MINUTES OF PRE-BID MEETING

Brief Description of Procurement: Hiring of Agency for Providing HIV-1 Viral Load Testing Services

IFB No.: SAMS/NACP/VLTS/SERVICES/10/2016

Date and Time of Pre-Bid Meeting: 21st September, 2016 at 15:00 Hrs.

Venue of Pre-Bid Meeting: Strategic Alliance Management Services Pvt. Ltd. (SAMS), B01-B03, Vardhaman Diamond Plaza, Motia Khan, D B Gupta Road, Paharganj, New Delhi- 110055

The following Bidders' Representatives attended the pre-bid meeting:

Sr.No.	Name & Designation	Name of Prospective Bidder/Firm
1	- Ms. Bhoomika Rawat, Manager – Marketing - Mr. Mahesh Semwal, AGM-Sales	DSS Imagetech Pvt. Limited, New Delhi
2	- Mr. Chirag Khatri, Vice President - Operations	Quest Care Pvt. Ltd., Kutch, Gujarat
3	- Mr. Vijay Soni, Dy. General Manager (Business Development)	Metropolis Healthcare Ltd., Mumbai
4	- Mr. Raj Sehgal, AVP – International Sales	Dr. Lal Pathlab Ltd., Gurgaon
5	- Mr. Ravinder Singh, Commercial Lead - Ms. Rashmi Khadapkar - Mr. Gaurav Jain, Marketing Manager	SRL Ltd.
6	- Mr. Sachin Bhole, Director	Infexn Laboratories Private Ltd., Thane (W), Maharashtra
7	- Dr. Ravi Gaur, Chief Operating Officer	Oncquest Laboratories Ltd., New Delhi
8	- Mr. Rajiv Sharma - Mr. Gurpreet Singh	Abbott Healthcare Pvt. Ltd.
9	- Mr. B.A Patil	Rusan Pharma Ltd., Mumbai
10	- Mr. Avanish Mani Tripathi, Dy. Regional Manager - Mr. JayaBharath Reddy, Head Molecular Diagnostics	Roche Diagnostics India Pvt. Ltd., New Delhi
11	- Mr. Umesh Trivedi, Sales Manager - Mr. Sudit. Dwivdi, Branch Manager	Inkalp Instruments Pvt. Ltd.

The following NACO's representatives were present in the pre-bid meeting as observer:

Sr.No.	Name and Designation
1.	None

The following SAMS's officials were present in the pre-bid meeting:

Sr. No.	Name and Designation
1.	Mr. Sanjay Rastogi, Director,

Sr. No.	Name and Designation
2.	Ms. Ritu Khusu, Associate Director
2.	Mr. Anil K. Bhutani, Team Leader (Procurement)
3.	Mr. Satya P. Verma, General Manager (Procurement)
4.	Ms. Arpit Saxena, Senior Manager (Procurement)
5	Mr. Vivek Kumar, Dy. Manager (Procurement)
6	Mr. Dinesh Kumar, Procurement Officer

Proceeding of the pre-bid meeting is as follows;

1. At the outset, General Manager (Procurement), made a briefing about the scope of services and purpose of the pre-bid meeting.
2. Thereafter, prospective bidders were requested to put up their queries related to scope and terms and conditions given in the Bidding Document.
3. The queries from prospective bidders were appropriately responded. The representatives were also requested to send their queries in writing through e-mail within 3 days.
4. The responses to queries sought from prospective bidders in writing and those asked during the meeting have been compiled as per **Annexure-A**. It also includes Amendment No. 2, containing amendments in certain provisions given in the Bid Document and also the amendment in due date for receipt / opening of bids and also the due date of validity of bids.

(Satya P. Verma)
General Manager (Procurement)

Appendix-A

Responses / Amendments (Amendment No.2) with regard to queries/suggestions received for Bid Documents for Hiring of Agency for Providing HIV-1 Viral Load Testing Services

(RFP Ref.: SAMS/NACP/VLTS/SERVICES/10/2016)

As per provisions given in ITB para 7 & 8 of the Bid Documents and the queries/clarifications sought by the prospective bidders, the following responses/amendments are being issued as per table below. In addition, as per ITB Para 7.3, **the due date for receipt and opening of bids, as well as due date of validity of Bid is being amended** as per Sr. No. 57 of the table below.

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
1	Chapter-I: Instructions to Bidders (ITB): Para 4.1 (page no. 7)	This invitation for bids is open to all Organizations (Proprietorship Firms, Partnership Firms, Limited Liability Partnership Firms, Companies registered under Companies Act, 1956 or Societies Act, Trusts, Societies registered under respective Act and Jurisdiction in India) who fulfil the eligibility and qualification criteria as specified below. The bidder may form Consortium with other firms to enhance their qualifications. In such a case, the lead firm / bidder along with all the Consortium members shall be jointly and severely liable for satisfactory performance of services, in case contract is awarded	• Kindly explain the meaning of Consortium in legal terms and the documentation required to be submitted as proof? • What documents are required to be submitted by the consortium as a proof of formation of consortium? Whether an intimation on letter head regarding formation of consortium would suffice or separate incorporation proof needs to be submitted? • Who will raise invoices in case of Consortium, any partner / lead partner? • Whether consortium needs to obtain all the license or separate license possessed by either consortium partner remains valid and sufficient? • Whether the reports shall be generated by consortium or reports generated and sent by	• Consortium is a group of separate entities joining together to execute a project. Each entity within the consortium is only responsible to the group in respect to the obligations that are set out in the consortium's Agreement/MOU • The consortium can be formed by forming JV / signing an Agreement / MOU, clearly describing roles and responsibilities of each consortium partner(s) during entire contract period. JV Agreement / MOU should also indicate the name of lead partner. Such JV Agreement / MOU duly signed by each consortium partner(s) should be submitted along with technical bid. • The led partner shall raise invoices • Reports can be generated and sent to Client by such a partner who is responsible for the particular activity being reported. • The consortium terms can be changed with the approval of Client during contract period.

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
			consortium partner would suffice? • Can the consortium terms changed moving forward or they are fixed for the period of contract?	
2	Chapter-I: Instructions to Bidders (ITB): Para 4.1 (page no. 7)	This invitation for bids is open to all Organizations (Proprietorship Firms, Partnership Firms, Limited Liability Partnership Firms, Companies registered under Companies Act, 1956 or Societies Act, Trusts, Societies registered under respective Act and Jurisdiction in India) who fulfil the eligibility and qualification criteria as specified below. The bidder may form Consortium with other firms to enhance their qualifications. In such a case, the lead firm / bidder along with all the Consortium members shall be jointly and severely liable for satisfactory performance of services, in case contract is awarded	What is structure expected for consortium? Is it a loosely held entity or a formal JV Company or just a MOU between two companies to deliver the project?	We don't suggest any specific consortium structure. Please refer clarification provided in sr. no. 1 above
3	Chapter-I: Instructions to Bidders (ITB): Para 4.1(b) (page no.7-8)	The bidder or consortium partner(s) (as the case may be) should have testing laboratory of its own or have a tie-up with a testing laboratory accredited by 'National Accreditation Board for Testing and Calibration Laboratories' (NABL) for performing HIV-1 Viral Load Testing	Whether NACO allow inclusion of laboratories which are currently undergoing NABL Accreditation process for HIV Viral Load testing and could comply within 4-6 months?	Not allowed.
4	Chapter-I: Instructions to Bidders (ITB): Para 4.1(e) (page no.8)	The bidder and consortium partner (if any) should not be debarred / blacklisted by MOH&FW, GOI, or any other Central Govt. Department or State Government as on the date of opening of bid for any default related to HIV/AIDS field. The bidder and consortium partners (if any) should also not be debarred by the Global Fund	Why limited only for HIV/AIDS field?	The debarment / blacklisting which has been imposed on bidders / consortium partner(s) related to their default in HIV/AIDS field are covered under the clause.

