

CHIEF DISTRICT MEDICAL & PUBLIC HEALTH OFFICER, MALKANGIRI

No. 10757 /XIV-P (D&C)-18/2019, dated, Malkangiri the 29th Nov 2019

CORRIGENDUM

After pre-bid conference for procurement of Medical Equipments under SCA schemes held on 22.11.2019 at 11.00 AM in response to Bid Reference No.10053 Dt.11.11.2019 of CDM&PHO, Malkangiri the following modification of the Specification of some items of the Original Tender has been made. Further Specification for Fully automated Random Dry Biochemistry analyzer (Medium throughput) is included in the Original Tender Specification as Item 03(i). Hence the bidders have to download the modified and added Specifications directly from the website available at www.malkangiri.nic.in and submit their tender accordingly. **The last date of receipt of tender is extended up to 05.00 PM of 17.12.2019 through Speed Posts/ Regd. Posts only. Date of Opening of Technical Bid is also extended to 18.12.2019 at 11.00 AM.** The interested bidder who have intended to bid **Dry Biochemistry Analyzer** can be submitted their query if, any by **05.12.2019 up to 5.00 PM.**

The details changes/modifications are given below.

Sl. No	Tender Specification	Quarry raised by bidders	Remarks
Name of the Item: Electrolyte Analyzer			
	Measurement Parameter: Na (Sodium), K (Potassium), Ca (Calcium),	To Add two more parameters i.e Cl & PH	Amendment :CL is added with Na (Sodium), K (Potassium), Ca (Calcium),
	Range of measurement: 1. Sodium (Na+) 40 to 200mmol/L 2. Potassium (K+) 1.5 to 15mmol/L 3. Calcium (Ca+) 2 to 5.0 mmol/L	Range of measurement: 1. Sodium (Na+) 20 to 200mmol/L 2. Potassium (K+) 0.5 to 10mmol/L 3. Calcium (Ca+) 0.3 to 5.0 mmol/L 4.Chloride: 20 to 200mmol/L 5.PH: 6-9	Amended: Range of measurement: 1. Sodium (Na+) 40 to 200mmol/L 2. Potassium (K+) 1.5 to 15mmol/L 3. Calcium (Ca+) 2 to 5.0 mmol/L 4.Chloride: 50 to 200mmol/L
	It can be used for blood/plasma/serum, urine, body fluids, dialysate, aqueous & QC Fluids	It can be used for blood/plasma/serum & urine, only	It can be used for blood, serum, plasma and urine only
Name of the Item :High Pressure Liquid Chromatography (HPLC)			
	The system should be CE(IVD) & USFDA approved	The system should be CE(IVD) OR USFDA approved	NO Change

<u>Computed Radiography System</u>			
	Compatible computer System with 2 medical grade monitors	Compatible computer System with 2 TFT monitors	Amended: Compatible computer System with One Medical Grade Monitor & one TFT /LCD/LED monitor
	Digitizer (CR) system should have capacity to process more than 70 or more cassette/films per hour of 14 X 17" size.	Digitizer (CR) system should have capacity to process more than 40 or more cassette/films per hour of 14 X 17" size at a 6pixels/mm	Amendment: Digitizer (CR) system should have capacity to process more than 40 or more cassette/films per hour of 14 X 17" size at 5 pixels/mm or more.
	System should be USFDA/CE/BIS approved	System should be USFDA & CE approved	No Change
	It should have a resolution of 5 pixels/mm (Minimum) for standard resolution cassette &up to 20pixels/mm or more.	It should have a resolution of 5 pixels/mm (Minimum) for standard resolution cassette &up to 10pixels/mm or more.	Amended: It should have a resolution of 5 pixels/mm (Minimum) for standard resolution cassette &up to 10pixels/mm or more.
<u>300 mA HF X-ray machine</u>			
	<u>300 mA HF X-ray machine</u>	500mA x-ray machine	No Change
Fully automated Random biochemistry analyzer (Medium throughput)			
	Throughput: 300 tests/hour, up to 450tests /hour with ISE;	Throughput should be more than 170 test/Hour Biochemistry and 300 test /hour with optional ISE facility	Amendment:
	Suitable Water plant/ Purification System on RO or any latest technology has to be provided along with the machine to produce more than the desired volume for running the system.	If the water consumption of the machine is more than 3liter/hour then bidder should provide a distilled water plant	No change

