CENTRAL MEDICAL SERVICES SOCIETY
Ministry of Health & Family Welfare
(Autonomous Body under MoHFW, Govt. of India)
2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road,
Chanakyapuri, New Delhi-110021 PHONE -:011-21410905/6, Fax -:011-21410849

Date: - 09.08.2023

Minutes of Pre-bid Meeting
For Procurement of HIV (Rapid) Antigen Test Kit and Whole Blood Finger Prick Test Kit WBFPT (Kit-4) for NACO
GeM Bid No.: GEM/2023/B/3704667, dated 17.07.2023
Pre-bid Meeting held on 21.07.2023 at 11:00 AM

1. Following officials were present during the Pre-bid meeting: -
   (i) Mr. Sai Prasad Bhavsar, Dy. Director (NACO)
   (ii) Mr. D Mohapatra, GM (Finance), CMSS
   (iii) Ms. Anjana, GM (Procurement), CMSS
   (iv) Mr. Lava Mishra, AGM (Procurement), CMSS
   (v) Ms. Akanksha Jain, AGM (QA), CMSS
   (vi) Mr. Shailendra Gandharva, Associate Consultant (NACO)

2. Following representatives from prospective bidders were present during the Pre-bid meeting: -

Sr. No.	Name of Representative	Name of firm
1.	Ms Savita Saini, Mr. Indradeep Singh	M/s Avantor Performance Materials India Pvt Ltd.
2.	Mr. Abinash Mishra	M/s Medsource Ozone Biomedicals Pvt. Ltd.
3.	Mr. Govind Khatri, Mr. Aash Mohd.	M/s Q-Line Biotech Pvt Ltd
4.	Mr. Rohit Bhatnagar, Mr. Ashish, Mr. Arpit	M/s Meril Diagnostics Pvt. Ltd.
5.	Mr. Deepak, Mr. Prashant., Mr. Mudit Gupta	M/s Transasia Biomedicals Ltd.
6.	Mr. Prasad Bhat	M/s Bhatt Biotech Ltd
7.	Mr. Naresh Pal Singh	M/s Oscar Medicare Pvt Ltd

3. Queries from following prospective firms were received via email: -

Sr. No.	Name of the bidders	
1	M/s Avantor Performance Materials India Pvt Ltd.	M/s Q-Line Biotech Private Limited
2	M/s Medsource Ozone Biomedicals Pvt Ltd.	M/s Oscar Medicare Pvt Ltd
3	M/s Transasia Biomedicals Ltd.	M/s Bhatt Biotech Ltd
4	M/s Meril Diagnostics Pvt. Ltd.	

4. Points raised by representatives of prospective bidders were discussed. After due consideration of the queries, the remarks are enclosed.

TABLE-A

Pre-bid queries raised by the prospective bidders & remarks by CMSS

Sr. No.	As per tender	Tender clause no. & Pg No.	Bidder's Representation	Bidder's Name	Response
1.	Tenderer should have supplied 40% of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor/practicing chartered accountant of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 40% of the quoted/ similar items. **Similar Items here relate to the following: -** Similar item means quoted/ Any HIV, HBV, HCV Rapid Test Kit **Supply/Sale/Service order under loan license arrangement shall not be considered.**	4 (i), 6.2 (e) & Pg No. 12, 15	**For Schedule I, II & V:** Considering the last 2 years being greatly engaged in supply & distribution of Covid-19 testing kit's and related diagnostic product, the key focus to produce and supply HIV Test kit was minimal and hence, unfortunately, considering the current terms in the Tender document, we might not be able to showcase desired past performance of 40% of total required quantity. We humbly request you to **pls. Decrease / Relax the past performance percentage to 25% of total required quantity** for wider participation with the showcase of desired product to the authority.	M/s Avantor Performance Materials India Pvt Ltd.	**Clarified as:** **For Schedule I, II, III, IV & V:** Tenderer should have supplied 25% of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor/practicing chartered accountant of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 25% of the quoted/ similar items. **Similar Items here relate to the following: -** Similar item means quoted/ Any HIV, HBV, HCV Rapid Test Kit **Supply/Sale/Service order under loan license arrangement shall not be considered.**
			We request you to kindly reduce this 40% to 25% like last time (like previous tender corrigendum dated 22.02.2023) so that more number of manufacturer can participate in the bid. During 2020, 2021 and till mid of 2022 the IVD business badly affected due to Covid Pandemic lockdown and less purchase for the regular test kits like HIV, HBV, HCV, Malaria etc. in the public procurement and during tis time only covid products were having demand and other products had less demand and hence seeking 40% past performance may eliminate most of the manufacturer out of competing the bid. So, to have a fair participation, we request you to kindly reduce the past performance criteria to that of last tender where it is reduced from 40% to 25%. We request you to kindly consider similar item means all kind of rapid card tests like HIV, HBV, HCV, Malaria, Syphilis, HCG etc. If all kind of rapid tests can be considered, then more manufacturers will get a fair chance to participate in the tender. If it is restricted only to HIV, HBV and HCV ten only a few manufacturers may be eligible and then the other manufacturer left with no chance in bid participation. So, to attract and provide chance to the other manufacturer we request you kindly consider similar item means for all kind of rapid test kits.	M/s Bhatt Biotech Ltd	
			For Schedule I, II, III, IV & V: Request you to please amend it as "Tenderer should have **supplied 25%** of the quoted quantity of same or similar diagnostic tests (Similar means any **HIV/HBV/HBsAg/HCV kit**) during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor	M/s Medsource Ozone Biomedicals Pvt Ltd.	

