MINUTES OF PRE-BID MEETING
FOR
CD4 (Point of Care-POC) MACHINE- LOW THROUGHPUT
AND
CD4 (Point of Care-POC) MACHINE- MEDIUM THROUGHPUT

Brief Description of Procurement	Procurement of CD4 POC Machine- Low Throughput and CD4 POC Machine- Medium Throughput for NACO Project
IFB Nos.	1. SAMS/NACP/CD4 Machine (POC)/07/2016 (Low Throughput) 2. SAMS/NACP/CD4 Machine (POC)/08/2016 (Medium Throughput)
Date of Publication/ Notification	7th June, 2016
Date and Time of Pre-Bid Meeting	28th June, 2016 at 14:30 Hrs. (IST)
Venue of Pre-Bid Meeting	Strategic Alliance Management Services Pvt. Ltd., B01-B03, Vardhaman Diamond Plaza, Community Centre, D B Gupta Road, Paharganj, New Delhi 110 055.

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

Sr. No.	Name & Designation	Name of Prospective Bidder/Firm
1.	Mr. Amardeep Gupta, Business Manager Mr. Vineet Malhotra, Sr. Regional Sales Manager Mr. Parag Tavkar, General Manager	M/s Sysmex India Pvt. Ltd. Mumbai
2.	Mr. Anil Yadav, Tender Manager	M/s Alere Medical Pvt. Ltd., Gurgaon
3.	Mr. Sanjay Singh, Asst. Manager- Key Accounts	M/s BD India Pvt. Ltd., Gurgaon
4.	Mr. Vijay Mishra, Business Development Manager	M/s Beckman Coulter India Pvt. Ltd., New Delhi

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

Sr. No.	Name and Designation
1.	Dr. Mahesh Mhetre, Technical Officer (CST)
2.	Mr. Saurav Kumar, Technical Officer (SCM)

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

Sr. No.	Name and Designation
1.	Mr. Anil K. Bhutani, General Manager & Team Leader (Procurement)
2.	Mr. Satya P. Verma, General Manager (Procurement)
3.	Ms. Jyoti Singh, Senior Manager (Procurement)
4.	Mr. Vivek Kumar, Deputy Manager (Procurement)

Proceedings of the pre-bid meeting are as follows;

1. At the outset, General Manager (Procurement), SAMS described the brief features of CD4 Machine including 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 2 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**.
5. No Amendments are being made in pursuance to ITB Para 8 of the Bidding Documents

(Satya P Verma)
GM (Procurement)

ANNEXURE-A

CLARIFICATIONS-1 IN REGARD TO QUERIES/SUGGESTIONS RECEIVED TOWARDS IFB FOR CD4 POC MACHINE- LOW THROUGHPUT AND FOR CD4 POC MACHINE-MEDIUM THROUGHPUT FOR NACO PROJECT

Date of Issue: 07.07.2016

1. **IFB Reference: SAMS/NACP/CD4 Machine (POC)/07/2016 (Low)**
   SAMS/NACP/CD4 Machine (POC)/08/2016 (Medium)
2. **Date of Publication/Notification: 7th June, 2016**
3. **Date of Pre-bid meeting: 28th June, 2016**
4. **Date of Bid Submission: SAMS/NACP/CD4 Machine (POC)/07/2016 (Low) -21.7.2016**
   : SAMS/NACP/CD4 Machine (POC)/08/2016 (Med)- 26.7.2016

As per provisions given in ITB Para 7 of the Bidding Document and the queries/clarifications sought by the prospective bidders, the following responses are being issued:-

