SPECIFICATIONS FOR AUTOMATED BLOOD GROUPING SYSTEM

1. The analyzer should be capable to do all Immuno-hematologytests like blood grouping, antigen phenotype, weak, antibody screening & identification, and compatibility testing.
2. Should be a Fully Automated Continuous Random-Access system. Need to be fully automated, walk away, and have continuous loading (Samples & Reagents) Function
3. System should be a Floor Model so that it can be moved easily
4. System should be covered to avoid dust contamination.
5. System should have the facility of Wi-Fi connectivity and BI-LIS Connectivity. It should have the facility of Automatic backup. It should have the facility of automatic cross-checking of previous results.
6. System and waste containers to be within the system
7. The system should have dedicated software for antibody Identification to troubleshoot the samples along with an onboard reference guide.
8. Functions performed automatically: Full positive identification, cell suspensions, agitation of red cells, pipetting, incubation, centrifugation, reading, and interpretation.
9. Should have a STAT facility for emergency samples.
10. The system should have the facility to connect with smartphone mobiles to troubleshoot the emergency samples.
11. System should be able to read plate/card Barcodes automatically.
12. System should be based on Gel/SPRCA/Column Agglutination/EM/ Microplate Agglutinational technology.
13. Blood Grouping test should use Mono Clonal Antibodies.
14. Technology should have monoclonal reagents for "Following" tests - Blood Grouping, Cross Matching, and Anti Body Screening.
15. Should have a High-Resolution Camera for the Highest resolution image.
16. It should have the facility of identifying different types of sample tubes &pediatric tubes.
17. Should have Bi-Directional Communication with Laboratory information system.
18. Management of the internal Quality Control Procedure.
19. Barcode Management for Samples and Reagents before and after opening.
20. Secured reading and Interpretation of results.

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical Care
King George's Medical University, UP, Lko.

21. System should have a capacity to load more than100 samples or more at a given point in time
22. Cards/Plates should be room temperature stable
23. System should have the facility to load plates/cards continuously during the run
24. Should have Continuous refilling of system liquid (without interruption) and waste removal.
25. System should have different security levels for different users of the system
26. Should be able to give grading of reaction for choosing least compatible blood in cases of multiple transfusions. It should have the feature of liquid level detection, sample clot detection, and low-level notification.
27. The company should offer a complete panel of ready to use Red cell reagents for antibody screening & identification, an Extended Panel for multiple Antibody Identification including the Anti-D prophylaxis panel for Rh negatives, Crossmatch, Donor Pooled Antibody screening, and all other combinations of test performed on an automatic system.
28. System should be able to run multiple parameters at the same time without compromising the throughput or efficiency of the system.
29. Shelf life including Blood Grouping reagent should be approx., 8-12 months, plate/gel cards for Blood Grouping must be a minimum of 6 to 8 months Shelf life & the red cell panel for Reverse Grouping, Antibody screening & Identification should be 4 to 5 Weeks.
30. Instrument should have dedicated titration programs for IgG and the low titer samples as well as the high titer samples to avoid the wastage of consumables & time.
31. The system should have the facility to detect IgG and IgM antibodies in coombs cross-matchingtests. Along with the Titration procedure should be up to 1in 2048 titer value for both IgG&IgM on dedicated plate/Gel cards.
32. For Emergency samples system should have a Facility to do an immediate spin crossmatch (IgM Crossmatch)
33. User's list should be provided with a satisfactory report for the last three years from three licensed Blood Banks with contact details.
34. All media and consumables for setting up and standardization should be provided free of cost including calibrators and controls. The reagent red cell panels for antibody screening and identification should be available with the company. **Reagents for 1000 ABO grouping and Rh D typing should be supplied free with the equipment.**

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP
Head, Department of Critical Care
King George's Medical University, UP, ...

35. Suitable voltage stabilizer and compatible online UPS for entire machine and maintenance-free batteries for a minimum 1 hour back up should be supplied with the system.

36. The technical bid document must include the following details in a tabulated form:

a. Name of the test:

b. Reagents or kits required

c. Number of kits or reagents likely to be required as per the workload depicted below

d. Shelf life of reagents/kit.

37. Expected Workload:

i. Approximately 1000 blood samples per month for blood grouping, antibody screening, and Rh kell Phenotyping

ii. Cross-matching and antibody identification – optional/ need-based.

38. i) Depending on the above monthly workload, price quotation of individual test parameters, kit/pack size indicating the number of tests per kit, rate per kit, number of kits required per month, and total cost per month, per yearmust be made by the vendor separately- for the price bid in a tabular form. These prices will be frozen for a period of 5 years.

ii) The required number of tests/ days as per workload mentioned above and 300 days for the first year must be used for the purpose of quotation in the price bid and evaluation of the same. The total cost of these reagents will be added to the equipment cost and CMC from the 6th to 10th year for final price calculations and grading of the bid. There should be no mention of any financial aspects in the technical bid. It should only be done separately in the price bid.

iii) The bidder must also quote any other reagent, consumables, disposables, buffers, and wash solutions for the tests listed above for the required workload. All these rates shall be considered for the price bid evaluation. Any consumable not quoted in this table but essential for performing the above-listed tests shall have to be supplied free of cost for the entire workload during the validity of the contract. The rate will be reviewed after 5 years.

iv) Further in addition to the above tests the firm should provide details of all other parameters which can be done on the analyzer,quoted by the bidder, and manufactured by the bidder in terms of kit, number of tests per kit, and rate per kit in a tabulated form for all the parameters. These rates will also be frozen for five years. However, these rates will not be used for price bid evaluation.

Prof. Ayush Agrawal
MD, IDCC, IFCCM, FICCM,
Head, Department of Critical
King George's Medical University, U.P.

39. Accessory and spare parts- complete with a comprehensive set of spare parts should be mentioned. The make, rating, model, description, price, and quantity of each item shall be furnished separately. The rate contract will be for a period of 5 years.

40. System should include a molecular immune-hematology platform along with automation with the following –

a. An online bead-based array system should perform HEA, HPA, RHCE, and RHD Variant typing by DNA analysis and all other tests available for the platform.

b. It should be a 96-bead-based plate reader and 8 well bead-based strip reader system.

c. The instrument should have an automatic plate & strip (8-wells) reading procedure once initiated and the capacity to analyze 96 wells per batch (Maximum).

d. Automatic calibration, hands-free start up, shut down is required.

e. The accuracy or precision of the instrument should be good & the equipment should be provided with a hybridizer/ (Boekel Oven).

Conditions for tenderer:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and/ orEuropean CE be approved by 4 digits notified body.
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP
Head, Department of Critical Care
King George's Medical University

7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.
14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.
17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than

Prof. Avinash Agrawal
Head, Department of Critica
King George's Medical Univer

the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).

19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6^{th}, 7^{th}, 8^{th}, 9^{th} and 10^{th} years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6^{th} to 10^{th} year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.
20. Should provide 5-year CMC. CMC cannot be more than 5% of the contract value.
21. System configured application-specific educational video tutorials shall be provided as standard with the system.
22. Details of service outlet in India to render services during 5 years warranty period.
23. The principals must give a certificate if the supplier/vendor is changed during the course of the guarantee/warranty period, the principals would be responsible for the upkeep/maintenance of the quote/supplied equipment, besides honouring all the terms and conditions of CMC/AMC in letter and spirit.

Prof. Avinash Agrawal
MD, DM, FICCM, FICCM, FIACCM
Head, Department of Crit...
King George's Medical Univ...