



RAJASTHAN MEDICAL SERVICES CORPORATION LTD.

D- Block, SwasthyaBhawan, TilakMarg, C-Scheme JAIPUR (Raj)



Ph. No. 0141-2223887, Fax No. 0141-2228065

CIN: U24232RJ2011SGC035067

E-Mail -edepmrmsc-ri@nic.in

No. F-8() RMSC/EPM/M-1/NIB-528/2020-21/264

Dated: 15/12/2020

CLARIFICATION/CORRIGENDUM/ADDENDUM

Subject: Amended Technical Specification and revised bid schedule of bid document of item 1. Refrigerated Centrifuge for Blood Components 6-8 Bags 2. Centrifuge (Micro-plate) , under No. F-8() RMSC/EPM/M-1/2020-21/NIB-528/116 date: 14.10.2020

In reference to subject cited above NIB-528, various representation received from the firms and issues raised by the bidder are examined by the competent authorities and technical committee. The following clarification/corrigendum/addendum is issued for inclusion in bid document of items as below:-

Revised Technical Specifications of Refrigerated Floor Centrifuge for Blood Component Separation:-

1. For separation of blood components like packed cells, platelet rich plasma, platelet concentrate, plasma. Cryoprecipitate and Buffy coat.
2. Microprocessor controlled system to make operation **automatic**.
3. Programmable memory: Memory with tamper proof facility. The centrifuge must be able to store 9 or more program
4. Stainless steel chamber Easy to clean, corrosion resistant with provision of both drain and condense water collection container
5. CFC Gas free refrigerant.
6. Swing buckets blood bank rotor: With metal buckets, 4x1900-2000 ml. wind-shielded, 8 quadruple blood bag systems of 450 ml with filters, with SAGM bag and empty satellite bags. Machine should have facility to hang the rotor lid at the centrifuge door.
7. Removable plastic cups (adapters) with smooth edges to hold double/triple/quadruple, with provision to hold balancing weights, at the sides of the insert so it will not come in contact with blood bags. Supplied with set of balancing weights
8. Removable plastic inserts having smooth edges with built in hook adapter to spin buffy coat or small volume of blood. The metal plate and hook should be made of same material with clean finish. The insert should have provision to hold balancing weights at the sides so it will not come in contact with blood bags. Supplied with set of balancing weights.
9. **During supply of electricity or during absence of electricity, the safety lock of the lid should remain closed during run as long as rotor moving. This equipment should have facility of mechanical opening during the absence of electricity.**
10. Centrifugal force 5000-6000g.
11. Speed variation: Micro processor controlled rotor speed to within 10 rpm of set value. Acceleration and deceleration profile shall be available.
12. Temperature range: -10°C to + 40°C.
13. Micro processor controlled rotor temperature, within 1°C of set temperature regardless of the Centrifuge speed.

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14. Programmable time: 0-99 minutes with minimum resolution of 1 minute.
15. Digital display of temperature (2 digit), speed/RCF (4 digit) and time (3 digit or more).
16. Rotor imbalance detection: Automatic shut down of centrifuge if rotor load difference on opposite sides is 80 gram or more, with appropriate error message. The imbalance should be detected within 1200 RPM speed. Should incorporate alarms for imbalance detection, lid interlock, over temperature, rotor over speed.
17. Power requirement: 230 volts, 50 Hz. Single phase AC supply.
18. The equipment shall be suitable for operation from 0 to 40°C at 90% Relative humidity. Electronic circuitry shall be tropicalised for this ambient condition.
19. Noise and Vibration free operation at maximum speed. Noise level ≤ 55 to 58 dB. **Noise level related test report from NABL laboratory shall submit along with technical bid.**
20. The equipment shall have lockable castors.
21. Protection of data: In event of power interruption or complete failure data should remain stored.
22. Should have a provision for external connectivity.
23. It shall have a security lock to the unauthorized opening of the equipment.
24. Automatic line voltage corrector/Voltage stabilizer: A Line voltage corrector of appropriate, rating should form part of standard configuration Copper winding single phase automatic line voltage corrector conforming to IS:9815(PT.1)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
 1. Capacity/rating: 10 KVA. As per the requirement of the equipment.
 2. Input voltage: 160 to 260 volts, 50 cycles
 3. Output voltage: 220 volts to 240 volts
 4. The equipment should be supplied with 2 meter chord at input and fitted with plugs of appropriate rating (15 Amp.)
 5. Make of the line voltage corrector shall be indicated.
 6. **Should have overload protection.**
25. **Device should have USFDA approval / CE certificate issued by a notified body registered in the European commission, under relevant category. Related documents / certification shall be submitted along with technical bid.**
26. The manufacturer should be ISO 9001:2015 & ISO 13485:2016 certified. **Related documents / certification shall be submitted along with technical bid.**
27. Guarantee: Three years on equipment from the date of installation.
28. CMC: CMC will be given @5% of net rate - exclusive GST (as applicable) and yearly escalation of 5% on last year's CMC price: The CMC may be awarded for five years (on yearly basis) after completion of Guarantee period of three years.