			of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least **25%** of the quoted/ similar diagnostic tests".		
			Tenderer should have supplied **20% or more** of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor/practicing chartered accountant of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 40% of the quoted/ similar items. **Justification:** Over the proceeding tow financial years we have observed that the honorable Govt. of India has strictly implemented the Make in India preference in items to be procured and supplied for Government. With such restrictive, it could be clearly observed that the growth of indigenous manufacturers bloomed in the market, these manufacturers duly follow the strict regulatory to manufacture the kit. These manufacturers have the desired quality standards but limitation in the quantity and years of experience. Consequently, in the said bid, the authority has asked experience for 40% of the quoted quantity and 40% for the Item Schedule 5 'Whole Blood Finger Prick Test Kit WBFPT' comes out to be very high for any indigenous manufacturer to fulfil. Hence, the experience criteria for the Item Schedule 5 should be diluted so that maximum indigenous manufacturers can participate and better competition could be seen.	M/s Q-Line Biotech Private Limited	
			Tenderer should have supplied 25% of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor/practicing chartered accountant of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 25% of the quoted/ similar items. **Justification:** As the tender quantity is huge and requirement of supplies of 40% of the quoted qty as eligibility criteria will restrict the participation in the bid to only those few companies which have supplied	M/s Transasia Biomedicals Ltd.	

			in NACO tenders and good Indian manufacturers who can offer good quality products at very competitive rates will be deprived of the participation in the bid.		
2.	For all regulated products, the bidder should have at least two years i.e. 2020- 21and 2021-22 OR 2021-22 and 2022-23 of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCG (I) in less than two years ago. A permission from DCG (I) shall be required for all new regulated products to this effect. Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e. 2020-21 & 2021-22 OR 2021-22 & 2022-23 for compliance of tender clause no. 4 (d).	6.2 (f) & Pg No. 16	We hereby confirm that although we, Avantor is into continuous business since long, but we can showcase the market standing certificates only for the following tenure and the market standing certificate with issue date /year as 2022 is not available as our Company name got changed from Public to Private Limited and hence document arrangement from CDSCO took time during the conversion process. We humbly request you to **kindly accept the market standing for any 1 year except the year 2022** and this shall grant Avantor with a chance to be among the technically qualified bidders.	M/s Avantor Performance Materials India Pvt Ltd.	**Clarified as:** No changes.
			Sch. II and III Principle 3 Intercommunication Request you to please amend to at least for any of the one financial Year 2020-21, 2021 -22 OR 2022-23 for Each Schedule. **Justification:** Financial Year 2020- 21 was under covid Pandemic and Govt. Authority floated tenders related to covid Test and didn't generated enquiries for other products for throughout the financial year 2020- 21.	M/s Meril Diagnostics Pvt Ltd.	
			Sch. III and IV Principle-3 Immuno concentration Request you to please amend to at least for any of the one financial Year out of 2020-21, 2021 -22 OR 2022-23. **Justification:** Financial Year 2020- 21 was under covid Pandemic and Govt. Authority floated tenders related to covid Test and didn't generated enquiries for other products for throughout the financial year 2020- 21.	M/s Meril Diagnostics Pvt Ltd.	
			Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted. **Justification:** The restriction for the years involved in the market standing of the product and non-conviction of the firm should be removed. As yourself is well aware that during the high-time of Covid-19 pandemic, the supply chain of any organization is affected and many manufacturing organization were not in a state to supply their manufactured products in the Covid-19 pandemic tenure. Hence, for the market standing of the product and non-conviction of the firm the restriction for the years should be	M/s Q-Line Biotech Private Limited	

