Notice Inviting e-Tender

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Supply & Commissioning of different medical equipment to be used at ECMO Hub for treatment of COVID affected patient
(Submission of Bid through *online*)

Bid Reference No.: WBMSCL /NIT- 194/2021	Dated –21.06.2021

The following amendment have been made in the tender document,

Amendment –II (Revision of Technical Specification)

The revised technical specifications for the item is given below,

Item No – II

Manual Activated clotting time (ACT) machine

1. Equipment for assessment of Activated clotting time (ACT).
2. It should be compact & portable for bed-side testing.
3. It should have inbuilt mechanism to heat the cartridge.
4. Range 37.0.±2 Degree c.
5. It should require less than 2ml of blood for each test.
6. It should be capable of displaying two reports at one time.
7. Reagent and accessories for 100 tests to be supplied with machine.
8. Measurement range 0-1500 sec.
9. LED/LCD based screen for displaying results (fully digital display screen)
10. Environment-15degree-30degree C.
11. One Button Operation- Easy to Use.
12. Should be US FDA/EUROPEAN CE approved.
13. System should be microprocessor controlled designed to determine coagulation end points in whole blood, Citrated blood and plasma samples. Dual well testing method.
14. Accepts actalyte ACT tubes/cuvettes with celite, glass bead activator,

15. MAX ACT tubes with blended activator; all international technidyne Hemochron tubes. List of consumables with price frozen for 5 years should be quoted separately. List of users must be enclosed.
16. In case of malfunction/breakdown, the company should provide temporary back-up support within 24 hrs of registering the complaint till the time machine is repaired and returned. It should have a battery backup of 2 hrs.

Item No – III

Fiberoptic Bronchoscope

I. Fiber Bronchoscope

1. Should have minimum 90º field of view.
2. Should have a depth of field of 3 to 50 mm.
3. The insertion tube should have maximum 6mm diameter.
4. Should have at least 160º upwards and 90º downwards angulations.
5. Should have a total length 820 mm with working length of at least 540 mm.
6. Should have an instrument channel of at least 2.5 mm inner diameter.
7. Should have a light guide illuminating system.
8. Should be supplied with all standard accessories including different type of biopsy forceps, cleaning brushes and storage box.

II. Digital Camera System (High Definition)

1. Should be a single chip camera technology.
2. Should have composite video outputs and one S-video output.
3. Should have anti-moister filter for fiber scopes.
4. Should have fully automatic exposure control.
5. Should have automatic white balance with memory function.
6. Should have horizontal resolution of more than 450 lines.
7. Should provide compatible optical interface for the fiber bronchoscope supplied. 8. Should be supplied with 21" or more flat LED monitor.
9. Should work with input 200 to 240Vac 50 Hz supply.

III. LED Light Source

1. Should have 150 watts or more/ equivalent light source
2. LED Light Source
3. Light intensity control
4. Should have quiet operation
5. Should have light intensity indicator
6. Fiber optic light cable with straight connector size 4.8mm or above, length 300 cm or above , heat resistant

IV. Others

1. Should be supplied with suitable trolley
2. Trolley should have at least 5 power sockets to connect the camera, monitor etc.

V. Battery Operated Light Source

1. Should be light weight, LED light, battery operated, rechargeable type, charger to be provided

VI. Should be supplied with standard accessories and additional battery for battery operated Light Source

VII. Should have safety certificate from a competent authority CE issued by a notified body registered in European Commission / US FDA certificate

VIII. A laptop should be supplied with the following specifications - 1TB HDD, 4 GB RAM, i5 processor, 15 inch monitor, branded laptop Dell/ HP, mouse, Video grabber card, and software with necessary cables to connect the video. The software should be able to generate reports by including the images and the findings