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
5	Chapter-I: Instructions to Bidders (ITB): Para 4.1(c) and (g) (page no. 7) and Chapter-II: Scope of Services Para 3.5 (page no.8)	The testing laboratory should be enrolled in an External Quality assurance (EQA) programme for the test bidded for, provided by a laboratory that is certified as EQA provider as per ISO 17043 standard for the same test and should have achieved successful performance in last two cycles. The proposed testing facility/ies should be NABL accredited for performing HIV-1 Viral Load Assay using the proposed kit as per ISO 15189:2012. The accreditation should be renewed throughout the course of contract. The testing laboratory should comply with the requirement of Article4.1.1.3 of ISO 15189:2012, ISO 15190 regarding safe practices in medical labs and ISO 22367 regarding reduction of error in medical labs. In case, the testing laboratory is currently not complying with any one or all the above requirements, it should have clear plan to attain such compliances within 6 months of award of contract	• If a lab is using one brand of test and is enrolled in EQAS but bids with another brand is this a disqualification? • Although in 4.(g) it states ISO 15189:2012 is mandatory it provides for 6 months for implementation as per 3.5 on Pg 29. How should this point be read in conjunction with point 4.C on Pg 8 & 4.G on Pg 8 as above.	• The case referred shall be cause of disqualification if 2 EQA cycles have not been run with the brand mentioned in the bid • It is to clarify that the 6 month period allowed for attaining compliances (as given in Para 3.5 of Chapter-III) is permitted for ISO 15190 (regarding safe practices in medical lab) and ISO 22367 (regarding reduction of error in medical lab) only.
			We follow safety guidelines from CAP safety requirements, CLSI, IFC-Environmental Health & Safety guidelines, and best practices of globe from OHSAS 18001 Occupational Health and Safety Management System, ISO 14001Environmental Management Systems etc. We follow ISO15189:2012 and NABL112 guidelines for improving quality wrt reduction of error in the lab by way of Quality Indicators. Please confirm about the specific requirements of ISO 15190 and ISO 22367	ISO 15190 is regarding safe practices in medical lab and ISO 22367 is regarding reduction of error in medical lab. Please check standards equivalent to the above to ascertain equivalence to the standards being followed by you.
6	Chapter-I: Instructions to Bidders (ITB): Para 4.1(g)	The proposed testing facility/ies should be NABL accredited for performing HIV-1 Viral Load Assay using the proposed kit as per ISO 15189:2012. The accreditation should be renewed throughout the course of contract.	Is the NABL Certification required for the proposed testing facility performing the HIV 1 VL testing or the 'proposed kit' or both;	NABL Certification is required for performing HIV-1 VL testing on the kit proposed by the bidder. In case, in future, different kit is used, the NABL Accreditation should be availed prior to start of use of

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
	(page no. 8)		What happens if the facility is NABL accredited doing HIV-1 VL Testing but using a different kit.	the different kit.
7	Chapter-I: Instructions to Bidders (ITB): Para 4.1(i) (page no. 8)	Sample Identification – Double identifier should be provided against which one of them should be Barcode (patient and test specific).	Who will have the onus of defining the second marker for identification? is this a unique ID which will be given and managed by NACO or the bidder ?	The unique patient identifier (ART No.) will be given by NACO against which the service provider will provide barcode.(second marker)
8	Chapter-I: Instructions to Bidders (ITB): Para 4.2(e) (page no. 8)	"Notarized Affidavit giving undertaking to the effect that (a) the bidder and consortium partners (if any), is not debarred / blacklisted……."	What is the value of stamp-paper for the Notarized Affidavit to state "not debarred"? Please specify the value of stamp paper for affidavit.	The notarized affidavit can be given on non-judicial stamp paper of Rs.10/-
9	Chapter-I: Instructions to Bidders (ITB): Para 14.1 (page no. 11)	"Alternative Bids are not permitted. All those bidders shall be disqualified if any person (s) (i.e. partner (s) in case of a partnership firm, member (s) in case of a company or the proprietor in case of a proprietorship firm, as the case may be) holds 20% or more share (ownerships) in more than one bidding entities who have quoted for same product (s)".	• If ownership is less than 20%, is alternate bid allowed? • If ownership is more than 20% in two entities, will both bids be rejected or only one? What is selection criteria in this case? • What is the purpose of the provision made for a bidder to be a part of multiple bids in order for NACO to get a better solution?	• If any person has ownership of less than 20%, such person / may appear in two or more bids. • If ownership is more than 20%, all such bids shall be rejected where the person appears as partner/proprietor. • The purpose of this clause is discourage/avoid multiple owners (person/entities) appearing in multiple bids.
10	Chapter-I: Instructions to Bidders (ITB): Para 22.1 (page no. 13)	"The Technical Bid (Envelope-A) shall be opened at the first instance at 1300 hrs. on 14th Oct, 2016……."	There is a typographical error for technical bid opening time. It is mentioned "1300 hrs" instead of _____?	**The time and date to be treated and read as the due time and date for opening of bids as per amendment made at sr. no. 57 below.**

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
11	Chapter-I: Instructions to Bidders (ITB): Para 28.1 (page no. 17)	"The Client, through the above process of bid scrutiny and evaluation will determine to its satisfaction whether the bidder, whose bid has been determined as the lowest evaluated responsive bid, is eligible, qualified and capable in all respects to perform the contract satisfactorily."	How is the "lowest evaluated responsive bid" is determined? Is the "lowest evaluated responsive bid" same as "highest total score bidder" as defined in Section 26.3?	The bids shall be ranked in terms of total combined score carried out by giving weight to technical and financial bids in the ratio of 70:30. The proposal with the highest total score as above will be considered for award of contract
12	Chapter-I: Instructions to Bidders (ITB): Para 31.1 (page no. 18)	The contract will be awarded to the lowest evaluated responsive bidder decided by the Client	Will NACO introduce region wise agencies (NEWS) instead of single agency as per current bid requirements	No
13	Chapter-II: Conditions of Contract COC Clause 6.1 (page no. 22)	Within twenty one (21) days from date of the issue of intimation letter/ notification of award by the Client, the Service Provider, shall furnish Performance Security to the Client for an amount equal to five per cent (5%) of the contract value, valid up to one hundred and twenty (120) days after the date of completion of all contractual obligations by the Service Provider, including the warranty obligations.	• Since the values of samples are not fixed, even not defined for year 2 and 3, thus concept of contract value is ambiguous. • There should be a fixed value and not contract based figure. In any case, we request you to cap it below 1% of contract value. • Also, BG should be returned after every year and new BG to be submitted for new year.	• **The contract value for 3 years shall be based on indicative no. of tests to be performed for 3 years and per test rate quoted by successful bidder.** • **The performance security, in form of Bank Guarantee, submitted by the successful bidder shall be for an amount equal to 5% of contract value for 3 years and shall be valid for 38 months from date of commencement of services.**
14	Chapter-II: Conditions of Contract COC Clause 9 (page no. 23)	CONTRACT DURATION The contract shall be valid for the duration of 3 (three) years from the date of commencement of services. The contract may be foreclosed / extended for further period of max. 2 years based on performance of services by the Service Provider and requirement of services by the Client	Contract period should be 5 years with lock on of 3 years as it involves significant investments	The contract shall be initially signed for 3 year. There is a provision to extend the contract for further period of 2 years.
15	Chapter-II: Conditions of Contract COC	Prices to be charged by the Service Provider for provision of services in terms of the contract shall not vary from the corresponding prices quoted by the Service Provider in its bid	Will NACO consider provision for price revision – as reagents and kits are sensitive to forex rate fluctuations	No such provision is made.