	Minimum reaction volume of 150 µl built in/ standalone.	Minimum reaction volume of 250 µl built in/ standalone.	Amended:- Minimum reaction volume of 250 µl built in/ standalone.
	Must have built in Cooled reagent Compartment (5-15degree centigrade) with minimum 350 ml with sample volume 2-70 ml with increment of 0.1micro and 1micro resp. The refrigerated compartment should have at least 40 reagent positions.	Must have built in Cooled reagent Compartment (5-15degree centigrade) with minimum 350 ml with sample volume 2-70 ml with increment of 0.1micro and 1micro resp. The refrigerated compartment should have at least 30 reagent positions.	Amendment: Must have built in Cooled reagent Compartment (5-15degree centigrade) with minimum 350 ml with sample volume 2-70 ml with increment of 0.1micro and 1micro resp. The refrigerated compartment should have at least 30 reagent positions.
	Separate reagent probe for R1 and R2 and sample.	❖ system should have separate probe for probe for reagent and separate probe for sample along with that dedicated syringe should be there for sample and dedicated syringe for reagent to affect the accuracy of the result	❖ Amendment: system should have separate probe for probe for reagent and separate probe for sample.
Colour Doppler with Echocardiography			
	The system should incorporate facility for high resolution 2D, M mode, PW, Colour imaging Modes. It should be able to display combined modes, Dual Live modes& Should have provision for upgrade to 3D/4D& Electrograph in feature.	The system should incorporate facility for high resolution 2D, M mode, PW, Colour imaging Modes. It should be able to display combined modes, Dual Live modes& Should have provision for upgrade to 3D/4D Electrograph feature.	Amended: The system should incorporate facility for high resolution 2D, M mode, PW, Colour imaging Modes. It should be able to display combined modes, Dual Live modes& Should have provision for upgrade to 3D/4D Electrograph feature
	Note: Each transducer cost should be separately quoted which shall be taken into evaluation however order shall be placed as per requirement of the user.		

TECHNICAL SPECIFICATION (INCLUDED)

03(i). Fully automated Random Dry biochemistry analyzer (Medium throughput)

GMDN name: Fully automated dry biochemistry analyzer/Fully automated Random dry Biochemistry analyzer

GENERAL

1 USE

1.1 Clinical purpose: The Fully-automated Biochemistry Analyzer measures Biochemical indexes by analyzing blood and other body fluid, then combines with other

Clinical information, to help diagnose disease, evaluate organs function, identify disease

gene and determine the norm for future therapy.

1.2 Used by clinical department/ ward: Diagnostic laboratory

TECHNICAL

2 TECHNICAL CHARACTERISTICS

2.1 Technical characteristics (Specific to this type of device):

- Fully automated, random access dry bio-chemistry analyzer with micro slide technology based chemistry
- The equipment should be capable for all Routine STAT and special Biochemical tests including specific protein, therapeutic drugs, drugs of abuse and user defined applications.
- Assay Mode: Photometric end point, immuno-rate & direct ISE
- Throughput: At least 250 tests/hour, up to 40 samples at a time & minimum 40 on board parameters at a time. Continuous load and unload of routine samples as well as STAT samples.
- Equipment should use disposable tips for sample aspiration & dispensing
- Equipment should have detection capability for Clot, bubble & sample viscosity along with liquid level detection.
- Must have direct ISE Unit for Na, K and Cl Measurement..
- System should have refrigerated and humidity controlled reagent compartment/disk for better reagent stability.
- Must be close ended system with bar code reading for samples and reagents.
- System should have advanced reagent management facility to manage multiple reagent Lots, and Online inventory of the reagents with number of remaining tests and expiry on screen.
- System should have Resolution: 0.0001A or better with wavelength range of 340-650 nm
- System should be supplied with PC, windows based interface and Bi-directional Connection.
- Auto diagnosis of machine errors with message and correction steps.
- The shelf life of reagents should be more than 6months.
- Fluid consumption should be less than 1 litre/24 hours
- Sample dead volume maximum 100 µl in sample cup and maximum 30 µl in pediatric cups.
- Analyzer should have highly stable calibration technique, with calibration stability of at least 4 to 6 months or lot specific. Calibration should be linear factor, 2 point/point to point/ multi point and Exponential with maximum 8 calibrators per test.
- Sample type should include Serum, plasma, Urine, CSF, body fluids and supernatant with at least 40 sample positions and all position can be use as

for STAT sample. Sample tube size: Multiple primary tube sizes (diameter 12 to 16mm, height 55 to 100mm), Pediatric cups

- Should have Light Source with minimum 1000 hrs life cycle with bar code facility with option for bar code on/off.
- Should have 5,000 Patient Result Storage
- Online QC Tracking with Levy and Jennings Chart for up to 30 different points.

