CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health & Family Welfare
2nd Floor, Vishwa Yuvak Kendra, Near Teen Murti Marg
Chanakya Puri, New Delhi – 110021, India

Dated: - 21.05.2024

Minutes of Pre-Bid Meeting for Rate Contract for Procurement of Rapid Diagnostic Test Card Kits for Sickle Cell Disease Diagnosis under National Sickle Cell Anaemia Elimination Mission

TENDER No: CMSS/PROC/2024-25/NHM/008
Pre-bid conference held on 16.05.2024

Table-A

(Pre Bid Queries Raised by the Bidder and Remarks by CMSS)

Sr. No.	Bidder	Query/ Classification Asked	Clarification/Amendment
1.	M/s Alpine Biomedicals Pvt. Ltd.	**1. Clause 6.2 (n)** Real time stability data can be provided for 1 year and accelerated data can be provided which will demonstrate claimed shelf life of 2 years	Agreed Accelerated data to be submitted along with 1 year of Real time data.
		2. Clause 6.2 (g) NCC certificate requirement should be exempted just like MSC as it is a new product.	Agreed Non-Conviction Certificate of the firm from Chartered Accountant to be submitted for the last 2 years.
		3. Clause 6.2 (i) Capacity certificate certified by CA should be acceptable as CDSCO does not issue such certificate.	Agreed Capacity Certificate from Chartered Accountant to be submitted.
		4. Point B. in Technical Specification - Content of the kit - In Sub Point 4. (c) Page No 38 Our test requires 5ul blood only. Hence dropper marking should be for 0-10ul specimen.	Point 4 (c), Page No. 38 may be read as Disposable Specimen through device (Dropper) with graduated 0-10µl mark.
		5. Point-E. (4) Page No. 39 Temperature indicator requirement should be exempted since this product is stable at room temperature.	Point-E. (4) – Deleted
		6. CDSCO has issued a guideline that Sickle test falls under Class C category. Hence companies holding Class B license should not be considered.	*"Manufacturer should have valid own manufacturing license of the quoted item that should be valid on the date of tender opening packet 1. In case of failure to submit the same, the bid shall not be considered any further."* The Manufacturing License issued by CDSCO under Class C Category to be submitted.
2.	M/s Mylab Discovery Solutions Pvt. Ltd.	**1. Clause 4. Eligibility Criteria sub clause e)** We kindly request the tendering authority to consider revising this clause. Instead of "Tenderer should have supplied 40% of the quoted quantity of same or similar item during the last two	No Change

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Vishwa Yuvak Kendra, Chanakyapuri New Delhi - 21

Sr. No.	Bidder	Query/ Classification Asked	Clarification/Amendment
		financial years," we propose amending it to "Tenderer should have supplied 40% of the quoted quantity of same or similar item during the any two financial years. We would also like to request an amendment to this point: "The evaluation of supplied quantities should be based on the attached GST invoices and e-way bills, rather than attached order copies." It will ensure fair competition for all participants. We are seeking better cooperation from the tendering authority in favor of all participants.	
3.	M/s Meril Diagnostics Pvt. Ltd.	**1. Clause 6.2 (f)** 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 company's statutory auditor/licensing authority/ Chartered Accountant along with UDIN Number/Cost Auditor 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. A document issued by a Chartered Accountant along with the UDIN Number or by a Cost auditor is also authentic document to prove the proof of 40% Supply quantity.	No Change
		2. Clause 6.2 (h) Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for Current year 2024-25. A market standing certificate proves the stability and capacity of the bidder and the credibility of the product in the Indian market.	No Change
		3. Clause 6.2 (i) Request to delete this clause. And as per CDSCO guideline, Capacity certificate is not issued under Medical Device rule 2017.	Agreed Capacity Certificate from Chartered Accountant to be submitted.
		4. Clause 6.2 (g) Request to delete this clause or 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 the years i.e. 2024-25. The Government of India's Sickle Cell elimination project, ongoing for a year and a half, initially sought products covering A, S, and C variants. But following an ICMR circular excluding the C variant, tender specs were adjusted to focus on A and S only. However, companies with previous non conviction for all variants may face participation restrictions, as current certificates cover only A and S.	Agreed Non-Conviction Certificate of the firm from Chartered Accountant to be submitted for the last 2 years.
		5. Clause 6.2 (j) Performance Statement to establish 2 years market standing for similar items/Kits based on same principle as per format given in Annexure-IV. Signature of Statutory Auditor/ Chartered Accountant/ Cost auditor. A document issued by a Chartered Accountant along with the UDIN Number or by a Cost auditor shall also justify and prove past performance/ performance statement.	Performance Statement to establish 2 years market standing for similar items/Kits based on same principle as per format given in Annexure-IV. Signature of Statutory Auditor/ Chartered Accountant/ Cost auditor. A document issued by a Chartered Accountant along with the UDIN Number or by a Cost auditor shall also justify and prove past performance/ performance statement.