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
	Clause 13 (page no. 23)		We shall request yearly revision of prices (to account for inflation/volatility in forex)	
16	Chapter-I: Instructions to Bidders Para12.1 (page no. 11) Chapter-II: Conditions of Contract COC Clause 14 (page no. 23)	ITB Para 12.1 (Bid Prices): The Bidder shall indicate on the Price Schedule provided under Chapter IV, all the specified components of prices shown therein including the unit prices and total bid prices of the goods and services as per Scope of Services given in Bid Documents. All the columns shown in the price schedule should be filled up as required. If any column does not apply to a bidder, same should be filled as "Not Applicable" by the bidder. COC Clause 14 (Taxes and Duties) Service Provider shall be entirely responsible for all taxes, duties, fees, levies etc. incurred until delivery of the services to the Client	Will NACO consider direct impact of taxes (like GST/Service Tax) on the overall cost agreed in the bid, as and when they are imposed by the Government Lab will take existing tax structure into consideration while making a financial bid. However, there is regulatory uncertainty over GST. In case of any adverse impact of GST on diagnostics services, it needs to be absorbed by NACO. (1) In a later phase if GST or New Taxes will come in perview we have been assured that will be paid to us over and above the quoted price , please provide same in writing also. (2) Do we get duty exemption for these project when we import material.	NACO will consider revision in contract value due to changes in indirect taxes as amended by Government of India from time to time during contract period. The bidders are required to ascertain and consider duty exemption, if available to it as per prevailing act and rules and submit its bid accordingly.
17	Chapter-II: Conditions of Contract COC Clause 15.1(b) (page no. 24)	Monthly Status Report of the Quarter including the no. & date of samples collected / tests conducted / report submitted giving name of person, name of associated ART Centre, Patient ID and duly certified by the In-charges of ART Centres.	• Since name of the person may not be shared by NACO, request you to please remove this requirement. • Since it will be humanly impossible to get each report duly certified by In-charges of all 528 ART centres, request you to please remove this requirement Once the reports are released	• The name of person shall be shared • The monthly report is required to be signed by In-charge of ART Centres, not the Invoices. • Please refer clarification / amendment give in sr. no. 18 below. • **The text in the para "of the Quarter" stands deleted**

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
			and acknowledged by the Client, certification should not be required from In-charge of ART Centres. This shall be time consuming also	
			bills to be cleared centrally , as it would be difficult to reach more than 500 places to get invoice signed.	
18	Chapter-II: Conditions of Contract COC Clause 15.2 (page no. 24)	The Service Provider shall send its claim for payment, latest by 7th day of the next month preceding 3 months in the quarter	The payment cycle is too long. The invoices submission is once in a quarter and payment after 2 months is actually meaning payment cycle of 5 months which is suggested to be reduced.	**The Payment terms are hereby revised from "Quarterly" to "Monthly" basis. No advance payment shall be given.** **The para is being amended as under:** **"The Service Provider shall send its monthly claim for payment, latest by 7th day of the preceding month"**
			We request monthly Payment mode instead of quarterly and this can be clubbed on submission of monthly status report. In its present form, a credit period of 5 months will put tremendous financial burden and even good labs will not be able to afford such high overdues 30 % Advance payment for the year/s in question is requested as project involves significant capital expenditure.	
19	Chapter-II: Conditions of Contract COC Clause 15.3	The Client shall release payment within 60 days of receipt of claim as above	The Client shall release payment within 60 days of receipt of claim as above". Penalty for late payment is not defined, only for delayed /unsatisfactory service is defined. Request to kindly define late payment penalty as well.	It is assured that the payment as per time line given i.e. 60 days of receipt of claim shall be made.

<table>
<tr><th>Sr. No.</th><th>Clause reference/ Page No.</th><th>Content of Para / Clause under Reference as per Bid Document</th><th>Query/Suggestions</th><th>Response / Amendments</th></tr>
<tr><td></td><td>(page no. 24)</td><td></td><td>If payment is delayed there should by some late payment clause @1.5% PM or part thereof.</td><td></td></tr>
<tr><td></td><td></td><td></td><td>Can this be made in 30 days? As Volumes are high, a lot of money will get stuck.</td><td>No</td></tr>
<tr><td>20</td><td>Chapter-II: Conditions of Contract

COC Clause 16 (page no. 24)</td><td>If the Service Provider fails to perform the services as per performance indicators given in Scope of Services, the Client shall, without prejudice to other rights and remedies available to the Client under the contract, deduct from the contract price, as penalty</td><td>What is provision made in case sample is lost in transit i.e. after collection and before testing at our lab?</td><td>The service provider shall be permitted to take sample again in coordination with ART Centre, at its cost and responsibility.</td></tr>
<tr><td>21</td><td>Chapter-II: Conditions of Contract

COC Clause 16.2

(page no. 24)
Chapter-II: Conditions of Contract

COC Clause 16.2

(page no. 24)</td><td>The Penalty, if any shall be imposed at the time of quarterly review and based on performance assessment on criteria / indicators given in the table below:
<table>
<tr><th>Sr. No.</th><th>Performance criteria / Indicators</th><th>Acceptable value</th><th>Penalty Provisions</th></tr>
<tr><td>1</td><td>Providing soft copy of the test report to concerned ART Centre</td><td>24 hours from receipt of samples at testing facility</td><td>Deduction of 2% of the testing charges for every hour of delay beyond 24 hours subject to maximum of 100% of testing charges.</td></tr>
<tr><td>2</td><td>Non-availability of sample</td><td>1% cases in a</td><td>Deduction of amount equivalent to 1%</td></tr>
</table></td><td>Penalty clauses are too steep:

16.2.1: 24 hours is too less a time for an 8 hour run. We request you to increase it to 48 working hours, working hours to be defined. It should be read in reference to other points (Frequency of Collection, Sample Collection time, sample receipt time). Cut-off time for arrival, dispatch and testing time should be defined very clearly. Cut-off time should be used instead of absolute times since it is impossible to follow absolute times. E.g. Cut-off time for sample receipt should be 9:00 a.m. else to be considered as arrived on the next date.
16.2.2: 1% cases in a year is too less. We request you to</td><td>Please refer to para 4.C.(c) of Chapter-III: Scope of Services. The required timelines for reporting test report shall start from the time sample reached the laboratory.