Sl. No.	Clause reference / Page reference	Query/ Suggestions	Clarification
1	Section I: Invitation for Bids and ITB Clause No. 11-15, 17-20 Page No.- 11-17 Section II: Bid Data Sheet Clause No. 17.2 (a) and 17.2 (b) Page No. 30	If the bidder from outside India then; a. The Tender fee and EMD can be provided by the bidders India subsidiary/authorized Indian agent or only from the Bidder's Country? b. The bidder's Indian representation can be the part of the bidding process and complete responsibilities of installations and after sales services with proper authorization from the bidder?	a) Bidder should submit Tender Fee and EMD. In case an Indian Subsidiary/authorized Indian Agent is submitting bid as manufacturer's authorized agent, it can submit tender Fee and EMD. b) In case Bidder is not doing business in India, the Bidder should be represented by an Agent in the India, equipped and able to carry out the Supplier's maintenance, repair and spare parts-stocking obligations prescribed in the Conditions of Contract and/or Technical Specifications, as per ITB and Bid Data Sheet Clause 17.2 (b)
2	Section III: Evaluation and Qualification Criteria 2.1 Evaluation Criteria (ITB 34.6) Point No. (e) Page-37	As per ITB 34.6 (Evaluation Criteria) (e), Please specify the content of Reagents & Kits clearly. a. Item like, Lancets, Vacutainers, gouges, Spirit gouges, bandages, covers are the part of sampling process and cannot be justified unless and until quantified and specified. b. Kindly keep only those items under Reagents & kits which are directly consumed by the	The bidders must propose reagents and kit (consumables) including all their standard/ proprietary items to make the required testing process complete and whatever else is needed to complete required testing process. This may differ from one equipment to other offered by the different bidders. The general items normally available in the laboratory need

		instruments during testing process of CD4 and CD4% test and its startup and shut down.	not to be included. Bidders must indicate the list of such items being included in the bid for evaluation purposes.
3	Section III: Evaluation and Qualification Criteria 3.1 Post Qualification Requirements (ITB 36.1) Page-38-40	If the manufacturer is owned by a Global company having its own worldwide operations, then the India operation of that company can be considered as a. Manufacturer? b. Non manufacturer?	Such bidder may be considered under Non manufacturer category. If the Indian authorized agent/ dealer/ subsidiary is submitting the bid on behalf of manufacturer in some other country, then such bidder should submit all the documents required under category of Non-Manufacturer bidders as specified under ITB and Bid data sheet clause no. 17, 17.2 (a) and 17.2 (b) and Section III: Evaluation and Qualification Criteria (Post qualification criteria-3.1-B), wherever else applicable under bid document.
4	Section III: Evaluation and Qualification Criteria 3.1 Post Qualification Requirements (ITB 36.1) Page-38-41	In order to fulfil the requirement mentioned in the ITB 36, 3.1 (ii) (a) – Experience and Technical Capacity, a. Can the bidder use the existing supplies and after sales services provided by the manufacturers' ex-distributors or its agent of the world wide available installations. b. Is international user list or program certificate accepted?	a. the bidder can use the existing supplies made by their ex-distributors or its agents available worldwide, if the bidder is manufacturer. b. International user list or program certificates are acceptable, provided the user certificate is for the specific equipment quoted in the bid and all order details and contact details of users are given in the bid.
5	Section III: Evaluation and Qualification Criteria 2.1 Evaluation Criteria (ITB 34.6) Point No. (e) Pages- 37-38	Pack size of the Reagents & Kits mentioned in the price schedule of the related services are also found to be the multiple of 50 Tests. Since our standard pack sizes are 20 tests and 100 tests which are the multiple of 100 Tests so, providing 50 tests multiple will be difficult for us. So Kindly use the multiple of 100 tests. This will be a standard pack sizes for all the companies.	Required Pack Size for tests to be quoted are already in the multiple of 100.

