	TECHNICAL COMPLIANCE FORM		
Ref: Tender No:			
	TATA MEMORIAL CENTRE		
	ADVANCED CENTRE FOR TREATMENT, RESEARCH & EDUCATION IN CANCER		
	TECHNICAL SPECIFICATION OF :- MICROPLATE BASED FULLY AUTOMATED IMMUNOHAEMATOLOGY ANALYSER-1 No.		
	Intended Use: MICROPLATE BASED FULLY AUTOMATED IMMUNOHAEMATOLOGY ANALYSER FOR DONOR BLOOD GROUPING, DONOR ANTIBODY SCREENING & ABO ANTIBODY TITRE		
The Equipment should be on reagent rental, 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 relevant item quoted.**	**REMARKS**
B	**Name of the Manufacturer :**		
C	**Model Name / Model No. of the Equipment**		
D	**Year of Introduction Internationally**		
E	**Year of Introduction in India**		
F	**Technical Specifications/Scope of supply**		
G	**"MICROPLATE BASED Fully Automated Immuno Haematology 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	System should be floor model so that can be moved easily		
4	The system should be based on microplate technology for fully automated performance of donor blood grouping, donor antibody screening, determination of IgG and IgM ABO antibody titre		
5	Blood grouping employed in the fully automated equipment should include cell grouping antisera A, B, AB, D for detection of antigens and serum grouping with A cells, B cells and O cells for detection of antibodies specific to that blood group		

6	**The determination for Rh D type should include determination with anti D reagents from two different sources as per DGHS guidelines**		
7	The system should be standardized for performance of ABO antibody titre (IgG and IgM) at optimum temperatures and automatically interpret the IgG and IgM ABO antibody titre result without any technical assistance		
8	Should have the facility to automatically perform weak D testing in case of negative blood groups		
9	The system must be capable for upgradation of advanced tests like performance of platelet crossmatch tests to provide compatible platelet transfusion and performance of minor antigen phenotyping for Rh,Kell, Kidd, Duffy and MNS system		
10	The system should have the facility for bulk sample processing with provision for atleast 200 samples to be loaded together		
11	The system should have a throughput of minimum 100 blood grouping per hour and 100 donor antibody screening per hour		
12	The system should have independent pipetting arms for processing multiple samples and reagents		
13	The system should have onboard cooling facility of reagents to maintain stability of the reagents		
14	The system should have the feature of liquid level detection,sample clot detection and low level notification		
15	The system should have true STAT facility and sample oriented processing		
16	The system should have the facility for auto reading, capturing and interpreting results using suitable device and password protection		
17	The system should have a mechanism to identify hemolysed, lipaemic or icteric samples with indication of same to the users		
18	The system should be flexible to run single sampe or in a full batch and flexible sample tube type loading		
19	The system should have inbuilt cameras to record test reactions and results should be retrievable later		
20	User should be able to add samples, replenish reagents, read bar codes without interrupting or delaying tests that are already in progress		
21	System should be able to run multiple parameters at the same time without compromising the throughput or efficiency		
22	System should be able to run the tests in any order and in any combination		

23	The system should have a facility of continuous refilling of system liquid and waste removal without interrupting the ongoing tests		
24	The system should automatically perform daily QC of various test parameters (Blood grouping, Antibody Screening and Antibody Titre) as a startup protocol		
25	The system should automatically perform reagent Lot and other consummable Lot QC during the loading process		
26	The system should perform daily QC of hardware and software as a start up protocol		
27	The system should perform active monitoring of instrument QC status before each processed sample to ensure valid result and prevent repeat testing		
28	**All the batches of all the reagents employed for usage in the fully automated system should be NIB certified and the same has to be provided as a mandatory requirement of the regulatory guidelines.**		
29	**The complete equipment should be manufactured by the brand of manufacturer and an endorsement certificate regarding the same to be provided**		
30	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		
31	The firm should provide rate certificate from any Institution,preferably Govt. institute where similar equipment has been installed.		
32	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.		
33	The system should have the facility for automatic back up and automatic crosschecking of previous results		
34	All the samples should be identifiable by a bar code reader with a facility for integration with hospital information system		
35	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.		
36	System should have bidirectional interfacing with Laboratory information system/ Blood Bank Software & will be the vendor's responsibility to establish the interface		
37	System should have Inbulit Quality Control system to monitor the quality of result obtained		
38	The system should be able to notify the operator if an error message appears along with the steps to resolve the error		