There is no change in reporting requirement.</td></tr>
</table>

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
		collection facility to patient upon his / her visit to ART Centre. | year (measured each quarterly performance review) | of the performance security submitted by the Agency for every 1% case of default beyond 1% in a year. 3 | Percentage of test results found to be inaccurate in the proficiency testing done by NACO or an organization on its behalf | Nil | Deduction of double the amount of value of tests found inaccurate.	increase it to 4% 16.2 (1): Suggestive …..delay beyond of 48 hours instead of 24 hours 16.2 (2): Suggestive…… Number of cases from 1% should be increased to 5% 16.2 (1): Ideally it should note be there as this is a life threatening tests. Also current practice is to give results in about 5-7 days and its working well.	
			Penalty Provision and Termination Clause - Since one of the clause is related to Proficiency testing, the process, protocol and acceptance criteria for conducting and evaluating PT results should be well defined and should take care of technical aspects where the PT failure could be due to reasons beyond the analytical reasons, e.g. problem with the PT material, pre-analytical errors, sample integrity etc. Also since this comparison will be between just two labs (NACO designated nodal ART/PT testing lab), appropriate evaluation criteria in sync with global protocols will be very critical. At SRL, all internal and external Proficiency testing is co-ordinated by QA department, in this case also designated nodal center will need to work closely with QA for co-ordinating PT testing.	Upon receipt of proficiency testing results from a third-party testing labs, the reports shall be evaluated by NACO to assess quality and adherence to required testing procedure and protocols as per NABL Standards. The concerned testing lab shall also be asked to submit testing process and protocols followed by them. **In case of PT failure, the service provider shall be given option to umpire testing from another laboratory. An oversight committee will decide upon the quantum of penalty** **Parameters for successful Proficiency Testing are as under:** **1. Concordance would be defined with log 0.5 difference form the NACO's lab testing results.** **2. Concordance, within the said limits, of 90% of the samples would be deemed acceptable.** **3. In case the concordance in testing of blind samples is less than 90% in any given quarter, the agency / lab would be liable to provide justification and calibrate their testing platform with the designated**

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			16.2 point 3. Failed PT can not be penalized as there would be reasons beyond our control. E.g. Statistical error, random error, testing material issue etc.	**NACO EQAS lab.** **In case of poor performance in PT, within the said limit for concordance, for 2 quarters in the duration of contract, a penalty of 20% of performance security shall be levied and amount of penalty shall be deducted from Performance Security. Poor performance in every quarter would attract a penalty of 20% of the performance security.**
22	Chapter-III: Scope of Services Para 4. I (i) (page no. 34)	The committee shall review performance on Quarterly basis or any other frequency as deemed appropriate. After review, the Committee shall prepare Minutes of Review containing guidance / suggestions for improvement of services, if required	Criteria for inaccuracy or unacceptable results should be defined and known. It should be in sync with the criteria followed globally.	The criteria followed for inaccuracy or unacceptable results shall be as par NABL standards for HIV-1 Viral Load Testing
23	Chapter-II: Conditions of Contract COC Clause 19 (page no. 25)	19. TERMINATION FOR CONVENIENCE 19.1 The Client, by written notice sent to the Service Provider, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Client's convenience, the extent to which performance of the Service Provider under the Contract is terminated, and the date upon which such termination becomes effective. 19.2 The test reports of the sample which are already taken up the date of Service Provider's receipt of notice of termination shall be accepted by the Client at the Contract terms and prices.	Please elaborate the mechanism used to trigger "termination of the contract" at any time for its convenience. Is it subject to Arbitration? There should be a lock-in period or pre-closure penalty. request you to please link 19.1 (Termination for convenience) with 16.1 (sub-par performance) Unless there is any fault from service provider's side which is captured in clause 16.3 there should be either some fixed lock in time or compensation to be given for such foreclosures; No notice period or no right of service provider is unfair as substantial investment would be	The termination for convenience clause is invoked in exceptional circumstances, where Client decides to do away with the requirement of Viral Load Testing. In such a case, no penalty is imposed. The Clause 19 is not linked with Clause 16.3, instead linked with Clause 17 (Termination for Default)

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			made in freezers, gensets, data loggers etc.	
24	Chapter-II: Conditions of Contract COC Clause 20 (page no. 25)	20. FORCE MAJEURE 20.1 Notwithstanding the provisions contained in COC clauses 16, 17 and 19 the Service Provider shall not be liable for imposition of any such sanction so long the delay and/or failure of the Service Provider in fulfilling its obligations under the contract is the result of an event of Force Majeure. 20.2 For purposes of this clause, Force Majeure means an event beyond the control of the Service Provider and not involving the Service Provider's fault or negligence and which is not foreseeable and not brought about at the instance of , the party claiming to be affected by such event and which has caused the non – performance or delay in performance. Such events may include, but are not restricted to, acts of the Client either in its sovereign or contractual capacity, wars or revolutions, hostility, acts of public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes excluding by its employees , lockouts excluding by its management, and freight embargoes. 20.3 If a Force Majeure situation arises, the Service Provider shall promptly notify the Client in writing of such conditions and the cause thereof within twenty one days of occurrence of such event. Unless otherwise directed by the Client in writing, the Service Provider shall continue to perform its obligations under the contract as far as reasonably practical, and	In case of force majeure situations there should not be any penal consequences. Force Majeure should also include non-availability of reagents and kits from the manufacturer.	In case of force majeure, there are no panel consequences. The force majeure situation shall cover availability of reagents and kits from manufacturers, only in circumstances where the manufacturing / supply of reagents and kits is covered under the events given in Para 20.2.

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		shall seek all reasonable alternative means for performance not prevented by the Force Majeure event. 20.4 If the performance in whole or in part or any obligation under this contract is prevented or delayed by any reason of Force Majeure for a period exceeding sixty days, either party may at its option terminate the contract without any financial repercussion on either side. 20.5 In case due to a Force Majeure event the Client is unable to fulfil its contractual commitment and responsibility, the Client will notify the Service Provider accordingly and subsequent actions taken on similar lines described in above sub-paragraphs		
25	Chapter – III: Scope of Services Para 1.3 (page no. 28)	At present, NACO is implementing targeted HIV Viral Load testing in the program through 10 Viral Load testing Centers in government run facilities across the country and around 10,000 tests are done annually	Will NACO continue testing at these 10 Viral Load Testing Sites? If yes, who will take care of logistics (sample collection, sample dispatch, sample receipt, test run, report dispatch) for these sites.	NACO will continue testing at the 10 existing Viral Load Testing Sites. In-charge of such labs shall be responsible for all logistics.
			What would happen to the existing 10 centres. Shall the provider be given access to these centres / machines	Service Provider shall not be given access to these Centres.
			What was the testing platform used by NACO so far? What are the existing testing locations?	The Testing Platform used by NACO are Roche and Abbott The existing locations are at Mumbai, Delhi, Chennai, Chandigarh, Pune,Varanasi, Imphal, Hyderabad,Kolkata and Bangalore
26	Chapter – III: Scope of Services	NACO has plans to scale up the Viral Load Testing for routine monitoring of all patients on the first line ART, currently the number is about 9,50,000. It has been planned to do approximately 2,10,000 tests in the 1st year with appropriate increase in subsequent years	Increase in numbers for subsequent years (at least for three years) required to plan capacity build-up and provide budget estimation for project.	**The indicative number of additional tests in 2nd year shall be 2,15,000 tests and in 3rd Year shall be 2,55,000 tests.**

