

Running Contract Details	
Equipment Name	Fully Automated CLIA Analyzer Reagents on Rental Basis
Running Contract Valid Till	26-07-2027
Tender Ref No	KMSCL/EP/T426/1590/2021
Tendered Quantity	5
Supplier Name	M/s Tricore Medicals Systems
GST No	32AAHFT0313N1ZC
Installation & Delivery Period	8 Week(s)
Up-time / PM vist	95% & 0 Visits per year
Warranty period	0 Years

Supplier`s Details		
Address	Contact Details	
TC 25/1910(1) Cosmos Building Mele Thampanoor Thiruvananthapuram - 695 001	Contact Person	Praveen K.A
	Phone	0471 2333388
	Mobile No	8606078122
	Email	tricoremedicalsystems@gmail.com

Item-wise Price Details				
#	Item Details	Unit Rate (Incl.all taxes & charges)	Service Charges (Through KMSCL)	Grand Total
1	Fully Automated CLIA Analyzer Reagents on Rental Basis <i>Model & Make : Architect 2000</i>	0 Incl.GST :0%	0	0
2	CPRT of HIV (Fourth Gen)	42.29 Incl.GST :0%	3.49	45.78
3	CPRT of Anti HCV	128 Incl.GST :0%	10.57	138.57
4	CPRT of HBsAg	35.62 Incl.GST :0%	2.94	38.56
5	CPRT of Syphilis	33.39 Incl.GST :0%	2.76	36.15
6	CPRT of HBV Core Ab	166.3 Incl.GST :0%	13.74	180.04
7	CPRT of CMV	171.2 Incl.GST :0%	14.14	185.34

Item-wise Price Details				
8	CPRT of HTLV	266.1 Incl.GST :0%	21.98	288.08
9	CPRT of SARS COV 2	475.3 Incl.GST :0%	39.26	514.56
		1318.2	108.88	1427.08

Other terms & conditions

1. The supplier shall execute an agreement with the purchaser as per tender conditions (agreement format is given in the tender document).
2. The supplier shall submit performance security amounting to 5.00% of the value of the supply order.
3. The labour & comprehensive charges of equipment after the completion of warranty period is finalized by KMSCL as mentioned above.
4. Since discount rate is not applicable for equipment under Running Contract of KMSCL, purchase/supply order can be issued directly to supplier at the given rate with tax & other charges (exclusive of KMSCL service charges).
5. If purchase/supply order is issued directly to the supplier, KMSCL service charge need not be paid. But the copy of the said order may be forwarded to KMSCL for information.

Technical Specification

Equipment :Fully Automated CLIA Analyzer Reagents on Rental Basis

1. The machine should be brand new fully automated, random access immunoassay system
2. The complete system should be latest on the production line and must not be refurbished. Bidder must provide original documentary proof of the date and place of manufacturing of equipment at the time of supply.
3. Should be based on Chemi Luminescence technology.
4. The equipment and all reagents should be European CE-IVD, US FDA, CDSCO approved
5. Any necessary up-gradation in the equipment required in future will be the supplier's responsibility.
6. Parameters/ Investigations: 4th generation HIV Ag/Ab, HBsAg, Anti-HCV, HBV Core Ab, CMV, Syphilis, HTLV, SARS COV 2
7. Sample: Human serum (including serum collected in serum separator tubes) or plasma collected in potassium EDTA, heparin, sodium citrate, CPDA-1, CPD, CP2D.
8. Throughput should be should be 180 samples or more / hour.
9. The system should have the capability to do the assay in continuous, random batch and STAT mode.
10. Should have capacity to load at least 30 Reagents packs of different parameters at a time.
11. Reagent packs should be ready to use with automatic onboard reagent mixing to avoid manual intervention & human related errors.
12. On board reagent stability of minimum 4 weeks with calibration stability of minimum 4 weeks should be there.
13. The system should not have to be stopped to reload new reagent kits.
14. The system should have single point data entry and result viewing with windows-based operating system having wide touch screen monitor
15. Continuous printing facility of patient results, QC and calibration details should be available.
16. Option of taking back-up of patient results and QC reports on external services and USB devices should be possible
17. Onboard reagent inventory with automatic tracking and notification of remaining tests, onboard stability and expiration, calibration and storage conditions for each pack should be there. Reagent expiry should be minimum 4 months when supplied.
18. Reagent compartment with the required temperature for the reagent kits supplied by bidder should be available.
19. Should have access to samples during operation. Sample volume required should be 10-150?L depending upon the analyte.
20. Should have facility to do Pre dilution of samples

