SPECIFICATIONS FOR A FULLY AUTOMATED BLOOD BANK IMMUNOHEMATOLOGY SYSTEM ON A REAGENT RENTAL BASIS

- 1. Should be fully automated, with continuous loading and random-accessimmunohematology analyser for Blood Grouping, Cross-Matching and Antibody Screening.
- 2. The assay should be based on microplate/column agglutination technology.
- 3. Should be able to perform Blood grouping (Forward & Reverse), Phenotyping, Extended Phenotyping, Cross-Matching, Antibody Screening & Identification, Antiglobulin test, Weak D testing and Newborn blood grouping.
- 4. All the reagents for the above tests and quality control reagents should be CE/USFDA marks.
- 5. Equipment Certification: CE/USFDA mark.
- 6. Sample loading capacity should be at least 144 at a time.
- 7. All samples should be identifiable by a bar code reader with a facility for integration with the hospital information system.
- 8. User should be able to add or access samples, replenish reagents, and read bar codes without interrupting or delaying tests that are already in progress.
- 9. Should have a mechanism to identify hemolysed, lipemic or icteric samples with an indication of the same to the users.
- 10. Should have provision for clot detection, fibrin, and low-level indicator for liquid samples and reagents.
- 11. The system should have adequate pipetting arms for independent dispensing of samples and reagents.
- 12. Should have a STAT facility for emergency samples.
- 13. System should be able to check onboard reagent inventory before setting the run and alert in case of the absence of reagents.
- 14. Should be able to run the tests in any order and any combination
- 15. Should have positive and negative control during each protocol whenever applicable as per technology
- 16. Power input confirming Indian electrical requirements.
- 17. 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 equipment.

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- 18. Should have an inbuilt reader with HD cameras for recording and interpreting images of test reactions.
- 19. Should have a full audit trail including images of test results.
- 20. Sound and light alarm system in case of errors.
- 21. Should have monospecific DAT with IgG & C3d/IgG+C3d
- 22. The necessary IQ, PQ, OQ and Calibration certificates should be provided from time to time as and when necessary, by the supplier during the contract period.
- 23. Equipment should be delivered with Panel PC.
- 24. System should be able to run multiple parameters at the same time without compromising the throughput or efficiency of the system.
- 25. User Management Control through Login/Passwords with the ability to configure the rights for each user.
- 26. Decontamination of the probe after picking up each sample.
- 27. All the consumables except reagents, spares and accessories, along with the machine will be provided by the vendor throughout the contract period at no cost to the hospital.
- 28. Any consumable or non-consumable parts, except Reagents, along with accessories, which need replacement must be provided free of cost by the firm during the contract period.
- 29. Equipment will be maintained throughout the contract period at no cost to the hospital.
- 30. Further in case of breakdown of the equipment, the vendor will replace the equipment with a similar or higher model at their own cost till the repair/replacement of the equipment. Failing, it will be treated as a breach of contract and the Institute will take action as deemed fit.
- 31. Compliance report to be submitted in a tabulated and point-wise manner, clearly mentioning the page/ para number with authenticated catalogue/manual. Points not covered in the brochure must be specifically addressed in a separate certificate.

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).

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- 3. Should be USA FDA and/ or European CE be approved by 4 digits notified body.
- 4. Other necessary certifications, if any, 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.
- 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. Prof. Avinash Agrawal

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- 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 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., 6th, 7th, 8th, 9th and 10th 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 6th to 10th 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 MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA) Head, Department of Critical care, as standard with the system. King George's Medical University, UP, Lko.

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- 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.

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