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
	Para 1.5 (page no. 28) Chapter – III: Scope of Services Para 3.7 (page no. 29)	The Agency in consultation with NACO will select ART Centre for collection of samples for the 1st, 2nd and 3rd years to get a count of 2,10,000 in first year with a provision of increase in subsequent year. The name of ART Centres and indicative number of specimen to be collected during first year is given in Annexure-A	Clear volume forecast for testing for making a proper quotation covering the infrastructure cost over the period of contract.	
			The project attract huge upfront investment, so we request to the minimum commitment of HIV Viral Load test for 3 year to make the project more viable and get optimum per test cost benefit.	
			Minimum Gurantee of Business Should be assured, Rather than Projection	The no. of tests for 3 years are projections.
			Please share any indicative numbers for 2nd & 3rd year for planning the infrastructure and capacity build up.	As above
			We will request commitment of minimum guarantee of samples per year so that financial projections can be arrived at.	As above
27	Chapter – III: Scope of Services Para 3.3 (page no. 29) Para 4.B.(3) (c) (page no. 32)	The testing Laboratory(s) should establish / maintain Viral Load Testing platforms, accessories and keep inventories of all reagents/ testing kits, and other consumables etc. at all times. The Agency should not use different testing platforms at the same facility to avoid testing one patient across multiple platforms	What are the restrictions on testing methodology? Is there any weightage for the level of testing platform being used?	There is no such restriction. No additional weightage is given for level of testing platform used.
28	Chapter – III: Scope of Services Para 3.4	"The test proposed to be used should be WHO Pre-qualified, US FDA/CE approved and DCGI-India Licensed under IVD."	Are all the licenses required or either one will work? Kindly clarify the above requirement, whether it is mandatory or either	The tests proposed should be compliant to the three requirements as under: 1. WHO Pre-qualified 2. USFDA or CE approved

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
	(page no. 29)		will work.	3. DCGI-India licensed under IVD
29	Chapter – III: Scope of Services Para 3.6 (page no. 29)	The technicians with scheduled program will visit the ART centers to collect samples (Blood sample/Dried Blood Spot), pack them properly and arrange to transport the samples under controlled temperature as required directly or through courier service to the test laboratory. ART Centres will not be responsible for drawing blood samples or for further processing at site or to arrange transportation.	Will sitting space for the phlebotomist or space for refrigerator & centrifuge be provided? Will there be some storage space for keeping the consumables of the service provider?	Sitting space for the phlebotomist and space for refrigerator & centrifuge shall be provided at ART Centres
	Chapter – III: Scope of Services Para 4.A.2 (page no. 30)	SPECIMEN PREPARATION: Any requirement of specimen preparation including plasma separation from Whole blood, drying and packaging will be the responsibility of the bidder.	All ART Centres are equipped with their own sample collection staff (phlebotomist) and storage facility. Why not allow us to use them, may be at small price per sample? Otherwise our project cost will increase a lot. We can provide training, if need be.	The staff of ART Centres are not permitted to be used by the Service Provider
			Plasma separation equipment to be maintained at site or can we avail the facility at ART Centre on a rental basis.	No rental shall be charged for space for installation of plasma separation equipment at ART Centres. The space shall be provided free of cost.
			We have been assured that Internet connectivity is responsibility of ART Centers. Do we get Separate area for collection and Admin work	The Service Provider shall make its own arrangement for internet connectivity at ART Centres Separate area for sample collection and associated admin work shall be provided at ART Centres.
			In order to provide phlebotomy services, sample collection, preparing and processing, we request NACO to allocate centre space of 200 sq. ft within the ART premises with electricity and water facilities. Security of centre to be ensured as lab's	As above

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
			refrigerator, centrifuge and other consumables will be stored there	
30	Chapter – III: Scope of Services Para 3.9 (page no. 29)	The Agency shall upload results of tests carried out at the end of the day, every day, with all the patient details and the results as prescribed by NACO in the IMS software being maintained by NACO for which NACO will share the password	The IMS software is supposedly still under development as per Form B (B) (g). We suggest reports will be uploaded on server of the service provider and dedicated access with password provided to NACO	The IMS software is operational at ART Centres. The Agency shall upload results of tests carried out at the end of the day, every day, with all the patient details and the results as prescribed by NACO in the IMS software
31	Chapter – III: Scope of Services Para 4.A.1(b) (page no. 30)	Consumables for Specimen Collection – All consumables required for specimen collection including DBS cards, lancets, plasma EDTA tubes, evacuated EDTA Blood collection tubs, needles and syringes (sterile within shelf-life), single use spirit swabs, sterile gauze with sticking tape & tourniquet collection, tube holder etc. should be provided by the Agency	We suggest using K2EDTA gel tubes for the collection and transport of VL test samples. The K2EDTA Get tube combines a spray-dried anticoagulant and a gel material, which separates blood cells from the Plasma after centrifugation. These tubes can be directly transported at 2-8 degree C.	Bidders are free to use superior technology for sample collection.
32	Chapter – III: Scope of Services Para 4.A.1.(d) (page no. 30)	Frequency of collection - Specimen collection is expected on all 6 days of the week excluding Sunday between the operational timings of the ART Centers. The Agency is expected to maintain sample collection frequency on 'daily' basis at ART Centers with more than 2500 eligible patients (>10 samples per day) and on 'weekly' basis at ART Centers with less than 2500 eligible patients (<10 samples per day). The Agency should submit sample collection plan for every ART Centre along with the Technical Bid.	Frequency of Collection: Does collection time also include national holidays?	No
			The frequency mentioned here & as per footnote is desired collection every day; However the same is variable as per the list of ART Centres (Weekly/Bi weekly); Please clarify the exact frequency of collection.	The Para 4A.(d) gives principle to be followed for deciding frequency of collection. Currently, the frequency of collection shall be as per Annexure-A to the Scope of Services. In future, the frequency of collection may vary considering no. of eligible patient.