			removed.		
3.	Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company (as well as the manufacturer firm in case of non-manufacturer bidders) has not been convicted and the products quoted have not been cancelled during last two years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022- 23.	6.2 (g) & Pg No. 16	Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company (as well as the manufacturer firm in case of non-manufacturer bidders) has not been convicted and the products quoted have not been cancelled **Justification:** The restriction for the years involved in the market standing of the product and non-conviction of the firm should be removed. As yourself is well aware that during the high-time of Covid-19 pandemic, the supply chain of any organization is affected and many manufacturing organization were not in a state to supply their manufactured products in the Covid-19 pandemic tenure. Hence, for the market standing of the product and non-conviction of the firm the restriction for the years should be removed.	M/s Q-Line Biotech Private Limited	**Clarified as:** No changes.
4.	**For Sch. No. I, II, III & IV** Lot 1 - To be delivered between 90 - 120 days from the date of issue of LOA Lot 2 - To be delivered between 121-180 days from the date of issue of LOA Lot 3 - To be delivered between 181-270 days from the date of issue of LOA Lot 4 - To be delivered between 271-365 days from the date of issue of LOA **For Sch. No. V** Lot 1 - To be delivered between 0 – 90 days from the date of issue of LOA Lot 2 - To be delivered between 91 – 120 days from the date of issue of LOA Lot 3 - To be delivered between 121-150 days from the date of issue of LOA Lot 4 - To be delivered between 151-180 days from the date of issue of LOA	Annexure I & Pg No. 40	**Sch. V - Whole Blood Finger prick Test Kit WBFPT (Kit-4)** Hence, request you to increase the delivery period for the initial delivery to 120-150 days. **Justification:** Supply period also includes the time period for PDI and hence a certain part of it (15-20 Days) is not in the manufacturer's control.	M/s Meril Diagnostics Pvt Ltd.	**Clarified as:** No changes.
			Please amend it as "The supplier shall supply the ordered quantity within minimum required period of **150 days** from the date of award at the destinations mentioned. If the above day happened to be a holiday for CMSS, the supply should be completed by 5.00 PM on the next working day.	M/s Medsource Ozone Biomedicals Pvt Ltd.	
			Request you to please amend it as for All Schedules **and especially for Sch. No. V**– Because Sch. No. V has the highest quantity. "Lot 1 (25%) - To be delivered between 90 – 120 days from the date of issue of PO Lot 2 (25%) - To be delivered between 121-180 days from the date of issue of PO Lot 3 (25%) - To be delivered between 181-270 days from the date of issue of PO Lot 4(25%) - To be delivered between 271 – 365 days from the date of issue of LOA	M/s Medsource Ozone Biomedicals Pvt Ltd.	
5.		Annexure VI & Pg No. 50	We request you kindly consider the past performance for the FY 2019-20, 2020-21 or 2021-22, 2022-23 as this will allow more manufacturer to qualify as pre covid era and post covid era. If restrict only to 2021-22 and 2022-23 years, then only a few manufacturers will	M/s Bhatt Biotech Ltd	**Clarified as:** Kindly refer Sr. No. 1 of Table-A.

