TECHNICAL COMPLIANCE FORM			
Ref: Tender No:			
TATA MEMORIAL CENTRE			
ADVANCED CENTRE FOR TREATMENT, RESEARCH & EDUCATION IN CANCER			
TECHNICAL SPECIFICATION OF :- - COLUMN AGGLUTINATION BASED FULLY AUTOMATED IMMUNOHEMATOLOGY ANALYSER-1 No.			
Intended Use:COLUMN AGGLUTINATION BASED FULLY AUTOMATED IMMUNOHEMATOLOGY ANALYSER FOR PATIENT BLOOD GROUPING, CROSSMATCHING, ANTIBODY SCREENING			
The Equipment is for Reagent Rental only, Not for Outright purchase			
Sr. No.	**Name of the Vendor :**		
A	**Technical Specifications / Scope of supply**	**COMPLIANCE** **1) Mention "Complied /Not Complied"** **2) Highlight any deviations.** **3) Mention part number/Catalogue number of the**	**REMARKS**
B	**Name of the Manufacturer :**		
C	**Model Name / Model No. of the Equipment (If the equipment is a combination of more than one equipment then list down the model no. pertaining to each)**		
D	**Year of Introduction Internationally**		
E	**Year of Introduction in India**		
F	**Technical Specifications/Scope of supply**		
G	**" Column Agglutination Based Fully Automated Immunohematology Analyser" complete as per below mentioned configuration and specifications:**		
H	**Features and specifications required:**		
1	**System should be quoted on reagent rental basis only & not on outright purchase**		
2	System should be brand **NEW**, fully automated continuous loading analyzer with random access		
3	The system should be a stand alone system requiring minimal workspace		
4	System should be based on column agglutination technology for patient blood grouping, crossmatching, antibody screening,antibody identification, direct coombs test, monospecific direct coombs test(IgM/IgA/IgG/C3c/C3d)		

5	The functions performed automatically in the system should include red cell suspension preparation, continuous agitation of red cells thereby preventing the red cells from settling down, pipetting, incubation,centrifugation, reading and interpretation		
6	Blood Grouping employed in the system should include cell grouping antisera A, B, D antigens for detection of antigens and serum grouping with A cells, B cells and control cells for detection of antibodies specific to that blood group.		
7	The determination for Rh D type should include determination with anti D reagents from two different sources as per DGHS guidelines		
8	The system should be able to detect dual population of cells in blood grouping		
9	The system should be capable of performing automatically all the parameters required for pretransfusion testing		
10	The system should be able to display grading of reaction in compatibility testing for choosing best compatible blood in cases of multiple transfusions.		
11	The system should have the facility for auto reading,capturing and interpreting results using suitable device and password protection		
12	The system must be capable for upgradation of advanced tests like Extended minor antigen phenotyping for Rh,Kell,Kidd,Duffy and MNS		
13	The system should have the shortest turnaround time for performance of crossmatching and blood grouping		
14	The system should have a loading capacity of about 50 samples		
15	The system should have a throughput of performance of 80 units crossmatching per hour or 40 samples blood grouping per hour		
16	The system should have two integrated centrifuges for faster throughput independent of each other		
17	The system should have **true STAT facility** and sample oriented processing		
18	The system should have onboard cooling facility for the reagents to maintain the stability of the reagents		
19	The system should have individual well piercing capacity to prevent wastage of cards		

20	Should have inbuilt reader with HD cameras for recording test reactions and results should be retrievable later		
21	The system should have independent pipetting arms for pipetting samples to process multiple samples together		
22	The assay should perform decontamination of probe after picking up each sample		
23	The system should have the feature of liquid level detection,sample clot detection and low level notification		
24	The system should have a mechanism to identify hemolysed, lipaemic or icteric samples with indication of same to the users		
25	The system should be flexible to run a single sample or in full batch		
26	The system should have sample tube diameter detection facility		
27	The system should have flexible sample tube loading and identify different types of sample tubes like normal tubes,plunger tubes and pediatric tubes		
28	The system should eliminate the washing step for faster turnaround time for crossmatching		
29	The system should be able to detect both IgG and IgM antibody incompatibilities in crossmatching		
30	The system should have a facility of continuous refilling of system liquid and waste removal without interrupting the ongoing tests		
31	User should be able to add samples, replenish reagents, read bar codes without interrupting or delaying tests that are already in progress		
32	System should be able to run multiple parameters at the same time without compromising the throughput or efficiency		
33	System should be able to run the tests in any order and in any combination		
34	The system should automatically perform daily QC of various test parameters (Blood grouping, Crossmatching, Antibody Screening and Direct Coombs Test) as a startup protocol		
35	The system should automatically perform reagent Lot and other consummable Lot QC during the loading process		