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
			Sample Collection Frequency – Weekly: How is the day of a week decided for sample collection on a weekly basis – will it be different days for different Centres	The Bidder is required to propose the 'day' of 'week' for sample collection from particular ART Centre in the Sample Collection Plan
			None of the ART centres mentioned in list comply with the criteria for frequency of collection (> 2500 eligible patients or > 10 specimens/day or 3000 specimens/year). So we request weekly collection for all 528 centers. We understand that this weekly collection will require our phlebotomist to draw samples of all targeted patients for a particular ART on a designated day. Please confirm.	As clarified above
33	Chapter – III: Scope of Services Para 4.A.1.(e) (page no. 30)	Specimen type – A valid specimen for the assay should be collected by the Agency for Viral Load testing. The validation for assay for the recommended sample type should be as approved by NACO for proposed HIV-1 Viral Load test. Additionally, the Bidder should have two identifiers for each sample collected, unique for a patient. Bar coding of specimens (patient & test specific) must be made available	Will NACO allow use of in-house validated methods for testing?	No
			Definition of Valid specimen needs to be confirmed. Also clarification on whether validation data of recommended specimen type (EDTA Plasma?) needs to be forwarded to NACO for approval? If yes, what will be the process and timeline for the same?	A valid specimen implies EDTA whole blood for plasma separation/ any other as per requirement of the kit being used. Criteria for acceptance/rejection of sample should be defined and submitted to NACO at the beginning of contract. Once testing begins, the information no of samples rejected per month should be made available to NACO on quarterly basis.
34	Chapter – III: Scope of Services Para	Specimen Transportation: (a) Specimen transportation and associated documentation is the responsibility of the Agency. A copy of documentation should also be provided to ART Centre staff for record. Alternatively, an online system of specimen	During transportation if the sample is found to be deteriorated at the testing site then can the sample be recollected and tested again. In this case sample analysis will be	Service Provider is permitted to recollect sample at its cost and responsibility.

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
	4.A.3.(a) (page no. 30)	tracking must be made available. Any associated training requirement will be the responsibility of the Agency; (b) Temperature of specimen transportation– The Agency should mention/define temperature of transportation of specimen. In case of plasma specimen Bidder should demonstrate plan for transportation under cold chain. Sample should be transported within a predefined time period with appropriate temperature data loggers. Whole blood should be transported at 2-25°C and plasma should be transported at 2-8°C (with temperature logger). DBS may be transported at ambient temperature and dry conditions (with humidity indicator and desiccant). Temperature data logger will be required with whole blood and plasma transportation (to identify episodes of temperature excursions) till the sample reaches the testing laboratory. NACO should be given access to software and alarms for every transport batch. The temperature data logger should be of the temperature range -10°C to 40°C and WHO-prequalified approved. The Agency is required to provide technical specifications (and approval status as above) of temperature data logger proposed to be used during transportation of samples to the testing laboratory	done free of cost Scope of online tracking system needs to be clarified. Also whether the plan for transportation of cold chain shipments to be shared in the Technical Bid proposal?	 Bidders are required to propose system for specimen tracking as well as transportation plan as part of technical bid.
35	Chapter – III: Scope of Services Para 4.A.3.(c)	Time stipulation from sample collection time to delivery and testing site: This should be within the allowable limit as under: (i) Whole blood should be processed for plasma separation within 4-6 hours of blood-drawl when kept/transported at 2-25°C. Plasma should be transported at 2-8°C and should reach the testing laboratory within 24 hrs. of separation.	We wish to have some leniency in sample transportation time formats as they are very stringent. As mentioned in Para 4.A 3(c) where it is suggested that the Plasma can be tested within 5 days when kept at 2-8°C. We propose maximum 48	**The requirement given for reaching plasma sample to testing laboratory is being changed from '24 hrs.' to '48 hrs.'**

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
	(page no. 31)	(ii) Plasma can be tested within 5 days when kept at 2-8°C. Plasma can be tested within 6 months – 1 year after separation from whole blood when kept at -70°C.	hours as plasma transportation time to reach testing facility at 2-8°C. What if the sample is coming on Saturday evening or national holiday? How is TAT calculated in such instances?	**National / Public holidays are excluded from the timeline.**
			We request you to consider transportation time from 24 hrs to 48 hrs to 72 hrs mainly for the interior regions of seven north east states and the states like H.P./J&K etc. No courier could able to connect these north east states within 24 hrs to major cities and it requires min. 48 hrs to 72 hrs including Blue Dart / FedEx/DHL etc.)	As clarified above
			Transportation within 24 hours from remote location puts question on feasibility. Considering India's infrastructure deficit in odd / remote locations, we will need at least 48 hrs transit time as it depends on below parameters A) "Transit time" from ART Center to respective Airport B) Flight availability at that particular time (as cut off for booking shipment need to consider is 5 pm only) C) Only few flights accept Biological Samples + Dry Ice shipments in India which are Jet Air, Air India	As clarified above

<table>
<tr><th>Sr. No.</th><th>Clause reference/ Page No.</th><th>Content of Para / Clause under Reference as per Bid Document</th><th>Query/Suggestions</th><th>Response / Amendments</th></tr>
<tr><td></td><td></td><td></td><td>D) We need to check location wise air connectivity to Mumbai, for odd timings and to deal separately with Other Flight operations i..e Indigo, Go Air etc.</td><td></td></tr>
<tr><td></td><td></td><td></td><td>please provide us Relaxation in TAT to 48 Hrs from plain area and 72 Hours from Hilly terrain and interiors</td><td>As clarified above</td></tr>
<tr><td></td><td></td><td></td><td>It may be difficult in remote areas (36 hours is suggested).

What if the whole blood sample is stable at 25 degree for some kit?</td><td>In such a case, it shall be acceptable, but would not get relaxation for TAT.</td></tr>
<tr><td>36</td><td>Chapter – III: Scope of Services Para 4.A.3 (e). (page no. 31)</td><td>Standard Operating Procedure (SOP) – Well-documented specimen transportation SOP (including requirements for temporary storage) should be provided by the Agency.</td><td>Whether SOP for transportation of specimens to be submitted along with Technical Bid. If no, what is the timeline for submitting this SOP?</td><td>Yes</td></tr>
<tr><td>37</td><td>Chapter – III: Scope of Services Para 4. B.(1) (page no. 31)</td><td>B. Analytical Procedure –

(1) Assay Specification:

The assay used for testing should meet criteria specified in table below:
<table><tr><td>S.N.</td><td>Specification Criteria</td><td>Description</td><td>Requirement</td></tr><tr><td>1</td><td>Type of Assay</td><td>NAT</td><td>Real Time PCR/b-DNA / NASBA</td></tr><tr><td>2</td><td>Specimen Type</td><td>Plasma</td><td>Sample type should be as approved for</td></tr></table></td><td>Please confirm the type of ASSAY specimen to be used for the entire period of the contract, the document emphasizes on Plasma specimen but DBS is also mentioned.

Need clarification on this note “If WHO recommends DBS then the costing of sample transportation will have to be reworked”</td><td>The note under the Table stands deleted.</td></tr>
</table>

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document				Query/Suggestions	Response / Amendments
					proposed HIV-1 Viral Load test		
		3	Sensitivity & Specificity	1000 copies/ ml	Specificity:100%		
		4	Assay Principle	Target amplification of region of HIV-1 genome with maximum conservation	Target amplification of conserved region of the genome (pol/gag/LTR of HIV-1)		
		5	Sub-types Amplified	All HIV-1 sub-types including sub-type C	Group M, A-G, Group O. Group N		
		6	Linear Range	Copies/ ml	At least 40 to 10 million copies/ml		
		7	License / Certification	DCGI, India License-IVD	DCGI, India License-IVD		
				US FDA / CE for IVD	US FDA /CE for IVD		
				WHO pre-qualified	WHO pre-qualified		
		Note: If WHO recommends DBS then the costing of sample transportation will have to be reworked					

