CENTRAL MEDICAL SERVICES SOCIETY

(An Autonomous Body under Ministry of Health & Family Welfare, Govt. of India)

2nd Floor, Vishwa Yuvak Kendra, Teen Murti Marg,

Chanakyapuri, New Delhi-110021.

Date: - 30/06/2025

Minutes of Pre-bid meeting held on 30/05/2025 at 11:00 AM regarding Tender No.: CMSS/PROC/2025-26/NCVBDC/006, CPP Tender ID: 2025_CMSS_861894_1, Dated 27/05/2025 for Procurement of Bivalent- RDT (Malaria) for NCVBDC under Rate Contract System

Pre-bid queries raised by the prospective bidders and Clarification/ Amendments by CMSS:

Sr. No.	As per tender	Tender clause no. & Page No.	Bidder's Query	Clarifications/ Amendments
1.	Tenderer must submit Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for any two out of last three financial years i.e. 2023-24, 2024-25 and 2025-26. However, this would not apply to products which have been licensed by licensing authority less than two years ago.	Section-IV (d) & Pg No. 58	Request you to please amend the requirement of Market Standing Certificate issued by the Licensing Authority out of last three financial year i.e. 2022-23, 2023-24 & 2024-25 instead of 2023-24, 2024-25 and 2025-26. Since 2025-26 is the current financial year & the requirement should be amended to cover any two out of the last three completed financial years namely: 2022-23, 2023-24, and 2024-25.	**Clarified as:** Kindly follow the tender terms & conditions.
2.	The tenderer should not have been convicted by the Licensing Authority in the past three years prior to the date of bid submission. Bidder shall give explicit undertaking for the same in Form 4 of the Bid Document. Also, Tenderer must submit Non-Conviction Certificate issued by the Licensing Authority certifying that the tenderer (as well as the manufacturer firm in case of non-manufacturer bidders)	Section-IV (e) & Pg No. 58	Request you to please amend the requirement of Non-Conviction Certificate issued by the Licensing Authority out of last three financial year i.e. 2022-23, 2023-24 & 2024-25 instead of 2023-24, 2024-25 and 2025-26. Since 2025-26 is the current financial year & the requirement should be amended to cover any two out of the last three completed financial years namely: 2022-23, 2023-24, and 2024-25. We would also like to respectfully request that the tender evaluation criteria and required documentation allow for the inclusion of the financial	**Clarified as:** Kindly follow the tender terms & conditions.

	has not been convicted for any two financial years out of last three financial years i.e. 2023-24, 2024-25 and 2025-26.		year 2022–2023, particularly with reference to the Non-Conviction Certificate	
3.	Tenderer must submit long term stability data and CoA (Certificate of Analysis) in accordance with ITB 9.2.1 (5) along with copy of License Certificate authorizing bidder to manufacture stability batches. Long term stability data & COA should mandatorily include parameters like Assay Dissolution, "Uniformity of Weight" or "Content Uniformity" (whichever is applicable) and "Related Substance Parameters".	Section-IV (f) & Pg No. 59	The parameters like Assay Dissolution, "Uniformity of Weight" or "Content Uniformity" (whichever is applicable) and "Related Substance Parameters" are not applicable for Bivalent Malaria Rapid Test as well as the certificate of analysis. These parameters are applicable for pharma product. We request you please amend the requirement of these parameters in the Certificate of Analysis.	**Clarified as:** Kindly refer attached Corrigendum-2.
4.	The tenderer must have supplied at least the following quantity of the same or similar item during the last two financial years including the period of current F.Y. till the date of tender opening: **Minimum Quantity of the same or similar item during the last two financial years including the period of current F.Y. till the date of Tender Opening: 1,01,68,671 Tests**	Section-IV (g) & Pg No. 59	We request that you kindly consider the CMSS E-Aushadhi Portal acceptance for the proof of supply. We request to kindly add HIV, syphilis, hepatitis etc. As these are of similar testing. Note: Similar item means **Malaria Rapid Kit** / any kit of NCVBDC Asked Qty. in Tender is very huge and as per requirement of tender. As per eligibility criteria 20% performance qty is asked is comparably higher side because, In **NCVBDC** program is carried out for majorly two Products one is Malaria and Dengue, and both the products are seasonal.	**Clarified as:** Kindly follow the tender terms & conditions.