36	The system should perform daily QC of hardware and software as a start up protocol		
37	The system should perform automatic monitoring of the instrument QC status prior to each sample processing to ensure valid result and prevent repeat testing		
38	System should have Inbulit Quality Control system to monitor the quality of result obtained		
39	**All the batches of all the reagents employed for usage in the fully automated system should be NIB/NIIH certified and the same has to be provided as a mandatory requirement of the regulatory guidelines.**		
40	**The complete equipment should be manufactured by the brand of manufacturer and an endorsement certificate regarding the same has to be provided to the user**		
41	The firm should provide rate certificate from any Institution, where similar equipment has been installed.		
42	Original literature along with the user's list should be attached with the satisfactory report for the last three years from three users with contact detail.		
43	The system should have the facility for automatic back up and automatic crosschecking of previous results		
44	All the samples should be identifiable by a bar code reader with a facility for integration with hospital information system		
45	The instrument should have feature of integrated process control for complete traceability for each and every steps performed by the instrument during performing a test and provide report for the same.		
46	System should have bidirectional interfacing with Laboratory information system/ Blood Bank Software & will be the vendor's responsibility to establish the interface		
47	System should have the capability of inbuilt inventory management system for tracking all the reagents and supplies automatically and alert in case of absence of reagents		
48	The system should be able to notify the operator if an error message appears along with the steps to resolve the error		
49	**Response Time:** In case of any breakdown of equipment, the response time should not be more than 4 hours from lodging a breakdown complaint on toll free or by email.		

50	**Local Service Support:** Should have local office and service support/service engineer for attending the breakdown calls.		
51	The company should support with two semiautomated platforms as a back up equipment along with the fully automated equipment		
52	Further in case of any breakdown of the equipment, the vendor will replace the equipment with a similar or higher model at their own cost till the repair/replacement. Failing it will be treated as breach of contract		
53	**System should be able to process following parameters with Present Sample load for Reagent Rental basis & to be quoted as Cost per reportable test (Price of Reagents(Cleaner/Washer/Diluent) /cards/Kits/dilution plates/Calibrator/ Quality Control-t (Test specific) /Tips required /Any other accessories required for the enclosed parameters must be quoted and the rate will be frozen for 5 years**		
54	**A.Patient Blood Grouping**-a. Patient ABO blood grouping (Forward and Reverse)-400 tests per month (approx), b. Rh Blood Grouping (From two different sources)- 400 tests per month **B. Crossmatching-** a. Patient verify blood grouping (forward & reverse)- 800 tests/month, b. Donor Segment grouping (forward grouping)-2000tests/month, c.AHG crossmatch-2070 tests/month, d.NS crossmatch- 2070 tests/month,e. Repeat Antibody Screening of Patients-800 tests/month, **C. Antibody Screening of Patients**-400 tests/ month, **D. Antibody Identification- 50 tests/month, E. Direct Coombs Test(DCT)- 100 tests/month,F. Monospecific DCT (IgM/IgG/IgG/C3c/C3d)- 20 tests/month, G. Rh and Kell Antigen Phenotype- 20 tests/month**		
55	**OPTIONAL TESTS: Donor Blood Grouping (Forward and Reverse)**-100 tests per month, **ABO Antibody Titre (IgG & IgM)**- 400 tests/month, **Extended Phenotyping for Kidd,Duffy and MNS**- 20 tests, **Weak D testing**- 40 tests/month, **AIHA work Up: IgG Antibody Titre determination**- 30 tests/month, **Daratumumab Discrepancy work Up**- 10 tests/month		

56	With approximate monthly utilization mentioned , Cost per reportable test (CPRT) and how the calculation is done to arrive at it is to be indicated for tests: patient blood grouping,crossmatching, antibody screening of patients, antibody identification, Direct coombs Test and Rh and Kell Antigen Phenotype		
57	Cost Per Test (CPT) is to be indicated for the optional tests: Donor Blood grouping (Forward and Reverse), ABO antibody Titre (IgG and IgM), Extended phenotyping for Kidd, Duffy and MNS, Daratumumab discrepancy workup ,Weak D testing,AIHA work Up: IgG antibody titre determination		
58	**L1 will be identified based on total of all cost per reportable test (CPRT) / month of tests with the indicated sample volumes**		
59	**CPRT for Daily QC run of the tests to run will be included in L1 identification**		
60	For the period of staff training, all the necessary reagents should be supplied with the system for the standardization and calibration for all the test free of cost		
61	Incase if, the workload may increase/ decrease as per requirement of department , placement of additional equipment with increasing workload at no additional cost t shall be the responsibility of the vendor		
62	**Standard accessories (All the standard accessories should be part of the equipment)**		
63	**Essential consumables:**		
64	Indicate if the quoted model needs proprietary consumables (Equipment being closed or open system)		
65	Provide List of consumables with their prices in the Financial bid.to conduct the above mentioned tests in S No. 44, 45 & 46		
66	**Upgradibility capability (List down possible upgrades for the quoted model)**		
67	New software/technology updates are to be periodically installed in the system with no additional cost to the institute		
68	**On-Line UPS/Voltage Stabilizer/ Printer**		