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
38	Chapter – III: Scope of Services Para 4.B (3) (page no. 32)	STAFF, FACILITY AND INFRASTRUCTURE REQUIREMENTS; (a) The test should be performed by trained and appropriately qualified technician as per the kit protocol. (b) The Agency should maintain facility and infrastructure suitable to support volume of testing required under the assignment. (c) The Agency should not use different testing platforms at the same facility to avoid testing one patient across multiple platforms. (d) The Agency should keep same type of equipment as backup in case of breakdown.	If the testing facility has more than one platform for its routine molecular virology work, hope it is acceptable. Specifically for NACO Bid specimens, single platform acceptable to NACO will be used. Also the area of processing for NACO specimens can be accordingly demarcated.	Acceptable
			Please specify if Agency can submit bid with multiple platforms at different facilities (if they have different facilities). In other words, please specify if a bidder should only give one offering (brand of test & instrument) in his bid or if he can offer multiple types of brands for the VL test.	The bidders are free to submit bid with multiple platforms at different facilities. In such cases, all the testing platforms should qualify to the requirement stated in the bid document
39	Chapter – III: Scope of Services Para 4.C (c) 1 (page no. 32)	REPORTING OF RESULTS 1. To ARTC – Soft copies of the reports duly signed by signatory (as per NABL requirements) and in the format/software suggested by Client should be made available to ART Centres as soon as the report is available but not later than 24 hours of receipt of sample at testing facility laboratory. A hard copy of report for patient record should also be made available to ARTC within 72 hours of receipt of sample at testing facility.	TAT is ill defined. While analytical and post analytical TAT (soft copy only) should be same for all locations, logistics time should be location specific	No change in the requirement.
			36 Hrs of reaching the lab is suggested	
			Please confirm whether hard copy of the sample results printout can have “Digital signature of authorized pathologist/person” instead of hard written signature.	
			Clarification on 24 hrs reporting time will be required. It will be better to have upper limit defined for total number of specimens received per day. Basis the	

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
			requirement necessary planning for compliance of the criteria can be done. Even with best of logistics facility , it will not be possible to provide hard copy within 72 hours to all the 528 ART centre in consideration	
40	Chapter – III: Scope of Services Para 4.D.2. (page no. 33)	EQA – The testing laboratory should be enrolled in an External Quality Assurance (EQA) programme, for the test bidded for, provided by a laboratory that is certified as EQA provider as per ISO 17043 standard for the same test. The login ID for each lab should be shared with NACO so that NACO has access to lab performance reports	Is there any provision for Inter Laboratory comparison with NABL accredited laboratory instead of participating in EQAS programs?	No such provision has been made.
			The login IDs to CAP Website are individual based and hence cannot be shared, however as and when required Labs performance report in these surveys can be shared with NACO	No change in the requirement.
			we have been told to follow NABL Proficiency testing program , is CAP PT program Valid.	Please refer Para 4.D.1. of Chapter-III
41	Chapter – III: Scope of Services Para 4.F. (page no. 33)	CONFIDENTIALITY AND DATA STORAGE: Data generated under VL testing should be kept confidential. Bidder should be able to present a plan to ensure data confidentiality. Data stored at the testing sites should be transferred to NACO and discarded from the lab completely	What are the guidelines for confidentiality to be followed? At sample level and reporting level. We prefer names not being given to us. Only initials or nomenclature system that can be jointly derived works	Please refer Para 4.F of Chapter-III. Bidders should submit its plan to ensure data confidentiality.
42	Chapter – III: Scope of Services Para 3.9 (page no. 29) and Para 4.H.	The Agency shall upload results of tests carried out at the end of the day, every day, with all the patient details and the results as prescribed by NACO in the IMS software being maintained by NACO for which NACO will share the password. Integration of Agency's reporting system with IMS of NACO	Why not ask for weekly quality report instead of daily report. This will unnecessarily increase paper work	There is no change in the reporting requirement.

<table>
<tr><th>Sr. No.</th><th>Clause reference/ Page No.</th><th>Content of Para / Clause under Reference as per Bid Document</th><th>Query/Suggestions</th><th>Response / Amendments</th></tr>
<tr><td></td><td>d)
(page no. 34)</td><td></td><td></td><td></td></tr>
<tr><td rowspan="2">43</td><td>Chapter – III: Scope of Services Para 4.A.3.(b) (page no. 30-31)</td><td rowspan="2">The temperature data logger should be of the temperature range -10°C to 40°C and WHO-prequalified approved</td><td>What if the data loggers are not WHO-prequalified, but CE marked?</td><td>The requirement is being changed from ‘WHO-Prequalified’ to ‘USFDA/CE approved’</td></tr>
<tr><td>Chapter – VI – Other Standard Forms – Form B Para A.3 (d) (page no. 64)</td><td>Data Loggers are available as per CFR II compliant, WHO gives only recommendations, the specs shall be matched.

In all instances where temperature of 2-8 degrees is mentioned, what is the tolerance limit of lower and upper band

It is suggested that recording should be used rather than concurrently listening mechanism.</td><td>Noted.

No tolerance is provided. The Data logger should be of the temperature range -10°C to 40°C.

Please refer amendment made in sr. no. 53 below</td></tr>
<tr><td>44</td><td>Chapter – III: Scope of Services

Para 4.B(1) 5.

(page no. 31 & 65)</td><td>Assay Specification:<table><tr><td>S. N.</td><td>Specification Criteria</td><td>Description</td><td>Requirement</td></tr><tr><td>5</td><td>Sub-types Amplified</td><td>All HIV-1 sub-types including sub-type C</td><td>Group M, A-G, Group O, Group N</td></tr></table></td><td>All the WHO pre-qualified assay doesn’t cover the Group N except one. To the best of our knowledge the only reported Group N is from Cameroon and very few migration cases in Tongo and France. It is not seen in Asia as well in India.

Please remove Group N.</td><td>The Group N is hereby removed</td></tr>
</table>

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
			As per this criteria the assay should detect all HIV-1 subtypes Group M, A-G, Group O, Group N. It is evident from published literature that presently group M of HIV-1 globally causes 99.6% of all human infections. The other three groups N, O and P are quite uncommon and only occur in Cameroon, Gabon and Equatorial Guinea. Considering this status, we feel it will not be relevant to consider criteria for Group N relevant for the current scope of the tender and hence should be deleted. Removing the n sub-type amplification as it is not prevalent in India.	
45	Chapter-III: Para 4.D.3 (page no. 33)	Certification/accreditation – The proposed testing facility/ies should be NABL accredited for performing HIV-1 Viral Load Assay using the proposed kit as per ISO 15189:2012	NABL accreditation should be compulsory both for test as well as lab on the date of submission of bids. This only can ensure quality results.	Noted. Please refer ITB Para 4.1
46	Chapter-III: Para 4.D.4 (page no. 33)	Supervisory visits (without prior notice) and audits by NACO may be performed for verification purpose to testing facility/ies	We will prefer to have supervisory visit/audits with 24 hrs prior notice. This is just to ensure required representatives are available on site to co-ordinate the visit/audit. Also audit requirements need to be shared in advance.	There is no change in the requirement.
47	Chapter-III: Para 4.D.7 (page no. 33)	Calibration: Two levels armored RNA passing RNA extraction. The Agency is required to send calibration data for every new lot number of reagent to Client	Calibration, timeline and frequency for submission of calibration records to be stated (i.e. monthly/quarterly etc).	The calibration data should be sent to the Client an when the new lot number of Reagent is put on use.

