ALL INDIA INSTITUTE OF MEDICAL SCIENCES,
ANSARI NAGAR, NEW DELHI-110 029, INDIA.

TENDER ENQUIRY DOCUMENT

(Two Bid System for conclusion of Rate Contract)

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Advertised Tender Enquiry No: **XX-58/SO(DO)/RIA Kits/R.B./23-24/M&E**

Rate Contract items : **Procurement of Fluorescence / Chemiluminescence Immunoassay and Clinical Chemistryassay kits for diagnostic tests of various parameters on Reagent Rental contract basis for three (3) years (further extendable by 2 years).**

Period of Rate Contract : 3 Years (Further extendable by 2 years)

SECTION-I

ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-110 029

NOTICE INVITING TENDERS (NIT)

Advertised Tender Enquiry No : **XX-58/SO(DO)/RIA Kits/R.B./23-24/M&E.** On behalf of Director, AIIMS, Ansari Nagar, New Delhi-110 029, online bids are invited in two bid system (Techno-Commercial Bid and Financial Bid) from eligible and qualified firms/manufacturer for supply of following Goods for conclusion of Rate Contract for a period of one Year:-

S. No.	Brief Description of Goods	Estimated Quantity Per Year	Amount of Bid Security/EMD
1.	**Fluorescence / Chemiluminescence Immunoassay and Clinical Chemistry Assay Kits for diagnostic tests of various parameters on three years reagent rental contract basis.**	**As Indicated In Section VII**	**Rs. 1,80,000/-**

CRITICAL DATE SHEET

Published Date & Time	01-12-2023 at 04.00 pm
Bid Document Download/Sale Start Date	01-12-2023 at 04.00 pm
Seek Clarification Start Date	01-12-2023 at 04.00 pm
Seek Clarification End Date	07-12-2023 at 04.00 pm
Pre Bid Meeting	*NA*
Pre Bid Meeting Place & Address	NA
Bid Submission Start Date & Time	14-12-2023 at 04.00 pm
Bid Submission End Date & Time	02-01-2024 (Tuesday) at 03.00 pm
Bid Opening Date & Time	03-01-2024 (Wednesday) at 03.00 pm

Section – VII
TECHNICAL SPECIFICATION

1. Procurement of Fluorescence / Chemiluminescence Immunoassay and Clinical Chemistry assay kits on Reagent Rental contract basis as per list of assays in Table-1.

2. Kits should be approved for In vitro diagnostic (IVD) use. Certification and kit details of each parameter (FDA/CE/OIE/ International certified only) should be enclosed and same will have to match specifications.

3. For each assay, cross-reactivity should be less than 10% with closely related molecules.

4. Compatible and Fully automated auto analyzer having facility of continuous loading and random access system – three (03) units modular/integrated immunoassay and one (01) unit clinical chemistry analyzersalong with total lab automation system (track) have to be providedby the bidder on free of charge (FOC) basis. The specifications for the analyzers and total lab automation system (track) should match thosegiven in Table-2. All the machines will be maintained by the vendor free of charge (FOC),including all spare parts, during the contract period.

5. Price comparison will be made on "Composite rate basis" of kits. L1 will be determined for each assay and contract will be awarded to the bidder who is overall lowest quoted bidder (L1 for maximum number of assays).

6. The bidder should quote prices for individual kits and their compatible controls, calibrators, buffers and all other consumable items which may be required. Bidder should also quote price for the Multi-Constituent Control (MCC). Summary of the prices should be given in the format as specified in Table-3 and Table-4 for the comparison of the prices.

7. The rates quoted by the bidder should include applicable taxes, if any, otherwise it will be presumed that the quoted rates are inclusive of such taxes.

8. Approx. number of tests per year as mentioned in Table-1 may increase or decrease based on the actual requirements or patient load.