6	Section III: Evaluation and Qualification Criteria Pages-37-41 and Section IV: Bidding Forms Page Nos. 44-49	We assume that all the undertaking mentioned in the bid document can be submitted on the bidder's letter head. If not then please specify the type of document.	Bidders can submit all the undertakings on the Company's Letter Head.
7	Section III: Evaluation and Qualification Criteria 3.1 Post Qualification Requirements (ITB 36.1) Page-38-40	If the manufacturer has started their new subsidiary in India and has not completed five years, how will they meet the requirement of average annual sales turnover of 5 Years? Also, to get the mentioned annual sales turnover is difficult for the new company. a. Can it be relaxed? b. Can the bidder use the turnover of their parent company in this case	The eligibility and qualification requirements cannot be relaxed. The bidder (The Indian Subsidiary) cannot claim or use the turnover of its parent company. In case the Indian Subsidiary do not meet all the requirements, bid can be submitted by the Principal Company.
8	Section IV-Bidding Forms, Check list Point No. 5 (b) Page No. 68	Point no. 5 (b) Check List, Documentary proof of the manufacture's ex distributors/agent can be used for by bidders?	Please refer the Clarification at Sl. No. 7 above.
9	Section VII-Schedule of Requirements 3. Technical Specifications Page No. 82 and 83	As per the Technical Specifications mentioned in Page no. 89 of the bidding document: a. The requirement says CD4 Point of Care (POC) Machine –Medium Throughput/Low Throughput i. But as per the international guidelines of "POC" BD FACS presto doesn't qualifies the "POC" requirement. For the documentary proof please find attached the FDA document of BD FACS Presto. Kindly look into it and confirm. We request you to please make the principle as Flow Cytometer which is the reference method by WHO and it is considered as Gold Standard. b. Validation: As per the technical specification on the validation requirement our Instrument "Partec CyFlow Counter" has been working satisfactorily in NACP program since past 8 years. Its	a. (i.) No comments on any specific brands of CD4 machine. The requirement of CD4 (POC) machine is well defined under Technical Specifications of the bid document. Bidders are required to submit their bids as per technical specification/ standards/ qualification criteria mentioned in the bid document. The technical evaluation of the bids received shall be done as per the criteria already mentioned in the bid document. b. The technical specification mentioned in the bid document stands unchanged.

		performance has been quite good, so our request you to please consider this and provide an option for the acceptance of NACO validated instrument. i. Is waiver from GFATM is accepted for this validation c. Reagent Stability: We request you make the reagent storage temperature at 2-8°C, since 10°C also needs a refrigerator to achieve it.	i. No such waiver is allowed in the bid document. Bidding shall be done strictly as per criteria already mentioned in the bid document. c. The technical specification mentioned in the bid document stands unchanged.
10	Section VII- Technical Specifications Page No. -83	We also want to highlight the limitation of the CD4 instruments which is not based on Flow Cytometer principle. a. Principle other than Flow Cytometer is not a gold standard technique – CD4 absolute count result is decided by the software, real time monitoring is not possible. b. Limitation of reporting low Absolute count – Less than 50 CD4 count is not validated. c. Limitation of sample stability – Not recommended to use after 2 hours of sample addition to the cartridge. d. Instrument is not serviceable – replacement of the instruments is time consuming process which can disturb the control program. e. As per WHO, the near patients CD4 instrument has been found to provide almost 13% failure result. f. Reagents storage temperature 4 – 31°C (FACSpresto) and 2-30°C (PIMA) is not a room temperature – Needs a cool storage as similar to 2 - 8°C (needs proper refrigeration otherwise regents will deteriorate as in India weather condition is mostly around 30°C – 45° C during day time. g. Cartridge QC: rat anti-mouse	a.-f. The viewpoints given under a. to f. has been considered, however, the requirements given in the bid document remains unchanged. g. The standard Controls required for quality assurance of CD4 tests/ calibration of equipment, at least quarterly or as per manufacturer's protocol are to be included in the technical and financial bids proposed by the bidder. The bidders may refer GCC clause no. 12 and subsequent SCC clause no. 12.2 of bid document for repair services including testing & calibration, labor/ spares services to be provided during warranty period.