	In support of above, the tenderer shall submit details of past purchase orders executed by them along with the copy of GST invoice and E-way bill against the proof of execution of order for every submitted Purchase Order. If GST invoice is not applicable for any		Also sell of both product depends on demand as per season. Hence request you to please give either leverage by considering for other similar products like HIV/HbsAg/HCV Rapid Card test in performance criteria OR Please remove mentioned in NOTE OR please reduce requirement to 10% for performance criteria.	
	Purchase Order, the affidavit to that effect on stamp paper of Rs. 100/- should be submitted. For the supply of export, bidder should submit the copy of invoice, bill of lading/airway bill/any other document issued by custom authority against the proof of execution of order for every submitted Purchase Order. The details shall be duly certified by the practicing Chartered Accountant in the form 4.1. The certifying Chartered Accountant must indicate the details along with its UDIN. **Note: Similar item means quoted product/ any kit of NCVBDC**		With reference to the tender document, we respectfully request a clarification and amendment regarding the definition of "Same or Similar item." We propose that the definition be broadened as follows: "Same or Similar item" may include the quoted item or any rapid test kits such as: • HIV Rapid Test Kits • HBV Rapid Test Kits • HCV Rapid Test Kits • Rapid Antigen Test Kits for SARS-CoV-2 / COVID 19 • Typhoid Rapid Test Kits • Dengue Rapid Test Kits • Malaria Rapid Test Kits • Other similar IVD (In Vitro Diagnostic) rapid test kits This expanded definition will enable greater participation by qualified bidders who have relevant experience with similar diagnostic products, thereby enhancing the quality and competitiveness of the procurement process.	

5.	Tenderer should submit a scientific study report of product testing at designated ICMR laboratory in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use, thermal stability data etc. in reference to technical specification clause G (ii).	Section-IV (l) & Pg No. 60	Request you to please amend it as "Tenderer should submit a scientific study report of product testing at designated **ICMR laboratory/ WHO FIND/ NIMR** in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use, thermal stability data etc. in reference to technical specification clause G (ii)" **Since ICMR gives sensitivity and specificity report only.**	**Clarified as:** The in-house report of bidder may be considered for thermal stability data. Panel detection score can be indirectly calculated from sensitivity and specificity. The ease of testing is not being recorded in ICMR report.
6.	**Delivery Schedule:** **For Schedule I:** The bidder shall deliver @1,27,10,850 Tests within 60 days of issue of purchase order. **For Schedule II:** The bidder shall deliver @31,77,713 Tests within 60 days of issue of purchase order.	Section-V & Pg No. 62	Request you to please amend it as "1,27,10,850 Tests within 120 days of issue of purchase order. **Since this is a PDI item we request you to please extend the delivery period.** We respectfully request a revision in the delivery schedule period as stipulated in the tender document. The current schedule of 60 days from the date of issuance of the Purchase Order poses significant logistical challenges, particularly due to the need for sourcing specific components—namely capillaries, swabs, and lancets from third party sourcing. To ensure the delivery of quality materials and to maintain compliance with procurement and quality standards, we kindly request that the delivery period be extended to **120 days** from the date of the Purchase Order.	**Clarified as:** Kindly refer attached Corrigendum-2.

			The bidder shall deliver @1,27,10,850 Tests within 90-120 days of issue of purchase order. The asked quantity is 1.27 cr. to be supplied in one tranche is very huge and the material actually to be supplied at different locations across India, which would require sufficient time to deliver. Therefore, request you to please amend the delivery period from 60 days to 90-120 days which would help us to deliver the shipment within the amended timeframe.	
			The bidder shall deliver @1,27,10,850 Tests within 90 days of issue of purchase order. As 60 days is not sufficient for getting the product inspected and delivered to various consignees.	
7.	**Technical Specification of Bivalent- RDT (Malaria) FOR NCVBDC** Each test kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, heparinized capillary tubes (diameter -1 mm) with relevant markings and reaction tubes with stand/wells as required.	Section-VI (A) & Pg No. 64	Each test kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, **heparinized capillary tubes (diameter -1 mm) with relevant markings / Sample transfer device** and reaction tubes with stand/wells as required. Request you to please add **Sample transfer device** along with capillary tubes. **Sample transfer device** having similar function of sample handling and also it is more price towards sample volume. Request you to please change or add as a optional, **Sample transfer device** is also cost effective.	**Clarified as:** Kindly follow the tender terms & conditions.