IX. Color Inkjet Printer should be supplied with the machine

Item No – V

THROMBOELASTOGRAPH (TEG) ANALYZER

1. Complete clot analysis system with computer-based feedback for individual component-based clot analysis
2. Must provide all parameters in every single reading like initiation of clotting, maximum amplitude, beginning of fibrinolysis, shear angle etc. as a dynamic graph
3. Two (2) independent measuring channels per analyzer, up to eight (8) channels per computer.
4. Must include all cables and parts required to connect to the computer system.
5. Cup-drive-line-synchronized, with synchronous motor.
6. Each independent measuring channel must provide complete information under one roof (not in isolation) from clot formation to clot lysis.
7. Device must perform Native, Citrated whole blood, heparinised and citrated heparinised samples.
8. Device should have an Analog to Digital converter box.
9. Software should have facility to view results of all eight channels simultaneously, allow to view/print previous data, store data, ease data management.
10. Monitoring software and hardware (compatible computer with printer) must be provided.
11. Device must perform the platelet mapping test and monitor the adequacy of LMWH.
12. Should perform Electronic, Optical, Mechanical and Biological Calibration.
13. Temperature control- individual temperature control for each column.
14. Measuring Technique-Shear elasticity of a coagulating sample, determined by motion of the pin.
15. Transducer- Electrical-mechanical/optical transducer of movement of torsion wire connected to the suspended pin.
16. Sample Volume- 360-500 ~l
17. Power - External Power supply as per Indian standards; capable of running on battery back-up
18. Should be ready-to-use at all times; Initial Warm-up time- less than Five (5) minutes to warm sample.
19. Adequate disposables, reagents and kits must be supplied for optimum running of the system for at least two years (guarantee period)
20. Should be European CE or US FDA or BIS approved
21. Training must be provided to required number of hospital staff including nurses for optimum use

Item No –IX

Plasma sterilizer

1) A Low temperature hydrogen peroxide plasma technology based high speed sterilization system.
2) The sterilizer should use low temperature H_2O_2 (Hydrogen Peroxide) plasma sterilizer technology.
3) Should have cycle temperature of less than 55 degree Celsius.
4) Should be environment friendly and have no toxic by-products
5) Should have sterilization chamber more than 90 Litres usable volume with removable shelf.
6) Should have Microprocessor controlled system with clear user interface for control and display of cycle phases & parameters.
7) Should have inbuilt printer and touch screen LCD control panel
8) Should not have a need for to have additional Dryer Machine.
9) Should be easy to install without and civil/plumbing work and should be mobile on wheels for easy movement.
10) Should be European CE or US FDA approved. The process of the sterilizer has to be certified with EN ISO 14937 (certificate should be attached)
11) Should completely monitor its operations with clear LCD display and alarms.
12) Total cycle time should not be more then 40-80 minute.
13) The concentration of hydrogen peroxide should not exceed 50% to 60 %.
14) Must be able to sterilize flexible lumened instruments with inside diameter of 1 mm and length of 1000 mm or more without any additional accessories like booster/adapter. proof of lumen claim should be attached with the bid .
15) Should be able to sterilize rigid stainless steel lumened instruments with inside diameter of 1 mm and length of 500 mm.
16) The system should operate on single/three phase supply with no additional requirement for civil work like plumbing, water and drainage etc.
17) There should be minimum 10 installations with performance certificates for quoted model in India preferably in govt. institutes.
18) Should be supplied with all accessories like Incubator, Sealing machine. The machine should be provided with all the consumables needed to make the machine fully functional. The machine should be supplied with all the consumables required to run for a minimum of 200 cycles.
19) Should be supplied with printer paper and Printer Ink cartridge – 10 each
20) Should be supplied with minimum of six instrument trays and matching instrument tray mats (silicon) of three different sizes and lids.
21) Should also quote the prices for tender bill for consumables –

I. H2O2 Liquid Sterilant
II. Chemical Indicator Strips
III. Chemical Indicator Marked record keeper (Card/stickers)
IV. Biological Indicator vials
V. Packaging rolls in various sizes

Item No –XI

Portable Suction Machine

To be used at OT.

1. Should be designed for draining blood and other fragmetic secretions in operation room and emergency room in hospital.
2. Should be fitted with oil immersed noiseless motorized vacuum pump.
3. Cabinet made from stainless steel.

4. Two glass jars on the top of having minimum capacity of 2ltrs fitted with rubber air tight lids and overflow safety device.
5. Should be supplied with adequately long pressure tubing providing required pressure.
6. Should have vacuum control by knob.
7. Should be mounted on four caster wheels.
8. Should have motor of 1/4Hp capacity and power consumption not more than 250 Watts
9. Should have vacuum at least between-100mmHg to at least 575 mmHg (-75 kPa).
10. Noise level: should be <=45 dB
11. Suction capacity: 40-60 litre/minute or wider; provision for change of suction rate
12. International standards: The unit should comply with international standards and should have European CE or FDA certification.
13. Should have electrical safety certification

Item No –XII

Forced Air Warmer

1. Should have the facility for Forced Air warming.
2. Should have Two Air flow setting for the air flow 48cfm / 32cfm for adult and infant patient in same machine.
3. Should have single Hose for all type/Size of Blankets.
4. Should have at-least 3 temperature control sensor
5. Should have over temperature sensor at the end of the Hose.
6. Should have Digital Meter
7. Should have microprocessor control system to allow a multi-staged Heater.
8. Three heater elements to eliminate flicker of OR lighting.
9. Should have Temp. Range – Ambient to 43°C + 1.5°C Max.
10. Should have High Efficiency Air Filter of 0.2 Micro size.
11. The weight of Equipment should be less than 8.0 kg.
12. Should distribute even temperature across the blankets and patient.
13. Blanket should be approx. 200 gm. weight.
14. Should have safe warming avoids tissue damaging.
15. The equipment should have easy attachment to IV pole, Bedrail or Freestanding.
16. Should have service facility locally.
17. Meet Regulatory standard for leakage current.
18. The company and its products should be registered with the European CE or US FDA.
19. Should have electrical safety certification

Item No –XIV

Vibration free refrigerator for storage of Blood

1. **Purpose of Equipment**: A refrigerator for storing whole blood or red cell packs in a blood bank.

