 tests in 12 hrs.	No Change.
14	RFP Page No : 02	Earnest Money Deposit (Refundable) - Rs. 20,00,000/-(Twenty lakhs only)	Clarification needed: Whether it is in form of DD or BG. If in form of BG then format of BG/bank.	DD in favour of President SBTC must be submitted
15			It is not clear whether the bid is Two Bid system where Technical bid and Price bid documents are to be separately enclosed in two envelopes and both together put in one larger single envelope. Kindly clarify the same	It is a Two Bid system where Technical bid and Price bid documents are to be separately enclosed in two envelopes and both together put in one larger single envelope
16	RFP Page No 21, point No 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.	Clarification needed: Whether the second copy to be sent to the President, GB, SBTC & Addl. Chief Secretary to Govt. of Odisha H & FW Deptt, be in a separate envelope and not along with the price bid document? If separately, where should that envelope be sent? when will that envelope be opened?	No Change.

17	Point no. 3	The system shall be able to detect the viral targets either in single samples or in pool samples	It is a well known fact that any virus or pathogen has a better chance of being detected if tested in 1 ml of plasma/blood instead of mixing 6-8 samples comprising of 140-150 microlitres per sample. There are many national and international publications and studies that have concluded that Individual Donor NAT is ideal methodology for NAT screening of blood donors as dilution due to pooling may miss samples with low viral load.	No change
18	Point no. 5 &Point no. 23	Point no. 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 Point no. 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.	As per the order issued by the Ministry of Health via memorandum X.11035/379/2015/DFQC dt 20thFeb 2018 has issued guidelines regarding has asked institutes to relax norms for prior experience and turnover when requirement/non requirement of USFDA/CE Certification. Where ever Indian Standards are available (CDSCO/NIB evaluation in the case of NAT), these would be sufficient and the organization shall not insist on US FDA or CE Certifications etc. I am attaching the same circular as Annexure 1- Guideline Regarding Non-Requirement of US FDA & CE Certification in Procurement of Medical Devices. Furthermore, as per the order issued by In fact, the Ministry of Finance, Public Procurement Division via memorandum F. no 12/17/2019-PPD dt 20th May 2020. Where ever Indian Technical specifications/Standards are available (CDSCO/NIB evaluation in the case of	Submission is not acceptable because the norms are not mentioned in the original RFP.

			NAT), these would be sufficient and the organization shall not insist on foreign Technical Certifications and Accreditations. I am attaching the same circular as Annexure 2-Memorandum for not asking foreign QC certification May 2020.	
19	Point No 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 donation in 12 hrs. (Detection and Discrimination).	Out of the 7 sites mentioned in the list, the site at SCB MCH, Cuttack is expected to carry the maximum load of 76,000 samples a year. This means an average of 208 samples a day. We believe that the expectation of screening and discrimination 500 donations in 12 hours is arbitrary and not required as this means very big and expensive systems, not developed and designed with the Indian blood centres and blood donation scenario in mind, get selected leading to un-necessary increase in the price. A system that is able to handle 400-600 blood donor samples in a day is enough by all means. The country is going through a difficult time and it is very important to save the valuable resources of the country by not paying a higher price for an instrument manufactured outside India when we can achieve the same goals by relying on an instrument made with Indian conditions in mind.	No change.
20	Point no. 31	Quoted NAT machine must have proven installation base in India & must have installations in at least five licensed Government blood banks in Health Institute in INDIA with satisfactory report of last three years. The Bidders have to provide details of its supply	For a new manufacturer, this clause has to be relaxed. Mylab Discvoery Solutioons is a registered MSME. We have the necessary clearance and evaluation reports from CDSCO and NIB. We have published data in international journals and we have many licensed blood	Relaxation is not possible because it is a life saving procedure. So, minimum eligibility criteria can't be compromised for the greater interest of the public.

		to the Government Blood Banks with contact details	bank users in the private sector. However, being a new entrant, we do not have installations in five licensed Government blood banks. We request you to relax/change this clause to allow new Indian manufacturers to participate in the tender. In fact, the Ministry of Finance via memorandum No.F/20/2/2014-PPD(pt) dated 25th July 2016 has asked institutes to relax norms for prior experience and turnover when dealing with startups /medium enterprises. Attaching the same memorandum as Annexure 3 Relax Norms Startup Med Enterprise At a time when the government of India is emphasizing on 'Make in India' and 'Aatmanirbhar Bharat' initiatives, it is imperative that the state of Odisha and State Blood Transfusion Council supports the government in this noble initiative and procure an Indian manufactured and licensed Individual Donor Nucleic Acid Testing system thus helping the country can save vital resources and help in nation building without compromising the quality of healthcare	
21	Page 7 point no 5 under the heading "Eligibility Pre Requisite Qualification "	Vendors must specify the pack size & MRP of the regents supplied	Since Nucleic Acid Test (NAT) requires different set of reagents, controls, plastic wares and other consumables, which come with different pack sizes and consumption as per valid donations tested including any repeat, viral identification and discrimination testing. Hence, we humbly request for removal of this point (point no. 5 and Page 7)	The clause Page 7 point no 5 under the heading "Eligibility Pre-Requisite Qualification" is removed.