69	Suitable power UPS should be provided and the maintanence shall be entirely the responsibility of the vendor.		
70	Suitable Laser Printer shall be provided and the maintanence shall be entirely the responsibility of the vendor.		
71	**Periodic Calibration: Is the responsibility of the vendor as**		
72	**Regulatory Approvals, If any. Details with copies of**		
73	All the reagents for tests should be manufactured by the manufacturer		
74	All the reagents should be CE or USFDA approved		
75	Reagents should be acceptable by DCGI, N.Delhi & NIB, Noida		
76	**Safety requirements:**It should follow International / national safety requirement. Please specify certification with certifying agency and country with copies of certificate.		
77	US FDA/European CE-IVD/BIS/ICMED approved system certification for the equipment along with the validity period to be submitted		

78	**User's list:** A list of installations with the address and contact numbers to be provided. (User list should be for the quoted model.)		
79	**Input power supply requirements:** 240 V AC ± 10 %, 50 Hz, single phase. Specify if any other power supply requirement is recommended.		
80	**After Sales Service Support.**		
81	Complete operational manuals and technical information including circuit diagrams should be provided.		
82	The equipment should be entirely maintained by the company with periodic (One visit every six months) preventive maintenance, calibrations and break down repairs including spare parts. The company has to ensure uptime guarantee of 95% taking into consideration 313 working days in a year.		
83	**Preinstallation Requirements :- Provide details of preinstallation requirements, special ambient conditions, if**		
84	Vendor should visit and ensure the space provided for the installation of the equipment is adequate for their system.		
85	Ensure the Foot print of the machine should be a match with the installation site.		
86	**Installation, Commissioning, testing and Training**		
87	Unpacking and Shifting the consignment to the installation site is to be included in the scope of supply. Bidder/manufacturer/authorized service provider should take responsibility to lift/shift the consignment from unloading site to the installation site . Unloading site shall be "Stores Department, KS Building, ACTREC Campus". If needed, Bidder has to arrange for the labourers at no charge to ACTREC. (Before submitting the quotation, bidders may visit ACTREC to know unloading site and installation site)		
88	Installation,Commissioning and Training is included in the scope of supply. Bidder, Manufacturer and/or its authorized representative should undertake installation and commissioning of the equipment.		

89	Complete system should be installed, tested for its performance as per manufacturer's SOP/guidelines and demonstrated to the Institute's Users. In depth training should be provided to the Institute's users for maintenance,usage and applications.		
90	Certificate to be provided to the effect that shut down period of the machine must not exceed for more than 48 hours & back up equipment option in case of equipment breakdown.		
91	Warranty and after sales support: It will be a complete vendor's responsibility.		
92	**Important terms to be noted by the bidders:**	Agree/Not Agree	
93	Read the above scope of supply carefully and quote accordingly. Incomplete and /or partially complete offers are liable to be rejected.	- days	
94	**Mention the time required to install the system.**	Agree/Not Agree	
95	After opening of the Technical bid (Part-1), Physical demonstration of the quoted model may have to be shown / arranged by the bidder, if requested by the Institute. Physical demonstration may be shown at one of the end user's site/Principle company's application lab/manufacturing site located in Mumbai/Navi Mumbai/Thane cities. If there are no installations of the quoted model in Mumbai/Navi Mumbai/Thane cities, then the quoted model may have to be	Agree/Not Agree	
96	Past experience of the bidders in terms of quality of supplied equipments, after sales service and application support will be taken into consideration while technical evaluation. Bidders who has unsatisfactory past experience in last 2-3 years, in terms of quality of supplied equipments, after sales service and application support, bids of such bidders may liable to be rejected.	Agree/Not Agree	

97	Complete and detailed information should be provided in respect to each point specified in the specifications. Technical bids that are incomplete in any respect are liable to be rejected. Provide relevant supportive information, publications, catalogue, etc. Bidders providing misleading or wrong information are liable to be rejected. All technical claims should be printed in the technical brochure of the equipment.	Agree/Not Agree	
98	If any contradictory statements /figures/information is observed in the compliance chart and in the technical bid, then the technical information mentioned in the product literature/brochure will be considered true and further	Agree/Not Agree	
99	Remarks column may be filled with relevant data, figures, range etc. as applicable. Do not just mention "YES / NO / Complied ".		
100	**Decleration by the bidder**	Yes/No	
101	We have quoted for all the items meeting the description/scope of supply in the Financial bid as per prescribed format of the Tender documents and we agree that Partial/incomplete offers are liable for rejection.		