			Please amend it as "Each kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, heparinized **capillary or sample loop or inverted sample cup** convenient to perform test can be provided.	
8.	**Technical Specification of Bivalent- RDT (Malaria) FOR NCVBDC** **RDT Performance Criteria:** Each lot of RDT should be tested at a designated ICMR laboratory at the time of delivery. Only those lots with PASS report will be accepted for delivery.	Section-VI (A) & Pg No. 65	**RDT Performance Criteria:** Each **lot or consignment** of RDT should be tested at a designated **ICMR/NABL laboratory** at the time of delivery. Only those lots with PASS report will be accepted for delivery. Malaria RDT kits have be approved by ICMR at the time of licensing and evaluation report generation at ICMR Lab takes minimum 2 weeks of time where as NABL Lab report can be generated within 2-3 days therefore request you to kindly make the amendment.	**Clarified as:** Kindly follow the tender terms & conditions.
9.	**Technical Specification of Bivalent- RDT (Malaria) FOR NCVBDC** **Content of Kit and Packaging:** Storage conditions, expiry dates and limitations of the test should be provided. The small box should be packed in bigger cardboard carton containing 10 such small boxes. The cartoon should be sealed with a sealing tape.	Section-VI (B) & Pg No. 65	Request you to please keep the pack size as - The small box should be packed in bigger cardboard carton containing **5 such small boxes** in line with existing ongoing contracts.	**Clarified as:** Acceptable (in accordance with Content of Kit and Packaging accepted above)

10	**Technical Specification of Bivalent- RDT (Malaria) FOR NCVBDC** **Stability requirements at temperatures of intended storage, transport and use:** RDTs should have high thermal stability for use in areas with very high ambient temperatures as per evaluation by ICMR against a single cultured P. falciparum isolate at 200 parasites/µl at baseline and after 60 days of incubation at room temperature, 35 deg C and 45 deg C.	Section-VI (D) & Pg No. 65	Request you to please amend it as "Tenderer should submit an **in-house scientific study report** for use in areas with very high ambient temperature at base line and after 60 days at room temperature 35 deg C and 45 deg C." Since ICMR gives sensitivity and specificity report only and not at very high temperature of 35 deg C and 45 deg C.	**Clarified as:** The in-house report of the bidder can be considered for thermal stability data.
11	**Technical Specification of Bivalent- RDT (Malaria) FOR NCVBDC** **Marking/ Labelling:** The large carton (containing 10 small boxes) and small box (containing 10 test) should have the following markings:	Section-VI (F) & Pg No. 65	Request you to please keep the pack size as - The small box should be packed in bigger cardboard carton containing **5 such small boxes.**	**Clarified as:** Acceptable (in accordance with Content of Kit and Packaging accepted above)
12	**Technical Specification of Bivalent- RDT (Malaria) FOR NCVBDC** **Details regarding approval of license** – (ii) The Bidder must submit scientific study	Section-VI (G-ii) & Pg No. 66	Request you to please amend it as "Tenderer should submit a scientific study report of product testing at designated **ICMR laboratory/ WHO FIND/ NIMR** in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use,	**Clarified as:** The in-house report of the bidder can be considered for thermal stability data.