Sr. No.	Bidder	Query/ Classification Asked	Clarification/Amendment
		6. Annexure List of Items Quoted & Their Production Capacity (Page No 47) Annexure-vi list of items Quoted & their Production Capacity for Year 2023-24 As Govt. of India has newly launched Sickle cell program So Production Capacity, for the last financial year 2023-24 should be asked of the quoted product.	Accepted
		7. Point B. in Technical Specification CONTENT OF THE KIT - In Sub Point C. Asked Disposable Plastic Specimen transfer devices with graduated 10 µl mark. (Page No 38) Request to delete this clause. Every company having requirement of different volume of sample (Specimen) which vary from 5 to 15 µl.	Point 4 (c), Page No. 38 may be read as Disposable Specimen through device (Dropper) with graduated 0-10µl mark.
		8. Point E. in Technical Specification QUALITY ASSURANCE Sub Point - 4. (Page No 39) Request to delete this clause. Said Product is of Room Temperature. Cumulative time temperature indicator technology may unnecessarily increase the cost of product.	Deleted
		9. Additional Point- Request you to please accept manufacturing license of only Class C category. As Sickle cell Rapid test kits comes under Class C category for which license is issued by Central Licensing Authority - CDSCO as per Chapter 3, Rule 8 of MDR 2017.	*"Manufacturer should have valid own manufacturing license of the quoted item that should be valid on the date of tender opening packet 1. In case of failure to submit the same, the bid shall not be considered any further."* The Manufacturing License issued by CDSCO under Class C Category to be submitted.
4.	M/s Transasia Bio-Medicals Ltd.	**1. Point A-Description of the Test Kit. (Page No 38)** The rapid diagnostic kit should be point-of-care, qualitative, ICMR/CDSCO/US FDA /EU approved methodology (Competitive immunochromatographic/ Competitive Lateral Flow Assay (LFA) /any other approved method) assay for the simultaneous detection of Hb S and Hb A as bands in human whole blood capillary sample from finger/ heel prick for rapid diagnosis of sickle cell anaemia / disease. **Justification** Competitive assays prevents hook effect thus prevents false negative results and increases the sensitivity of the kit.	No Change
		2. Point E. QUALITY ASSURANCE Sub Point-4. (Page No 39) Request to delete this point. Cumulative time temperature indicator is generally used for cold chain product and Rapid kits are stable at room temperature.	Deleted
		3. Clause 6.2 (g) 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 the years i.e. 2023-24. **Justification** Kindly it may be noted that the licensing authority does not issue Non-conviction certificate od past years and hence many bidder will not able to provide last 2 years of Non-conviction certificate issued by the FDA/Drugs Controller of the State.	Agreed Non-Conviction Certificate of the firm from Chartered Accountant to be submitted for the last 2 years.
		4. Clause 6.2 (j) Currently manufacturing/production capacity certificate is	Agreed