			be qualified as during 2020-21 and 2021-22 there was a covid pandemic and no much purchases were happening for kits like HIV, HBV and HCV etc rapid kits. Only covid items were having demand and hence considering covid era, we request you to kindly consider either any two financial years out of last 4 financial years or change it to three financial years instead of 2 financial years. (in page no 17- pint k it is mentioned that for the annual turnover statement mentioned as 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23). Same like turnover criteria we request you to incorporate for Annexure-VI so that more number of manufacturer will get a chance to participate in the bid.		
6.	RTGS/NEFT e-receipt or Bank Guarantee (if applicable) in respect of EMD as per Clause 9 of this Tender document or in case of MSE, a copy of their valid registration certificate in support of their being an MSE and a notarised undertaking given in Annexure-VIII.	6.2 (a) & Pg No. 15	Request You to please accept EMD as FDR also.	M/s Medsource Ozone Biomedicals Pvt Ltd.	**Clarified as:** EMD in the form of FDR is Accepted.
7.	Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch of the quoted product should be submitted.	6.2 (n) & Pg No. 17	Please accept long term stability data of Serum & Plasma based product for last 2 years and for 1 year for the quoted product. Since the concept of Testing with Whole Blood is in market from last year only.	M/s Medsource Ozone Biomedicals Pvt Ltd.	**Clarified as:** As per tender terms & conditions.
8.	PDI (Pre-Dispatch Inspection) as mentioned in Annexure-I means, the QA inspection/testing shall be completed prior dispatch of supplies direct to consignees/ CMSS warehouses. After completion of manufacturing process, the supplier should offer goods for PDI inspection in writing to Quality Assurance department of CMSS at least 10 days before proposed inspection date. The samples of each batch will be collected and sent to designated laboratories (Government/ Private Drugs Testing Laboratories) for	16.5 & Pg No. 31	We request you to please clarify the apex laboratory for testing/ designated laboratory for HIV testing.	M/s Medsource Ozone Biomedicals Pvt Ltd.	**Clarified as:** As per tender terms & conditions.

	testing as decided by the CMSS. Non-PDI (Post Delivery Inspection) as mentioned in Annexure-I means, the supplier will deliver/dispatch the manufactured items (as per the technical specifications) directly to CMSS warehouses. The samples will be collected from the warehouse of CMSS and sent to designate Quality Control Labs in respect of supplied goods at any point during specified shelf life as per decision of CMSS.				
9.	The prices of technically qualified bidders of Schedule I to IV (Both Principles) shall be opened on GeM portal. After that, in first instance, the prices of Schedule II & IV shall be compared. The lowest price (L1) between Schedule II & IV shall be denoted as "Kit-3" and the actual quantity of "Kit-3" i.e. 3,44,640 tests shall be procured from the schedule of lowest rate.	Annexure-I & Pg No. 40	Please clarify how the two different principles can be compared as mentioned in Sch. No. II & IV	M/s Medsource Ozone Biomedicals Pvt Ltd.	**Clarified as:** As per tender terms & conditions.
10.	**Sch. No. I, II, III, IV:** 2. Should be solid phase coated HIV 1 & 2 recombinant and/ or Synthetic peptide antigens	Annexure-I & Pg No. 42	Please clarify which detection you require since as per nomenclature you have asked for Antigen Testing Kit but as per specification you are asking detection of HIV 1 & 2 which are antibodies.	M/s Medsource Ozone Biomedicals Pvt Ltd.	**Clarified as:** The approved Technical Specification for HIV Test Kit 2,3 and WBFP Test Kit for HIV are clear. The prospective bidders are requested to comply the Technical Specification.
11.	**Sch. No. I, II, III, IV:** 12 (b). The assay component should include HIV positive and negative serum controls, sufficient for conducting 20% of the test (10% negative and 10% positive controls).	Annexure-I & Pg No. 42	Generally rapid test kits are available without any +ve/ -ve controls to perform the test. **Request you to please remove the +ve and -ve controls. Or** Please clarify can we send +ve and –ve controls separately, if we understood and interpreted this correctly.	M/s Medsource Ozone Biomedicals Pvt Ltd.	No changes.