	report of product testing at designated ICMR laboratory in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use, thermal stability data etc.		thermal stability data etc. in reference to technical specification clause G (ii)" **Since ICMR gives sensitivity and specificity report only and not thermal stability data.**	
13	The requirement of the Turnover for the last three financial years i.e., 2022-23, 2023-24, and 2024-25.	Form 4.2 & Pg No. 155	We kindly request you to amend the financial years mentioned as 2021–22, 2022–23, and 2023–24 instead of 2022-23, 2023–24, and 2024–25. **This is because the audit for the financial year 2024–25 has not yet been completed for any manufacturer.**	**Clarified as:** Kindly refer attached Corrigendum-2.
14	**For Schedule I:** CMSS will conclude Rate Contract with L-1 bidder and three higher quoting bidders subject to their matching the L-1 rates. **For Schedule II:** CMSS will conclude Rate Contract with two bidders i.e. L-1 bidder and next higher quoting bidder subject to their matching the L-1 rates.	SECTION III, 13.1.3 (4) & Pg No. 55	Please clarify how the L1 will be decided for both the schedule i.e. separately for schedule 1 and schedule 2 or any schedule L1 will be the L1. Please confirm how L1 will be declared.	**Clarified as:** The same was briefed during Pre-bid meeting, however the bidder can send their query to CMSS, if any.
15	Schedule I is regular tender schedule and Schedule II is developmental tender schedule. Maximum of 25% quantity shall be sourced from developmental tender schedule. Balance	SECTION III, 13.1.3 (6) & Pg No. 55	Please clarify how order can be placed.	**Clarified as:** The same was briefed during Pre-bid meeting, however the bidder can send their query to CMSS, if any.

	quantity shall be sourced from regular tender schedule. The criteria for award of Purchase Orders against various schedules are detail below as under: **For Schedule I:** 1. 1st Purchase Order Award Criteria Purchase order for 70% of the quantity required shall be awarded to L-1 Rate Contract holder and remaining 30% to L-2 Rate Contract holder. L-3 and L4 RC holders will remain as reserve suppliers in case of default by L-1/L-2 RC holders.			
16		SECTION II, 9.2.1 & Pg No. 27	As per from 4 Qualification Criteria b. Valid WHO GMP Certificate c. Valid COPP Certificate but as per ITB 9.2.1.3 The requirement of Valid WHO GMP Certificate and Valid COPP Certificate is deleted. Kindly clarify. It will help in participating in the bid.	**Clarified as:** Kindly refer tender clause no. 9.2.1.3 of Section-III of tender document.

17	Last date and time for bid submission: 19/06/2025 at 03:00 PM Date and time for tender opening (technical bid): 20/06/2025 at 04:00 PM	Section I & Pg No. 3	We respectfully request an extension of 10 additional days to the current bid submission deadline. This request is made in light of the need to collect and compile multiple documents, complete several prescribed formats, and obtain mandatory certificates from relevant authorities, which require additional time due to procedural formalities. We assure you that this extension will enable us to submit a more comprehensive and compliant proposal in line with the tender requirements.	**Clarified as:** Corrigendum-1 has already been issued for the same.
18	**Technical Specification of Bivalent- RDT (Malaria) FOR NCVBDC**	Section-VI & Pg No. 64	PROPOSED AMENDMENT: 1)Replace sterile steel lancets with **AUTO DISABLE LANCETS** 2)Other materials remain unchanged Each test kit should contain all the material required for conducting the test including AUTO DISABLE LANCET for pricking, heparinized capillary tubes (diameter -1 mm) with relevant markings and reaction tubes with stand/wells as required. JUSTIFICATION: The Existing Sterile Steel lancets are: 1) Painful 2) Environmentally hazardous 3) Can be mistakenly reused & "Auto-disable lancets offer significant advantages in clinical and public health programs by	**Clarified as:** Kindly follow the tender terms & conditions.

			enhancing safety and infection control. Designed for single use, they prevent cross-contamination and reduce the risk of transmitting blood-borne infections such as HIV and hepatitis. With built-in mechanisms that retract or conceal the needle after use, they also minimize accidental needlestick injuries. Easy to use and preloaded, they are ideal for mass screenings and field programs. Their controlled penetration depth ensures consistent sampling with minimal pain and tissue damage, improving efficiency and patient compliance in institutional use."	

Note: - Above changes will be part of the tender document and apart from above, all other terms & conditions of tender document will remain unchanged.

Sd/-

In-charge GM (Procurement)