Wet demonstration to check Quality Control counts and Yield of blood components to be satisfactory as per the NACO/AABB guidelines. Also should demonstrate specifications of Centrifuge with all quoted accessories as per tender specifications. The parameters like Speed and Temperature to be verified with calibration tools like tachometer and temperature probe respectively. The tools should use traceability of NABL standards with valid certificates.



Company should have **Technical Expert support** and should provide onsite training. Please give details of your set up with full address, contact number and names of **Technical Expert** with ID and address proof.

Other terms and condition to be covered during 03 years guarantee period by the supplier-

Response time- <48 Hours after logged the complain in complain portal
Service hours- As per health facility schedule.
Preventive Maintenance Schedule (PM)- **minimum 02PM in a year**
Calibration Schedule - **minimum once in a year.**
Up Time - 95% (346 Days)
Technical & Application Support, Demonstration & Trainings - As & when required
Toll Free No –
Life of the equipment - As per OEM

Revised Technical Specifications Microprocessor based CAT/Gel Card Centrifuge with Incubator:-

1. Purpose of Equipment:

- a) Immuno-hematologic Gel/ CAT-microcolumn-Card-centrifuge to perform manual centrifugation step for Blood Grouping, Cross Matching, antibody screening or identification or phenotyping by coombs and enzyme phase by gel microcolumn technique to detect both IgG & IgM antibodies, and also potentially usable for C3d, Partial/weak D, Single Rare antigens, (Should be optional- PNH, Heparin/PF4 Ab Test (HIT), Syphilis antibody test etc).
- b) Must be designed specifically for blood bank use. Commercial or modified commercial centrifuges for other purpose are not acceptable

2. Quality Standard:

- a) Manufacturing should be compliant with ISO 13485 (Valid documentation should be submitted in technical bid).
- b) Should be compliant with European CE with notified body number according to IVD Directive 98/79/EC or US FDA for this specific purpose. (Valid documentation should be submitted in technical bid).
- c) Equipment must be certified for electrical safety specifications of IEC for "Safety requirements for electrical equipment for measurement, control, and laboratory"

3. Capacity, Construction and Functioning

- a) Centrifuge head should have minimum 10- 12 slots to accommodate 10- 12 of corresponding manufacturer's immuno-hematologic Gel microcolumn cards.
- b) Swing out suspensions for Gelcard slots
- c) Aerodynamic compact construction with vibration free performance; Noise level should be less than 60dB.
- d) Bottom of the microcolumn should have a conical (v) shape, u shaped bottom is not acceptable.

4. Lid

- a) The lid of the centrifuge should be transparent and should have auto-locking during spinning

5. Electrical characteristics:

- a) Must be compatible with Input voltage: 220/240V 50/60 Hz Ac

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- b) Should have an integrated voltage stabilizer or should come with external stabilizer.
 - c) Microprocessor controlled programming with LCD screen displaying Rpm or RCF, time and other functions should be displayed real time
6. Should supply with compatible incubator with a set of compatible variable volume micropipette.
 7. **Guarantee:** Three years on equipment from the date of installation.
 8. **CMC:** CMC will be given @ 5 % of net rate – Rate exclusive of GST (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC may be awarded for five years (on yearly basis) after completion of Guarantee period of three years.
 9. 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.
 10. Installation will be done by supplier free of cost.
 11. **The complaint of this equipment shall attend with in 72hrs.**
 12. Four Preventive Maintenance services annually during Guarantee and CMC period are essential.
 13. Demonstration of equipment is must for final technical approval.
 14. **Consumable:** Consumable kit. Rate of Consumable kit should be provided by bidder along with technical bid.

Revised Bid Schdeule--

E-bids are invited as per following revised time schedule:-

Existing Dates			Extended Dates		
Last date & time for sale of bid form	Last date & time of receipt of bid form	Date & time of opening of technical bid	Last date & time for sale of bid form	Last date & time of receipt of bid form	Date & time of opening of technical bid
<u>17.12.2020</u> <u>11:00 a.m.</u>	<u>17.12.2020</u> <u>6:00 p.m.</u>	<u>18.12.2020</u> <u>03:00 p.m.</u>	<u>28.12.2020</u> <u>11:00 a.m.</u>	<u>28.12.2020</u> <u>6:00 p.m.</u>	<u>29.12.2020</u> <u>03:00 p.m.</u>

- Note:-** 1. It is also clarified that information of award of contract shall be communicated to all participating bidders on the website www.rmhc.health.rajasthan.gov.in and sppp.raj.nic.in. Please note that individual bidder will not be intimated.
2. Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-V, Schedule of Supply, and Point no. 3) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

Executive Director (EPM)
RMSCL, Jaipur