2. **Type of Equipment**: Compression type refrigerator that uses CFC–free refrigerant gas/ green gas.

3. **Capacity**: 150 Ltrs.

4. **Type**: Vertical

5. **Construction**:

- Internal: Stainless steel (min. 22g).
- External: Corrosion Resistant (CR at least 1mm thickness).
- External Paint: Heat resistant, minimum 7 tanks process (Duly certified by the manufacturer).
- CFC - free insulation.
- Drawers: Roll out type, Stainless steel scratch resistant material, perforated on the bottom for perfect and homogeneous distribution of cold air. The separators, if provided in the drawers, should be such that blood bags are held in a vertical position with the label side visible. There should not be any obstruction while rolling out the drawers for loading or unloading purpose.
- Door:
  - Glass door, opening angle should be minimum 90° or more.
  - Insulation and gasket should be silicone/rubber.
  - Good quality Polyurethane Insulation should be minimum 50 mm.
  - Door opening audio and visual display alarm.

6. **Temperature range**:
   - 2°C to 6°C adjustable / factory set temperature with setting accuracy of ±0.5°C (or better).
   - User Parameter settings: set point, high alarm point, low alarm point, buzzer off time, C/F Temperature choice.

7. **Electrical Characteristics**: Input voltage: 220/240V 50Hz.
   - A line voltage corrector of appropriate rating will form part of standard configuration. The servo voltage corrector should be capable to correct input voltage range from 160 – 280 V AC to 220/240 VAC , 50Hz.

8. **Minimum Compressor Starting Voltage**: 22% below nominal voltage.

9. **Internal Temperature Control**:
   - Electronic temperature control, range +2 °C to +6 °C with setting accuracy of ±1 °C whatever the load.
   - Fan air cooling.

10. **External Ambient Temperature**: Performs in an ambient temperature of +10 to +33°C

11. **Hold-Over Time**: A full load of blood packs at +4 °C (±1 °C) takes at least 30 minutes to rise to above +6 °C

12. Internal temperature hold over time in case of power failure should be at least 1.5 hours, if door not opened.

13. **Cooling Down Time**: A full load of blood packs at +25 °C takes a maximum of 1 to 3 hrs for all the packs to reach below +6 °C.

14. **Temperature Monitoring:**

- Digital temperature (LED) display with 0.5°C or lower gradation.
- Microprocessor based temperature controller with integrated audio visual temperature and power alarm function with digital monitoring display.
- Independent safety thermostat to avoid negative temperatures.
- At least 2 Temperature Sensors: Sensor for temperature monitoring shown on front display, Sensor for managing use of compressor.

15. **Temperature recording device**

- Visual and audible alarm system indicating unsafe temperatures.
- Battery backup for alarm and temperature recording device.
- Facility for remote alarm.
- Seven days circular chart recorder.
- Seven days graphic temperature recorder with range of 0°C to +15°C (or wider) with data logger & program reader, with supply of free circular charts for a period of warranty.
- Ideal compressor running time of 27% at room temperature.
- Door locks should be available.
- Audio and visual alarm for variation in temperature.
- Interior lighting.
- External ambient temperature +10°C to +40°C.
- Auto defrosting.
- Cooling time – Maximum 1 to 3 hours for all the packs to reach below +6°C.

16. **Certifications:**

- **Product certification:** European CE or BIS or USFDA
- The Company should have ISO 13485

Item No –XV

Fully Automated Coagulation Analyzer

1. System: Fully automated random-access coagulation analyzer with multiple measuring modes for clot based, chromogenic and immune turbidimetric tests.
2. Test panel/ Assay: provisions for PT, APTT, FIB, TT, Extrinsic Factors & Intrinsic factors (Factor 2, 5, 7, 8, 9, 10, 11, 12), ATIII, DRVVT Screen & Confirm, Chromogenic Protein C, Chromogenic free Protein S and D-dimer.

The cost/ test (Rate offered must be exclusive of GST) should be provided for the test/ assay mentioned in the Price format [as per Form 8(b)] which will be taken for evaluation.