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
48	Chapter – III: Scope of Services Para 4.F. (page no. 33)	CONFIDENTIALITY AND DATA STORAGE: Data generated under VL testing should be kept confidential. Bidder should be able to present a plan to ensure data confidentiality. Data stored at the testing sites should be transferred to NACO and discarded from the lab completely.	This would lead to data inconsistency in provider's system. Deletion from service provider system is not recommended as it need to maintain trail however confidentiality shall be maintained. The client would do retesting randomly at a later date. How would the provider come back with initial results if data is deleted from his system? Data transfer to be done is expected at what periodicity (daily/weekly/monthly)?	The Service Provider can keep data properly secured at testing sites. **Data transfer should take place on monthly basis.**
49	Chapter-III: Para 4.G. (page no. 33)	After Award of Contract, the agency is expected to submit an inception report, within 2 weeks of signing of contract which includes, as the minimum, the following: a) A detailed process document for indicative list of services b) Detailed formats for standard reports c) Details of dedicated phone lines d) Details of connectivity including internet connectivity e) Details of process control, data control, fraud prevention and data security f) Details of assigned staff with their profile as noted in the proposal g) QA process within the BPO h) Communication and Escalation Protocol i) Project Plans j) Project Governance Protocol k) Any others information deemed appropriate by the Agency	ub-Para (i) and (j): Will prefer to have formats from NACO for submitting project proposal plan and project governance protocol.	The selected agency shall be required to submit its own project plan and project governing Protocol.

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
50	Chapter – III: Scope of Services Para 4.H.3.(a) (page no. 34)	"The Agency's testing services are expected to be operational within 4 weeks of date of award of notification".	This is too short a time. We request more time to supply third party items to remote locations. It will be convenient if a phased-manner implementation plan is shared by NACO for equality of evaluation.	**The requirement is being changed from '4 weeks' to '8 weeks'.**
			We need to know the estimate of workload per day for first 3 months, this will help to assess the feasibility of initiating operations within 4 weeks of confirmation	The estimated work load can be derived from the Annexure-A to the Chapter-III: Scope of Services
51	Chapter – III: Scope of Services Para 4.H.3.(d)(page no. 34)	Integration of Agency's reporting system with IMS of NACO	We need access to IMS to ensure successful integration	The access to IMS shall be provided
52	Chapter – III: Scope of Services Para 4.H.3.(e) (page no. 34)	All contemporary state of the art Business Intelligence Tools including but not limited to Automatic Roster Workforce Management Tool, Call Back Manager with Dialler, Voice Mail module (not only on IVR but for all agents across all services), Screen recording & Barging & Online Reports & Management Dashboards for NACO	Screen recording & Remote barging is difficult to maintain on daily basis, please evaluate if this is really necessary for operation.	Screen recording & Remote barging is necessary.
53	Chapter – III: Scope of Services Para 4.H.(i) (page no. 34)	NACO officials should be able to concurrently listen into calls, preferably through remote access".	Since it will not be possible to have remote access for concurrent listening from two separate sites, request you to please accept call recordings instead.	**The requirement stands deleted. In place, the Agency shall be required to provide call recording.**
	Chapter – VI – Other Standard Forms –		It is suggested that recording should be used rather than concurrently listening mechanism	

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
	Form B Para H(i) (page no. 69)		Need more definition on the process and feasibility of the requirement Since it will not be possible to have remote access for concurrent listening from two separate sites, request you to please accept call recordings instead.	
	Chapter – III: Scope of Services Para 4.H.(m) (page no. 34)	"Nodal Officer / Senior Medical Officer / Medical officer will also sign / validate the VL report of PLHIV."	This will increase timeline of test results being reported. Request to revisit this point. Co-ordination at root level will be difficult to handle. Central Nodal officer should be appointed who will do the validation of reports at a single window. Time frame should be defined for any discrepancy received. Maximum time frame – one week for penalty and payment purposes. In case this validation is not provided within stipulated time frame, the invoices should not be stopped due to this reason but automatically considered as accepted. Such time bound issues should not stop payment for other accepted results since it will be humanly impossible to get each report duly certified by In-charges of all 528 ART centres, request you to please remove this requirement	**The requirement stands deleted.**

Sr. No.	Clause reference/ Page No.	Content of Para / Clause under Reference as per Bid Document	Query/Suggestions	Response / Amendments
			Meaning or relevance of this point. Since it will be humanly impossible to get each report duly certified by In-charges of all 528 ART centres, request you to please remove this requirement.	
54	Other questions:		1. How many different types of platforms can be provided? 2. Will tender go to one bidder? In case of multiple bidders being qualified, what is the qualifying criteria? And how will division of contract take place? 3. For a project of this magnitude, we request for quarterly advance to enable initial investment in project.	1. There is no such restriction. 2. A single agency shall be selected. 3. No advance payment shall be given.
55	Chapter – IV: Financial Bid Footnote no.5 (page no. 59)	The purpose of seeking price of sample collection and transportation is to negotiate the cost at later stage when there is a shift from whole blood to dried blood spot. In such a case NACO may use its own resource at ART Centre to collect samples send dried blood spot directly sent to laboratory	Please specify when to shift from Whole Blood to DBS. The service provider has already invested in infrastructure (fridge, centrifuge, data loggers etc.) & recruited huge manpower for this project. What would happen if the project migrates from Whole Blood to DBS? It is suggested that the project to start & complete with one technology only.	The project shall be executed with Whole Blood during the initial contract period of 3 years. The shift from Whole Blood to BDS may take place during 4th and 5th year.
56	Chapter – VI – Other Standard Forms – Form B	Temperature data logger will be required with whole blood and plasma transportation (to identify episodes of temperature excursions) till the sample reaches the testing laboratory. NACO should be given access to software and alarms for every transport batch.	Alarm can be in the form of outliner in excel sheet, What is the frequency of data capture – 1 min – 30 min.	The temperature data capture and storage shall be on real-time basis.

<table>
<tr><th>Sr. No.</th><th>Clause reference/ Page No.</th><th>Content of Para / Clause under Reference as per Bid Document</th><th>Query/Suggestions</th><th>Response / Amendments</th></tr>
<tr><td></td><td>Para A.3 (c) (page no. 64)</td><td></td><td></td><td></td></tr>
<tr><td>57</td><td>Notification – Page No. 2 and Amendment No.1 issued on 7/10/2016</td><td><table><tr><td>TIME AND DATE FOR RECEIPT OF BIDS</td><td>1430 hours on 25th Oct, 2016</td></tr><tr><td>TIME AND DATE FOR OPENING OF BIDS</td><td>1500 hours on 25th Oct, 2016</td></tr><tr><td>DUE DATE OF VALIDITY OF BID</td><td>25th March, 2017</td></tr></table></td><td></td><td><table><tr><td>TIME AND DATE FOR RECEIPT OF BIDS</td><td>1430 hours on 28th Oct, 2016</td></tr><tr><td>TIME AND DATE FOR OPENING OF BIDS</td><td>1500 hours on 28th Oct, 2016</td></tr><tr><td>DUE DATE OF VALIDITY OF BID</td><td>28th March, 2017</td></tr></table></td></tr>
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