<table>
<tr><td></td><td></td><td>antibodies bound to polystyrene beads confirm only presence of sample and reagent. It's not an QC for CD4 count. The QC cartridges confirm the working of the instrument and reagent quality but it doesn't validate the CD4 count provided by the instrument. Please confirm the control requirement exactly.</td><td></td></tr>
<tr><td>11</td><td>Section I: ITB Clause 35.1 Page No. 24
and

Section IV: Bidding Forms, Price Schedule Page Nos. 51 to 54</td><td>Should we will get the Custom Duty Exemption Certificate from your side to get the benefit?</td><td>Currently, Customs / Excise Duty exemption is not available. Reimbursement of the Custom /Excise Duty paid against the contract shall be provided.

If Customs/ Excise duty exemption made available during the period of contract, the same exemption will be provided.</td></tr>
<tr><td>12</td><td>Section VII- Schedule of Requirements

Technical Specifications

Page No. -82</td><td>Please refer Tender specification point no. 2.-

<table><tr><th>Characteristics</th><th>Specifications</th></tr><tr><td>Validation</td><td>WHO pre-qualified / ERP approved</td></tr></table>
We understand that the WHO-Pre-Qualified is a mandatory requirement for the instruments of intended use. However, just wish to seek you kind Clarification / Guidance, are WHO-PQ and ERP a mutually alternate and accepted pathways for HIV product approval for adoption in nation program?</td><td>The equipment quoted by bidders should be either WHO pre-qualified or approved by Expert Review Panel for Diagnostics (ERPD) as per Global fund Quality Assurance Policy for Diagnostics Products implemented in March, 2011 and reviewed in February, 2014.</td></tr>
<tr><td>13</td><td>Section II: Bid Data Sheet Clause No. 39.1

Page No. -34

and

Section III: Evaluation and Qualification Criteria

Page No.-38</td><td>Under Section III. Evaluation and Qualification Criteria; in sub section 2.1. Evaluation Criteria (ITB 34.6) (e) the projected requirement is mentioned as under:
<table><tr><th>Year (starting from the date equipment become operational)</th><th>Projected requirement (no. of tests per year for total quantity given in Schedule of Requirement) considering pack size of 1000 tests</th></tr><tr><td>Year 1</td><td>610,000</td></tr><tr><td>Year 2</td><td>630,000</td></tr><tr><td>Year 3</td><td>6,50,000</td></tr></table></td><td>The actual requirement of nos. of tests/ year may vary (either increase or decrease) by 25% of quantities as projected in the bid document, as per ITB and Bid Data Sheet clause no. 39.1.</td></tr>
</table>

		Kindly let us know if there is any deviation expected in the above mentioned nos. or is it a fixed requirement?	
14	Section III: Evaluation and Qualification Criteria 3.1 Post Qualification Requirements (ITB 36.1) Page Nos. 38-39	Qualification (ITB 36); 3.1 Post qualification Requirements (ITB 36.1); (A) If Bidder is Manufacturer; (ii) Experience and Technical Capacity The Bidder shall furnish documentary evidence to demonstrate that it meets the following experience requirement(s): *[list the requirement(s)]* a. The bidder must have supplied and provided after-sales services satisfactorily the specific Good to the extent of at least **50%** of the quantity indicated against the schedule under "Section – VII: Schedule of Requirements" **during any one of the last five calendar years**. The supply should have been made to end-users and not to the dealers/distributors. There should not be any adverse report regarding supplies for at last five years preceding the date of bid opening. We hereby request you to reduce the above after sales services satisfactorily the specific Good may change to the extent of 10% instead of 50%	Please refer sub para (ii) c under 3.1 Post Qualification Requirements (ITB 36.1) of Section III: Evaluation and Qualification Criteria of bid document. The bidder shall furnish documentary evidence (Client's Certificate) to the extent of minimum 20% of quantities mentioned in the bid document, in support of the satisfactory operation of the goods supplied.

(Satya P. Verma)
GM (Procurement)