39	**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.		
40	**Local Service Support:** Should have local office and service support/service engineer for attending the breakdown calls.		
41	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		
42	**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) /Kits /microplates/dilution plates/Calibrator/ Quality Control- t(Test Specific) /Tips required /Any other accessories required for the enclosed parameters according to the mentioned number of tests must be quoted and the rate will be frozen for 5 years**		
43	**A. Donor Blood Grouping** -a. ABO blood grouping (Forward and Reverse)- 700 tests per month (approx), b. Rh blood grouping (from two different sources)- 700 tests per month,c. Weak D Testing- 20 tests/month **B. ABO antibody titre (IgG and IgM)**-300 tests per month, **C. Donor Antibody Screening by Pooled Cells**-700 tests/month		
44	**OPTIONAL TESTS**: **Platelet Crossmatch**- 40 tests/month, **Rh and Kell Antigen Phenotype**- 40 tests/month, **Antibody Screening for Patients**- 200 tests/month, **Blood Grouping for Patients**- 200 tests/month, **Direct Coombs Test**- 40 tests/month, **Donor Antibody Identification**- 20 tests/month, **Daratumumab discrepancy workup**- 10 tests/month		
45	**With approximate monthly utilization mentioned , Cost per reportable test (CPRT) and how the calculation is done to arrive at it is to be indicated.**		
46	Cost Per Test (CPT) is to be indicated for the optional tests: Platelet crossmatch, Rh and Kell Antigen Phenotype, Antibody Screening for patients, Blood Grouping for patients, Direct Coombs Test, Donor Antibody Identification and Daratumumab Discrepancy workup		
47	**L1 will be identified based on total of all cost per reportable test / month of tests with the indicated sample volumes**		
48	**CPRT for Daily QC run of the tests to run will be included in L1 identification**		
49	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		

50	The workload may increase/decrease as per the requirement of department and placement of additional equipment with increasing workload at no additional cost will be the responsibility of the vendor		
51	**Standard accessories (All the standard accessories should be supplied as the part of the equipment)**		
52	**Essential consumables:**		
53	Indicate if the quoted model needs proprietary consumables (Equipment being closed or open system)		
54	Provide List of consumables with their prices in the Financial bid.to conduct the above mentioned tests in S No. 33, 34 & 35		
55	**Upgradibility capability (List down possible upgrades for the quoted model)**		
56	New software/technology updates are to be periodically installed in the system with no additional cost to the institute		
57	**On-Line UPS/Voltage Stabilizer/ Printer**		
58	Suitable power UPS should be provided and the maintanence shall be entirely the responsibility of the vendor.		
59	Suitable Laser Printer shall be provided and the maintanence shall be entirely the responsibility of the vendor.		
60	**Periodic Calibration: Is the responsibility of the vendor as per standard norms.**		
61	**Regulatory Approvals, If any. Details with copies of approvals.**		
62	All the reagents for tests should be manufactured by the manufacturer		
63	All the reagents should be CE or USFDA approved		
64	Reagents should be acceptable by DCGI, N.Delhi & NIB, Noida		
65	**Safety requirements:**It should follow International / national safety requirement. Please specify certification with certifying agency and country with copies of certificate.		
66	US FDA/EUROPEAN CE-IVD/BIS/ICMED approved system certification for the equipment to be submitted.		
67	**User's list:** A list of installations with the address and contact numbers to be provided. (User list should be for the quoted model.)		

68	**Input power supply requirements:** 240 V AC ± 10 %, 50 Hz, single phase. Specify if any other power supply requirement is recommended.		
69	**After Sales Service Support.**		
70	Complete operational manuals and technical information including circuit diagrams should be provided.		
71	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.		
72	**Preinstallation Requirements :- Provide details of preinstallation requirements, special ambient conditions, if any, space requirement, any other special needs.**		
73	Vendor should visit and ensure the space provided for the installation of the equipment is adequate for their system.		
74	Ensure the Foot print of the machine should be a match with the installation site.		
75	**Installation, Commissioning, testing and Training**		
76	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)		
77	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.		
78	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.		
79	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.		
80	Warranty and after sales support: It will be a complete vendor's responsibility.		
81	**Important terms to be noted by the bidders:**		
82	Read the above scope of supply carefully and quote accordingly. Incomplete and /or partially complete offers are liable to be rejected.	Agree/Not Agree	

83	**Mention the time required to install the system.**	- days	
84	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 brought in at ACTREC for demo purpose **within 10 days from the date of request.** Physical Demonstration may be requested to confirm the availability of any or all technical features as mentioned/stated in the technical bid. Physical Demonstration will also be a part of technical evaluation process. If the bidder does not comply, such bids are liable to be disqualified. (Demonstration of quoted model is to be shown and not the demonstration of similar models with different technical specifications and features)	Agree/Not Agree	
85	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	
86	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	
87	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 evaluation will be done based on the information given in the product literature/brochure.	Agree/Not Agree	
88	Remarks column may be filled with relevant data, figures, range etc. as applicable. Do not just mention "YES / NO / Complied ".	Agree/Not Agree	
89	**Decleration by the bidder**		
90	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.	Yes/No	