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No. F-8(249) RMSC/EPM/M-2/NIB-588/2021-22/ 1313

Date:- 15/11/2021

Clarification/Corrigendum/Addendum

Subject:- Revised Technical Specification for NIB No. F-8(249) RMSC/EPM/M-2/NIB-588/2021-22/1118 Dated 28.09.2021 for item (i) Digital Hemoglobin Meter (Strip Based) (ii) Hemoglobin Meter Strips With Lancet

In Reference to subject cited above and NIB-588, the various representations received from the firms and issues raised by the Bidders are examined by the competent Authorities and technical committee. The following Corrigendum/Addendum is issued for inclusion in bid document as below:-

1. Revised Technical Specification of Digital Hemoglobin Meter (Strip Based)

S.No.	Technical Specification	Comments	
1.	Name	Digital Hemoglobinometer	
2.	Clinical purpose	Direct hand held battery operated device used for haemoglobin testing in clinical setting/population-based screening. The device is intended to be used for quantitative measurement of haemoglobin in capillary, venous or arterial whole blood samples taken from forearm, upper arm, hand thigh, calf, or fingers.	
3.	Should be used by	Medical officers/ Laboratory Technician/ Staff Nurse/ ANMs/ Mid-Level health providers at HWCs.	
Technical Characteristics			
1.	Working principle	Reflectance Photometry/ Absorbance Photometry	
2.	Parameter	Blood haemoglobin level	
3.	Range of Hb estimation	0-20 gm/dl	
4.	On screen patients result display	Yes (LCD Display)	
5.	Maximum volume of sample required	Not more than 50µl (One full blood drop)	
6.	Sample material	Capillary, venous or arterial whole blood	
7.	Measuring time	Less than one minute	
8.	Auto-calibration	Auto/self calibration	
9.	Sensitivity	More than 80%	Findings should be published in two peer reviewed indexed journals. The studies should be done in two different Indian settings by two independent teams of investigators.
10.	Specificity	More than 80%	
11.	Bias (Limits of agreement)	0.5 gm/dl (±1 gm/dl)	
Users Interface			
1.	Memory to store data	Desirable- up to 500 tests with date & time	
2.	Bluetooth Connectivity	Desirable	
3.	Data Transfer	Desirable- provision for data transfer to printer and PC	
Physical Characteristics			
1.	Dimensions (Metric)	Not more than 15cm×10cm×20cm	
2.	Weight (Grams)	Should not be more than 500 grams	
3.	Mobility/Portability	Should be mobile & portable	
Energy Source			

(Handwritten signature)

1.	Power requirements	Preferably battery operated. Should also be able to work on direct connection with electricity source (AC). The manufacturer must provide the charger & the cable for electricity power connection, wherever required by the equipment.
2.	Battery	3.7 volt Lithium-polymer rechargeable battery/1.5 volt 4 AA batteries/etc. should be able to perform up to 500 tests when full charged.
3.	Automatic shut down	On battery power the device should turn off after approximately of 5 minutes of no use.

Environmental Consideration:

1.	Working temperature	Should be able to perform in the temperature range of 10-40°C
2.	Working humidity	5-95%
3.	User's care/ Cleaning	The part of the equipment which comes in contact with blood should be easily cleanable. The factors which affect the haemoglobin estimation (ex. Haziness of lens) after repeated use should be clearly mentioned in the manual. The cleaning material for the lens & strip should be easily available.

Accessories

1.	Strip (Working Environment)	Disposable & stable at specified environmental (Working temperature- 10-40°C, Working humidity- 5-95%) condition.
2.	Strip (Storage Environment)	Should be stable at temperature of 25-30°C & humidity of 5-95%. Shelf life for storage should be at least one year.
3.	Strip packaging	Strip should be packed in packaging of 50 Nos. in a air tight bottle/vial (50 lancet should be provided free of cost with each 50 Nos. Strips), 200 Nos. Strips with 200 lancets and 1 Lancing pen Must be supplied free of cost with Digital Hemoglobin meter.

Quality Control

1.	Intra-sample variation (Accuracy)	Should be less than 5%
2.	Control solution to check quality	Should be available for low, normal and high haemoglobin values. Calibration facility should be available.
3.	Certification	US FDA/ European CE(notified body)/ ISO 13485:2016 certification.

Service Support

1.	Service support contact details	Contact details of manufacturer, supplier and local service agent to be provided
2.	Training	Free onsite training should be provided for the doctors, ANM and ASHA. At least, two trainings (one training at the time of installation and another training after six months i.e. refresher training)
3.	Warranty	3 Years


2. Amendment in Past Performance/supply experience

S.No.	Existing Tender Requirement	Amendment
1.	Past Performance/supply experience - The goods offered/being procured should have been in production for at least Three Year and Bidder should have supplied, installed and commissioned (if required) at least 10% of the indicative quantity of the goods under procurement in last 36 months.	Past Performance/supply experience - The goods offered/being procured should have been in production for at least One Year and Bidder should have supplied, installed and commission (if required) at least 10% of the indicative quantity of the goods under procurement in last 36 months.

3. Date extension of Bid:

Existing Dates			Extended Dates		
Last Date & Time of Online Downloading of Bidding Document	Last Date & Time of Online Submission of Bid	Date & Time of Online Opening of Technical Bid	Last Date & Time of Online Downloading of Bidding Document	Last Date & Time of Online Submission of Bid	Date & Time of Online Opening of Technical Bid
22.11.2021 06:00 PM	22.11.2021 06:00 PM	23.11.2021 03:00 PM	25.11.2021 06:00 PM	25.11.2021 06:00 PM	26.11.2021 03:00 PM

All other terms & conditions remains the same.


Executive Director (EPM)
RMSCL, Jaipur