21. Equipment should be able to work with all types of sample containers including standard primary tubes (both vacuum and non-vacuum tubes), System should accommodate multiple sample tube size / sample cups.
22. Universal barcode reader should be able to read multiple barcode type.
23. Stat prioritization should be available on the system without interrupting the routine run. Dedicated STAT position should be available
24. System should be able to perform assays with zero carry over.
25. System should perform assays in discrete disposable cuvettes/cells
26. All disposables and consumables (All controls, calibrators, wash reagents, assay diluents, disposable sample probe tips, reaction cuvettes and other consumables necessary for the investigations) should be included in the cost.
27. Should have on board sample auto dilution at least up to 1000 times.
28. Should have Clot detection, bubble detection and low sample detection facility, hemolysis and icteric sample detection facility.
29. Should have lot to lot calibration for each assay. The calibrator and controls should cover all investigations/ parameters mentioned above. Certificate of Traceability for calibrators, traceable to national/ international reference standards to be submitted by the supplier. 4th generation controls for relevant assays should be provided.
30. Reaction time should be within 10 – 60 minutes for the listed parameters.
31. System should have automatic reflex testing
32. Should have facility for continuous random access, including loading and unloading of reagents, other consumables and samples without stopping the analyzer.
33. Servicing instruments by remotely capturing operational data available in the system
34. Random access calibration should be possible.
35. Provision of inbuilt QC monitoring system by L J plots and Westgard and Configurable QC based rules should be available.
36. It is the responsibility of the supplier to integrate the software of the equipment with the existing HIS of the hospital for interfacing the results, free of cost. All necessary hardware and software required for connecting the equipment to the hospital network shall be provided..
37. HIS port, Ethernet port and USB port should be available along with the equipment
38. Real time monitoring of QC violations, and turn around time for samples should be available.
39. Instrument should provide integrated process control that monitors from sample aspiration to assay processing and report the same. Operator should be able to see the report for any discrepancies and able to take print out for audit purpose.
40. On board sample data storage capacity should be a minimum of 25000 patient results.
41. Should be able to work with Voltage: 200-240 V and Frequency 47- 60 Hz.
42. UPS - 3KVA with 30 minutes battery backup should be supplied with equipment. Appropriate battery backup should be arranged and maintained by the bidder with no extra cost.
43. The required plumbing/waterplant facility should be provided and the same shall be maintained by the supplier itself.
44. All the pre installational requirements for the machine except electrical and civil works should be done by vendor at no additional cost.
45. Floor drain kit should be set up by the bidder to route waste directly to floor drain
46. The vendor should inspect the site before installation and prepare the site for installation and proper functioning of the equipment round the clock, free of cost.
47. The supplier shall be responsible for installation, commissioning and trial runs providing free trial kits for all tests along with respective calibrator and control.
48. The firm should provide one kit per parameter at no cost for trial and training purpose. The equipment being installed should be validated in-house and documents for IQ/OQ/PQ has to be provided to the Institute
49. The supporting systems like UPS, Water System, Computer, Computer table, Printer, Refrigerator, and peripherals like Air Conditioner shall be provided with no extra cost to the Institute.
50. Three levels of internal QC should be provided by the bidder from a FDA-approved third party manufacturer six monthly.
51. NABL standard will be adhered for running QCs and the number of QCs will be paid as per CPRT.
52. On failure of QC, the cost per reportable test (CPRT) for trouble shooting will be borne by the firm.
53. Demonstration and onsite training of staff up to their satisfaction by the application experts is an absolute must.
54. A unit from the same manufacturer with a throughput equivalent to that of main equipment should be provided as standby equipment, free of cost if required in case of breakdown/ not rectified within two days from the date of receipt of complaint. CPRT will remain the same for this equipment also.
55. The estimated number of tests has been calculated from previous years tests done at MCH Kottayam. No assurance to the supplier on minimum guaranteed number of investigations in a financial year will be provided by the Institute.
56. The expected sensitivity and specificity of the assays are as follows:

Test	Sensitivity	Specificity
HIV	100%	99.5%
HBsAg	100%	99.5%
HCV	100%	99.5%
Syphilis	100%	99.5%

II. General Rental Conditions

1. Payment – Instrument will be placed on rental basis and the institution will only make payment for the number of tests performed on the instrument at the rate agreed upon. *(Instrument, other equipment, maintenance of all these equipments, spare parts, reagents, consumables, Preventive Maintenance Kits, calibrators, tests performed for calibration and ensuring accuracy of calibration, etc will not be paid for).*
2. The bidder should offer the **Cost Per 1 Reportable Test – CPRT (Inclusive of all GST)** in the BOQ – for all parameters that can be performed on the instrument. The L1 shall be calculated based on the average workload mentioned and the same shall be automatically done by the BOQ.

The detail of the parameters that is taken for L1 calculation and the work load (not actual workload of any user institution) is given below.

Test	Expected work load
1. HIV (Fourth Gen)	10000 tests/ year
1. Anti HCV	10000 tests / year
1. HBsAg	10000 tests/ year
1. Syphilis	10000 tests/ year

The following optional parameters are Not Taken for L1 calculation and bidders are requested to offer the CPRT if the kits are available.

1. HBV Core Ab
2. CMV
3. HTLV
4. SARS COV 21

3.The bidders are requested to mention the available pack size of all the tests in the Offer form and the orders shall be placed as per the CPRT. The calibration requirement and the no. of tests used for calibration, etc for each test shall also be mentioned in the Offer Form

4.CPRT calculation – CPRR should include cost of reagents, consumables, calibrators, tests for calibration and ensuring accuracy of calibration, spares, service costs, etc

5.CPRT fixation period – will be fixed for a period of three years

6. Equipment maintenance – Care and maintenance of the all instrument and accessory equipments & Items supplied shall be the responsibility of the supplier

7.All the necessary items other than the test reagents shall be provided by the bidder free of cost including the calibrators, Preventive Maintenance Kits, Spares/ consumables, Tubing, Light sources or any other such things. If any equipment/ item not mentioned here and needed for getting the test results shall be provided free of cost.

8.The user institution shall place order for reagents at the CPRT only and the order for the consumables shall be placed as free of cost items

- 9.The user institution/ bidder can withdraw from the agreement by giving an advance notice of intimation for a period of 180 days
- 10.The bidder should be able to supply the reagents for the test parameters as when required – within 7 days from the date of intimation
- 11.This tender is invited as Running Contract. Orders will be issued during the running contract period to install the equipment under the same conditions to any Govt hospitals either by the Tender Inviting Authority / User Institutions. The L1 bidder can evaluate the work load of the said institution and inform the feasibility to install the system to the Tender Inviting Authority / User Institution within 7 days of receipt of intimation. Penal actions shall not be initiated against the L1 bidder if the feasibility is informed within the allowed time to deny the offer.