22	Point 13 under the heading "Technical Specifications for Nucleic Acid Amplification Testing	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	Considering that NAT testing is extremely important and the role of reagent is paramount, any additional step required for reagents preparation may impact the assay performance and / or integrity of the result. While, the same topic has been already adequately covered in point 20 of the technical specifications bid which stipulates that the system/ assay should have ready to use reagents. However, Point 13 allows for additional reagent preparation prior to testing which may attract manual intervention and related challenges. Hence, we would request for removal of point no. 13 from the requirements.	No change
23	Point 21 under the heading "Technical Specifications for Nucleic Acid Amplification Testing	Assay Performance - they should be able to detect accurately the following viral markers of a) HIV(A11 HIV variants including subtypes) b) HCV genotype 1,2,3,4,5 and 6 c) HBV genotype A,B,C,D,F and G	Based on Scientific evidence and empirical data it is evident that the HBV has very wide genotypes and is most prevalent virus among all and Nucleic Acid Test has contributed significantly with detection in the form of NAT yield along with other virus. Therefore, for wider coverage and detection, assay should be able to detect HBV Pre-core Mutant for maximum genotype coverage and maximizing the Blood safety. Hence, we would request and submit for the inclusion of Pre core Mutant detection in HBV along with already mentioned genotypes in the specification.	Amended as "the assay should accurately detect maximum and all prevalent genotypes".
24	Point 22 under the heading "Technical Specifications for Nucleic Acid	Analytical sensitivity of the complete assay performed on system (with a 95% detection probability) will be at least: a) HIV-1 : < 55 IU/ml.	We would like to submit for the confirmation or modification of Analytical sensitivity mention in point (d) for HIV or HIV 2 , Since HIV 1 is already covered in point no (a), Hence for	Amended as : Analytical sensitivity of the complete assay performed on system (with a 95% detection probability) will be at least: a) HIV-1 : < 55 IU/ml.

	Amplification Testing	b) HCV : <7 IU/ml. c) HBV : <5 IU/ml. d) HIV : <8 IU/ml.	clarity we would request for kind consideration and modification of point (d) as HIV-2	b) HCV : <7 IU/ml. c) HBV : <5 IU/ml. d) HIV-2 : <8 IU/ml.
25	Point 30 under the heading "Technical Specifications for Nucleic Acid Amplification Testing"	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 donation in 12 hrs. (Detection and Discrimination).	As each Blood Centre have limited space, keeping in mind the same the workflow should allow for minimizing the space required used in instrumentation. While the throughput requirement of minimum 250 donations in 8hrs and 500 donations in 12 hrs (Detection and Discrimination) can be met by putting together multiple instruments in a single room that will lead to space wastage. We request to limit the throughput requirements to a single instrument	No change.
26	Point mention on page 3 under the heading "Points of Request For Proposal (RFP)"	The RFP submitted by the Organization should have a minimum annual turnover of Rs 40 crores in each year for last three consecutive years proof documents should be enclosed	As this is a prestigious large scale project for the state of Odisha, financial performance and stability of the winning bidder is paramount. In this respect, we would like to submit and request for the consideration for the minimum annual turnover to be more than or at least equal to the total 5 year budget of the project. That will attract serious and financially stable bidders participation during bidding /RFP submission.	No change
27	Point mention on page 10 under the heading "Key terms & conditions for the installation of maintenance free Equipment"	Quoted NAT machine must have proven installation base in India & must have installations in at least three 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."	Whereas, Point 31 under the heading "Technical Specifications for Nucleic Acid Amplification Testing" "Quoted NAT machine must have proven installation base in India & must have installations in at least five licensed Government Blood Centers 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	Amended as "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."

			details also need to submit user list for the quoted model in India." We would like to request you to clarify, whether we need to submit the installation proof or satisfaction report from 3 licensed government blood banks or 5 licensed government blood banks as both places refer to different numbers.	
28	Point mention on page 5 under the heading "Role and Responsibilit y of Govt of Odisha"	Will be responsible to provide only required amount of space as per requirement of the serv ice provider at the identified centres."	As per current practice of various PPP project of the state governments as well as government institutions, the electricity, generator backup, and space are the minimum facilities provided from the government side. In the ongoing Odisha Govt. NAT project as well, electricity, generator backup, and space are provided from the government side. Hence, we would like to request you to clarify whether Govt, will provide the minimum facilities like electricity and generator backup along with the space in all the identified blood centers	No change

General Clarification: Mentioned letter no-386 dated.15.05.2021 has modified and clarified as below and this should be considered as the final corrigendum amended.

- To avoid any confusion, if a bidder performs 1000 valid donation screening and agreed rate is X plus taxes, then Govt. will pay 1000 x X plus Taxes only. No payment will be made for any repeat tests, Controls, Calibrations or any other purpose.
- The amendments mentioned above are to be treated as amendments in the technical specifications and terms & conditions of the above tender reference. All other terms and conditions of the above mentioned Request for Proposal (RFP) will remain unchanged.

19/5/2021

Director Blood Safety cum
Ex-Officio Director SBTC

19/5/21.

Special Secretary (MS) to Govt
Health & Family Welfare Department