			Request you to please consider HIV I control requirement only. **Justification:** Due to the worldwide scarcity of control specifically of HIV II it was difficult to manage the qty required to supply along with each kit.	M/s Meril Diagnostics Pvt Ltd.	
			We request you kindly confirm that HIV Positive Control should be HIV 1 and HIV 2 separate controls. If yes, we request you kindly allow only HIV 1 positive control, it is very difficult to arrange the HIV 2 positive control, it is not available in the market.	M/s Oscar Medicare Pvt Ltd	
			HIV-2 control to be supplied on demand only. **Justification:** As discussed in the pre-bid meeting the HIV-2 controls are not commercially available in the market due to which it is very challenging for any indigenous manufacturer to supply the controls of HIV-2. The HIV-2 controls could only be supplied for selective demand including evaluation study. Hence, the specification should be amended as suggested.	M/s Q-Line Biotech Private Limited	
12.	**Schedule V:** 3. The clinical data to determine the performance characteristics of the kit on whole blood sample should be made available by the manufacturer.	Annexure-I & Pg No. 43	The manufacturer should provide Inhouse test report/Certificate of analysis for the performance characteristics of the kit on whole blood sample. **Justification:** The clinical evaluation of the kit using Whole blood sample is challenging for any indigenous manufacturer since it is very difficult to arrange whole blood in high quantity for clinical studies. For performance evaluation of the kits, the in-house tests reports or Certificate of analysis should be accepted.	M/s Q-Line Biotech Private Limited	No changes.
13.	**Sch. No. I, II, III, IV:** 13. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport of kits at 2-8 deg C. The cumulative time temperature indicator technology used should be pre-qualified by WHO.	Annexure-I & Pg No. 42	All Rapid Test Kits are stable at 'Room Temperature' and there is no requirement to keep these kits at controlled temperature. Also, since you have asked to supply +ve and –ve controls separately at s. no. 10 of technical specification, so there is no need to store and transport these kits at 2- 8 deg C. So, request you to please delete this point.	M/s Medsource Ozone Biomedicals Pvt Ltd.	No changes.
14.	**Sch. No. – V:** 9. The manufacturer/ authorized agent should ensure maintenance of cold chain during storage & transport of kits at 2-8 deg C. The cumulative time temperature	Annexure-I & Pg No. 43	All Rapid Test Kits are stable at 'Room Temperature' and there is no requirement to keep these kits at controlled temperature. Also, since you have asked to supply +ve and –ve controls separately at s. no. 10 of technical specification, so there is no need to store and transport these kits at 2- 80C. So, request you to please delete this point.	M/s Medsource Ozone Biomedicals Pvt Ltd.	No changes.

	indicator technology used should be pre-qualified by WHO.				
15.	**Schedule V:** 12 (b). The assay component should include HIV positive & negative serum controls sufficient for conducting 20% of the test (10% negative & 10% positive control).	Annexure-I & Pg No. 43	Sch. V - Whole Blood Finger prick Test Kit WBFPT (Kit-4) Request you to please omit the the separate control requirement along with the kit as each test contain 2 separate bands / Dot for HIV 1, HIV 2 and Control. **Justification:** Due to the world-wide shortage of control specifically of HIV II it was difficult to manage the qty required to supply along with each kit.	M/s Meril Diagnostics Pvt Ltd.	No changes.
			HIV-2 control to be supplied on demand only. **Justification:** As discussed in the pre-bid meeting the HIV-2 controls are not commercially available in the market due to which it is very challenging for any indigenous manufacturer to supply the controls of HIV-2. The HIV-2 controls could only be supplied for selective demand including evaluation study. Hence, the specification should be amended as suggested.	M/s Q-Line Biotech Private Limited	
16.	Schedule-V Whole Blood **Finger Prick** Test kit for HIV	Annexure-I & Pg No. 43	In the Schedule-5 Whole blood finger prick is mentioned while in the specification no finger prick related requirement is mentioned. In its regards, it should be clarified that the successfully bidder has to supply finger prick itemsLancets, swabs with the kits?	M/s Q-Line Biotech Private Limited	**Clarified as:** The supplier has to provide the testing kits as per the approved technical specifications of tender document.
17.	Vide Gazette no. CG-DL-E-26062020-220191 dt. 26.06.2020, Ministry of MSME have revised criteria for classifying the enterprises as Micro, small and medium enterprises with effect from 1st July 2020 therefore following firms will be exempted from submission of EMD.	9.2 (ii) & Pg No. 21	We request you kindly consider that Medium Enterprises are exempted for EMD.	M/s Oscar Medicare Pvt Ltd	**Clarified as:** As per tender terms & conditions.
18.	Schedule V: 6. The Kits should have a shelf life of six months 24 months, at least 5/6th of the minimum shelf life must remain at the time of dispatch to the consignee.	Annexure-IA & Pg No. 43			**Amended as:** 6. The Kits should have a shelf life of six months 24 months, at least 5/6th of the minimum shelf life must remain at the time of receipt by the consignee.

Note: - Above changes will be part of the tender document.

-sd/-
GM (Procurement)

TABLE-B

REVISED CRITICAL DATE SHEET ARE AS UNDER:

Description	**Scheduled date**
Bid Submission End Date and Time	16.08.2023 till 03:00 PM
Last date of submission of original documents	16.08.2023 till 03:00 PM
Bid Opening Date and Time	16.08.2023 at 03:30 PM

Note: - Apart from above, all other terms & conditions of tender document will remain unchanged.

-sd/-
GM (Procurement)