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Sr. No.	Bidder	Query/ Classification Asked	Clarification/Amendment
		currently not specified under provision of Medical devices Rules, 2017 and hence is not issued by CDSCO.	Capacity Certificate from Chartered Accountant to be submitted.
5.	M/s Voxtur Bio Ltd.	**1. Point B. CONTENT OF THE KIT (Page No 38)** C. Disposable Plastic Specimen transfer devices with graduated 10µl mark. We provide a 5µl marked sample dropper, as the test requires 5µl of whole blood. Hence 5 µl Disposable Plastic Specimen transfer devices provided in our Kit collects perfect 5 µl whole blood for correct report, also approved by ICMR.	Point 4 (c), Page No. 38 may be read as Disposable Specimen through device (Dropper) with graduated 0-10µl mark.
		2. Point E. QUALITY ASSURANCE Sub Point-4 (Page No 39) The cumulative time temperature indicator technology may be used along with the product package to monitor recommended storage conditions during storage & transportation of the kits.	Deleted
6.	Additional Points	**Additional Points:-** **Point No. B. 4(h):-** Sterile lancets (optional*). **Point No. B. 4(i):-** Patient Test Data Sheet Cards (optional*) **Technical Specification**	**Point No. B. 4(h):-** Sterile disposable Lancet pack of 100 required to be submitted with the product. **Point No. B. 4(i):-** Patient Test Data sheet cards not required. Hence, Clause deleted. **Technical Specification:** - The test kit should be CDSCO approved & I.C.M.R validated.
All Certificated issued by Chartered Accountant shall mandatory include UDIN No.			

GM (Procurement)
CMSS

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Ministry of Health & Family Welfare (Government of India)
2nd Floor, Vishwa Yuvak Kendra, Pt Uma Shankar Dikshit Marg, Near Teen Murti Road, Opposite Chanakya Puri Police Station, New Delhi – 110021, India

Dated: - 21.05.2024

AMENDMENT NO. 1

TENDER NO: CMSS/PROC/2023-24/NTEP/061 Rate Contract for Procurement of Rapid Diagnostic Test Card Kits for Sickle Cell Disease Diagnosis under National Sickle Cell Anaemia Elimination Mission

1. **The following amendment in the submitted bid document is made.**

Sr. No.	Clause No.	Existing Clause	Amendment
1	**Clause 6.2 (n)**	Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life.	Agreed Accelerated data to be submitted along with 1 year of Real time data.
2	**Clause 6.2 (g)**	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.	Agreed Non-Conviction Certificate of the firm from Chartered Accountant to be submitted for the last 2 years.
3	**Clause 6.2 (i)**	Capacity certificate issued by Licensing authority should be submitted	Agreed Capacity Certificate from Chartered Accountant to be submitted.
4	**Technical Specification Point B. 4. (c) Page No 38.**	**Technical Specification Point B. 4. (c)** Disposable Plastic Specimen transfer devices with graduated 10 µl mark.	Point 4 (c), Page No. 38 may be read as Disposable Specimen through device (Dropper) with graduated 0-10µl mark.
5	**Point-E. (4) Page No. 39**	The cumulative time temperature indicator technology may be used along with the product package to monitor recommended storage conditions during storage & transportation of the kits.	Point-E. (4) – Deleted

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Sr. No.	Clause No.	Existing Clause	Amendment
6	**CDSCO has issued a guideline** that Sickle test falls under Class C category. Hence companies holding Class B license should not be considered.	Manufacturer should have valid own manufacturing license of the quoted item that should be valid on the date of tender opening packet 1. In case of failure to submit the same, the bid shall not be considered any further.	Manufacturer should have valid own manufacturing license of the quoted item that should be valid on the date of tender opening packet 1. In case of failure to submit the same, the bid shall not be considered any further. The Manufacturing License issued by CDSCO under Class C Category to be submitted.
8	**Technical Specification QUALITY ASSURANCE Point E. 4. (Page No 39)**	The cumulative time temperature indicator technology may be used along with the product package to monitor recommended storage conditions during storage & transportation of the kits.	Deleted
9	**Point No. B. 4(h)**	Sterile lancets (optional*)	Sterile disposable Lancet pack of 100 required to be submitted with the product.
10	**Point No. B. 4(i)**	Patient Test Data Sheet Cards (optional*)	Patient Test Data sheet cards not required. Hence, Clause deleted.
11	**Additional Point**	Technical Specification	Technical Specification: - The test kit should be CDSCO approved & I.C.M.R validated.

GM (Procurement)
CMSS

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Vishwa Yavak
Kendra,
Chanakyapuri
New Delhi - 21