The cost/ test should be calculated as per the following criteria and cost of one test should be mentioned in the Price format [as per Form 8(b)].

The cost (exclusive of GST) of all reagents, consumables, accessories, dead volume, cuvettes, balls, cleaner or equivalent solution which are required to perform 100 test/ assay at a time should be considered.

For e.g. to perform 100 tests, 2 cleaning process may be required, in such case the cost of 2 cleaning procedures divided by 100 shall be included in the cost per test. Similarly all reagents, consumables, accessories, dead volume, cuvettes, balls, etc required to perform 100 tests divided by 100 shall be included in the cost per test.

3. The bidder should produce a certificate from the manufacturer stating that all the above tests can be performed and validated in the instrument.

4. The consumption/ volume of reagent, dead volume, accessories, consumables, cuvette, balls, and any other items which are required to conduct 100 test / assay of all parameters should be mentioned in the offer form. The consumption specified and the rate offered in the the Price format [as per Form 8(b)] should tally. The price bid will not be considered for evaluation if any discrepancy in the quantity mentioned in the offer form and price bid.

5. The standard pack size and rate for the above parameters should also be mentioned in the Price format [as per Form 8(b)] (Ensure the pack size and the rate is used for calculating the cost/ test calculation). This rate shall be fixed for 3years.

6. The number of QC reagent required to perform QC test for the above listed parameters should be mentioned in the offer form. The cost along with pack size of the QC's should be mention in the the Price format [as per Form 8(b)] and which will not consider for L1 evaluation.

7. The number of calibrators required to calibrate the above listed parameters should also be mentioned in the offer form. The cost along with pack size of the calibrators should be mention in the the Price format [as per Form 8(b)] and which will not consider for L1 evaluation

8. Test / Assay Principle: Clot Based, Chromogenic & Immunoturbidimetric Assay.

9. Main Detection Methodologies: Electromagnetic Ball method / Photo optical Method / Optical Density for chromogenic & Immunoturbidimetric tests.

10. Light source: Two or more wavelength with optical clot waveform analysis/ optical measurement 11. Sample handling capacity: Rack / drawer system with 25 sample tubes with continuous loading facility. Any tube adaptation including paediatric Eppendorf and pour-off. STAT any time and any position.

12. Reagent handling capacity: Minimum of 20 reagent position with continuous rack / drawer loading.

13. Reaction cuvettes: Minimum 400 test cuvettes loading capacity with > 400 test walkaway facility, and continuous loading of consumables during analyses.

14. Throughput of: ?120 Test / hour for PT + APTT, PT+ APTT + FIB ?100 test / hour

15. Open system: for any coagulation reagents with at least 80 numbers of assay definitions.

16. Assay Calibration: with multiple calibrations curve with automatic Dilution options.

17. Quality control: Fully fledge QC program with Levey Jennings charts, Westward rules modules. 18. Operating interface: Icon based touch screen software.

19. Maintenance: Fully automated task with less than 10 minutes per day. Maintenance free fluidic and optical system.

20. Alarm system to detect any error in the system/ operation.

21. UPS with backup suitable for the machine.

22. Machine should be working in at least two reputed lab/medical college.

23. Should have safety certificate from a competent authority European CE or US FDA certificate.

Amendment –III :

Only for Item No –XV (Fully Automated Coagulation Analyzer), the new Price format has been included:

Form 8(b): Details of cost of reportable test result and Reagent pack

Sl. No.	Test / Assay Regent	Test interval	Cost of reportable test result	Pack Size (No. of test in each pack)	Cost of pack
				(a)	(b)
1.	PT	Daily			
2.	APTT				
3.	FIB				
4.	TT				
5.	Intrinsic & Extrinsic Factor				
a.	Factor 2	Twice in a week			
b.	Factor 5				
c.	Factor 7				
d.	Factor 8				
e.	Factor 9				
f.	Factor 10				
g.	Factor 11				
h.	Factor 12				
6.	ATIII	Daily			
7.	DRVVT Screen & Confirm				
8.	Chromogenic Protein C				
9.	Chromogenic free Protein S				
10.	D-dimer				
11.	Quality Control (Cost of 100 μl should be quoted in place of Cost per test)				

N.B.

a) Quoted costs should be excluding of GST;

b) The bidder should also include the following during calculation of reportable test result e.g. to perform 100 tests, 2 cleaning process may be required, in such case the cost of 2 cleaning procedures divided by 100 shall be included in the cost per test. Similarly all reagents, consumables, accessories, dead volume, cuvettes, balls, etc required to perform 100 tests divided by 100 shall be included in the cost per test.