2.2 User's interface: Built - in / automatic

2.3 Software and/or standard of communication (where ever required): Built - in/ Automatic/ compatible, window based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis.

3 PHYSICAL CHARACTERISTICS

3.1 Dimensions (metric) : NA

3.2 Weight (lbs, kg) : NA

3.3 Configuration: NA

3.4 Noise (in dBA): NA

3.5 Heat dissipation: Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism.

3.6 Mobility, portability: Stationary lab Installation

4. ENERGY SOURCE (electricity):

4.1 Power Requirements: "Recharging unit: Input voltage- 220V-240V AC, 50Hz

4.2 Battery operated: Online Battery backup with 30mints (On line UPS)

4.3 Tolerance (to variations, shutdowns): $\pm 10\%$ / 00

4.4 Protection: Should have over-charging cut-off with visual symbol.

4.5 Power consumption

5 ACCESSORIES, SPARE PARTS, CONSUMABLES

5.1 Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (closed system) "

1. Accessory list to be provided with equipment

2. External printer.

3. UPS on line pure sine wave for back up of system with PC and IT peripherals for half hour.

4. Closed system

5. light source-4no

6. Probes -2nos

7-All tubings required for preventive maintenance should be replaced in scheduled time in the warranty period.

NOTE: The number of light source, probes, tubes, glass cuvettes, tubings, filters etc has to be replaced by the supplier in view of the preventive maintenance in time as per the manual of the quoted model in free of cost within the warranty period.

6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS

6.1 Atmosphere / Ambiance (air conditioning, humidity, dust ...):

1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.

2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%."

6.2 User's care, Cleaning, Disinfection & Sterility issues:

1) Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a cover.

2) Sterilization not required."

7 STANDARDS AND SAFETY

7.1 Certificates (pre-market, sanitary) : Performance and safety standards (specific to the device type);Local and/or international

1. Should be USFDA/CE (from a notified body) as per IVD.
2. Manufacturer should be ISO 13485 certified for quality standards.
3. Shall meet internationally recognized for Electromagnetic Compatibility (EMC) for Electro medical equipment: 61326-1 4.Certified to be compliant with IEC 61010-1, IEC 61010-2-281

8 TRAINING AND INSTALLATION

8.1 Pre-installation requirements: nature, values, quality, tolerance

- 1) Availability of 5 amp socket
- 2) Safety and operation check before handover.
- 3) AC to be provided

8.2 Requirements for sign-off: Certificate of calibration and inspection from the manufacturer

8.3 Training of staff (medical, paramedical, technicians)

- 1) Training of users on operation and basic maintenance;
- 2) Advanced maintenance tasks required shall be documented

9 WARRANTY AND MAINTENANCE

9.1 Warranty: 3 years

9.2 Maintenance tasks : NA

9.3 Service contract clauses, including prices: NA

10 DOCUMENTATION

10.1 Operating manuals, service manuals, other manuals Should provide 2 sets (hardcopy and soft-copy) of:-

- 1) User, technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams;
- 2) List of equipment and procedures required for local calibration and routine maintenance;
- 3) Service and operation manuals (original and copy) to be provided;
- 4) Advanced maintenance tasks documentation;
- 5) Certificate of calibration and inspection"

10.2 Other accompanying documents List of important spares and accessories, with their part numbers and cost;

11.1 Service Support Contact details (Hierarchy Wise; including a toll free/landline number) "Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;"

11.2 Recommendations or warnings any warning signs would be adequately displayed

The cost of the cartridge for individual parameters has to be quoted in the price bid which may be taken into consideration at the time of evaluation. The cost of CMC /AMC may also be quoted with the price bid for evaluation.

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