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F-8(210) RMSC/EPM/M-2/NIB-491/2020-21/1-683

Dated: 02/09/2020

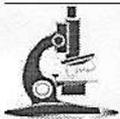


Clarification/Corrigendum/Amendment

Subject:-Revised Technical Specification for NIB No. F-8(210) RMSC/EPM/M-2/NIB-491/2019-20/3550 dated 17.02.2020 for item Haemoglobin Meter strip, Haemoglobin Meter Cuvette.

1. Revised Technical Specification of Haemoglobin strip –

S.N.	Specification							
1.	All strips should have at least 1 year expiry from the date of manufacturing and open vial stability should not be less than 3 months.							
2.	Test Strips should be stable on a working temperature of 10-40°C and working humidity should be 5-95%.							
3.	Auto disable lancet/safety lancet should be provided free of cost with each strip.							
4.	Strips should have packing of 50/100Nos.							
5.	Manufacturers should have the quality control provided to check the precision.							
6.	Equipment should be calibrated before supply and calibration report must be submitted.							
7.	<p>Note-</p> <p>1. Compatible Hemoglobin meter should be provided free of cost on purchase of every 2000 strips.</p> <p>2. Cost of one single strip should be provided in BOQ.</p>							
Technical Specification of Hemoglobin meter to be provided free of cost with strips-								
1.	Method : Reflectance Photometry/Absorbance Photometry							
2.	Strip should be reagent less/dry reagent and a factory calibrated analyzer.							
3.	Should work on single wavelength.							
4.	Accuracy of the system should be less than 5%.							
5.	Measuring Range: 0 to 20g/dl.							
6.	Manufacturer should have ISO 13485 certification.							
7.	Instrument complies with IVD Medical Device Directive 98/79/EC Analyzer and should carry CE mark (Related certificates should be submitted in Technical Bid).							
8.	<table border="1"> <tr> <td>Sensitivity</td> <td>More than 80%</td> <td rowspan="3">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.</td> </tr> <tr> <td>Specificity</td> <td>More than 80%</td> </tr> <tr> <td>Bias (Limits of Agreement)</td> <td>0.5 gm/dl (±1 gm/dl)</td> </tr> </table>	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.	Specificity	More than 80%	Bias (Limits of Agreement)	0.5 gm/dl (±1 gm/dl)
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Specificity	More than 80%							
Bias (Limits of Agreement)	0.5 gm/dl (±1 gm/dl)							
9.	Device should measure hb within 60 seconds.							



10.	Sample Material- Capillary, Venous or arterial whole blood.
11.	Sample Volume: Not more than 50µl (One full blood drop)
12.	Memory : up to 500 tests with date and time.
13.	Data Transfer: Provision for data transfer to printer and PC.
14.	Quality Control: Internal electronic self test.
15.	Power: Preferably Battery operated (3.7 volt lithium-polymer rechargeable battery/1.5volt 4AA Batteries), should also be able to work on direct connection with electricity source(AC).The bidder should provide the adapter and the cable for electricity power connection and equipment should be able to perform min. 500 tests when fully charged. Power Saver Mode: On battery power, the analyzer to turn off after approx 5 minutes of no use.
16.	The Machine will be approved after extensive demonstration by technical committee applying the standards of precision and accuracy.
17.	Warranty will be of 3 years from date of installation and Firm should free of cost repair/ replace the equipment in case of breakdown in warranty period.
18.	Operating manual should be provided with the Equipment, Contact details of manufacturer/supplier and local service agent to be provided.
19.	Free onsite training should be provided for the Doctors, ANM and ASHA.
20.	The company should submit technical compliance sheet as per technical specifications mentioning the make & model of quoted item along with catalogue in the Technical bid.
21.	Demonstration of equipment is must for final technical approval
22.	Provide the following details- 1. OEM Preventive Maintenance Schedule - 2. OEM Calibration Schedule – 3. Toll Free No/ Complaint lodge number- 4. Life of the equipment declared by OEM –

Revised Technical Specification of Haemoglobin cuvette

S.N.	Specification
1.	All Cuvette should have at least two years expiry from the date of manufacturing and open vial stability should be minimum one year.
2.	Cuvette should be stable on a working temperature of 10°C - 40°C.
3.	Auto disable lancet/safety lancet should be provided free of cost with each Cuvette.
4.	Cuvette should have packing of 50Nos/ 100Nos
5.	Manufacturers should have the quality control provided to check the precision.
6.	Cuvette may be reagent base or reagent free.
7.	Equipment should be calibrated before supply and calibration report must be submitted.
8.	Note- 1. Compatible Digital Hemoglobin meter should be provided free of cost on purchase of every 1500 Cuvettes. 2. Cost of one single Cuvette should be provided in BOQ.



Technical Specification of Digital Hemoglobin meter to be provided free of cost with Cuvette-	
1.	Device should based on broad spectrum photometric/isobestic points working on cyanmethhaemoglobin/azidmeth or imidazole./methemoglobin hemoglobin method.
2.	Device should have Coloured/ black and white LCD Display.
3.	Device should measure Hb within 5 seconds.
4.	Should in built with Li-Ion battery/power backup with AA or AAA batteries, over 24 hours usage with a fully charged battery
5.	Device Should programmed with detachable or Automatic cuvette holder.
6.	Should always ready for measurement, even in standby mode.
7.	Measurement accuracy should be $\pm 1.5\%$ compared to ICSH method.
8.	Measuring range 0–24 g/dL.
9.	Power supply 100–240 V AC , 50–60 Hz
10.	Should work on Dual wavelength to compensate for turbidity.
11.	Should find reference in WHO Manual to ensure high quality.
12.	Provision for Data Transfer to Printer and PC.
13.	Power Saver Mode: On battery power, the analyzer to turn off after approx 5 minutes of no use.
14.	Certification:- European CE(Notified Body) /US FDA and IVD approved.
15.	Transport Box should be supplied additionally with Equipment.
16.	Warranty – Three years from the date of installation.
17.	Quality control has to be run quarterly free of cost by the firm with minimum 3 levels and supplier should provide calibrator and calibration certificate once in a year free of cost during guarantee period.
18.	Company should have their own QC and R&D wing.
19.	Rate of Consumable item should be provided by bidder in BOQ.
20.	Final rate of consumable kit after negotiation will be freezed for two years.
21.	The company should submit technical compliance sheet as per technical specifications mentioning the make & model of quoted item along with catalogue in the Technical bid.
22.	Demonstration of equipment is must for final technical approval.
23.	Provide the following details- 1. OEM Preventive Maintenance Schedule - 2. OEM Calibration Schedule – 3. Toll Free No/ Complaint lodge number- 4. Life of the equipment declared by OEM –

2. Amendment in Bid Security/Prior Experience

S. No.	Tender Requirement	Amendment/ Clarification recommended by Firm
1	Bid security as applicable in bid condition or mentioned in table-1 and R.I.S.L. processing fee of Rs.1000.00 shall be deposited through three separate prescribed challans (formats enclosed in BF-1) and can be downloaded in any branch of the Punjab National Bank account no. 2246002100024414 anywhere in the country/or through D.D. /B.C. payable to RMSCL Jaipur. The bidder shall submit/upload scanned copy of all the challans in technical bid (Cover-A) Bid Security : 54,00,000 (For S. No. 1 Hemoglobin Meter Strip)	Bid security as applicable in bid condition or mentioned in table-1 and R.I.S.L. processing fee of Rs.1000.00 shall be deposited through three separate prescribed challans (formats enclosed in BF-1) and can be downloaded in any branch of the Punjab National Bank account no. 2246002100024414 anywhere in the country/or through D.D. /B.C. payable to RMSCL Jaipur. The bidder shall submit/upload scanned copy of all the challans in technical bid (Cover-A) Bid Security shall be accepted in Bank Draft/ banker cheque/bank Guarantee of a scheduled bank.



2	The goods offered/ being procured should have been in production for at least three financial years and a minimum of 10% units should have been sold and have been in operation satisfactorily for at least three years.	The goods offered/ being procured should have been in production for at least one year and a minimum of 10% units should have been sold and have been in operation satisfactorily for at least one year.
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3. Date extension of Bid:-

Please note that all clarification/amendment/corrigendum in technical specifications/bid conditions/time extension is the integral part of the bid document. This corrigendum/ addendum should be signed and annexed with bid document.

Previous Last Date & time of receipt of Bid Form	New Last Date & time of receipt of Bid Form	Previous Date & time of opening of technical bid	New Date & time of opening of technical bid
07.09.2020 06:00 PM	24.09.2020 06:00 PM	08.09.2020 11:00 AM	25.09.2020 11:00 AM

All other terms & conditions remains the same.


कार्यकारी निदेशक (ई.पी.एम.)
राजस्थान मेडिकल सर्विसेज कॉरपोरेशन
जयपुर