Table-1: List of Assays

S. No.	Name of Assay	Type of Assay	Approx. No. of tests per year
Immunoassays			
1	Total T3	Immunoassay	5,000
2	Total T4	Immunoassay	5,000
3	TSH	Immunoassay	15,000
4	Free T3	Immunoassay	500
5	Free T4	Immunoassay	500
6	Anti TPO	Immunoassay	1,000
7	Anti.Tg (Anti-thyroglobulin)	Immunoassay	200
8	Luteinizing Hormone (LH)	Immunoassay	2,000
9	Follicle Stimulating Hormone (FSH)	Immunoassay	2,000
10	Prolactin	Immunoassay	2,000
11	Testosterone	Immunoassay	1,000
12	Progesterone	Immunoassay	100
13	Estradiol	Immunoassay	500
14	DHEA-S	Immunoassay	200
15	Cortisol	Immunoassay	500
16	Sex Hormone Binding Globulin (SHBG)	Immunoassay	200
17	Total β-hCG	Immunoassay	500
18	Intact PTH (Parathyroid Hormone)	Immunoassay	5,000
19	Cytomegalovirus (CMV) - IgG	Immunoassay	100
20	Cytomegalovirus (CMV) - IgM	Immunoassay	100
21	Rubella - IgG	Immunoassay	100
22	Rubella - IgM	Immunoassay	100
23	Toxoplasma - IgG	Immunoassay	100

24	Toxoplasma - İgM	Immunoassay	100
25	Active Vitamin B12 (Holotranscobalamin)	Immunoassay	4,000
26	Ferritin	Immunoassay	2,000
27	Folate	Immunoassay	3,000
28	25-hydroxy Vitamin D	Immunoassay	10,000
29	Insulin	Immunoassay	500
30	C-peptide	Immunoassay	100
31	Alpha FetoProtein (AFP)	Immunoassay	1,000
32	CA-125	Immunoassay	1,000
33	Total PSA (Prostate Specific Antigen)	Immunoassay	1,000
34	CEA	Immunoassay	1,000
35	CA 19.9	Immunoassay	1,000
36	CA 15.3	Immunoassay	100
37	HE 4	Immunoassay	100
38	Free PSA	Immunoassay	100
39	BNP	Immunoassay	1,000
40	STAT CKMB	Immunoassay	200
41	Homocysteine	Immunoassay	100
42	Troponin I (High Sensitive)	Immunoassay	500
43	Anti-CCP	Immunoassay	1,000
44	Procalcitonin	Immunoassay	5,000
Immunoassays / Clinical Chemistry Assays			
45	Cyclosporine	Immunoassay / Clinical Chemistry	200
46	Sirolimus	Immunoassay / Clinical Chemistry	100
47	Tacrolimus	Immunoassay / Clinical Chemistry	100

48	Methotrexate	Immunoassay / Clinical Chemistry	200
Clinical Chemistry Assays			
49	HbA1c (Glycated Hemoglobin)	Clinical Chemistry	500
50	Total Bile Acids	Clinical Chemistry	100
51	C-Reactive Protein (CRP)	Clinical Chemistry	200
52	D-dimer	Clinical Chemistry	100
53	Lactate Dehydrogenase (LDH)	Clinical Chemistry	100
54	Iron	Clinical Chemistry	100
55	Transferrin	Clinical Chemistry	100
56	Unsaturated Iron Bnding Capacity (UIBC)	Clinical Chemistry	100

Table-2: Specifications for AnalysersandTotal Lab Automation System (Track) (to be provided on FOC basis)

S. No	Specification
A.	**Analysers to be connected to Track:**
	Specifications: 3 units of modular Immunoassay (IA) to be connected and 1 unit Clinical Chemistry (CC) to be connected on the Track
1	**System:** Should be Floor Model, Multi-channel, Random Access, with automatic rerun, and integrated Immunoassay & Clinical Chemistry Analyser.
2	System should be modular and scalable to accommodate more modules of IA and CC to manage higher workloads with single user interface.
3	**Desired Throughput:** It should have through put of minimum 200 tests for Immunoassay &800 tests forClinical Chemistry per hour for each module.
4	**Sample containers:** It should accommodate primary sample tubes, sample cups, aliquot tubes in same rack.
5	The system rack should be compatible & should be directly loaded on Track sample sorter / IOM to avoid duplication of work.
6	It should communicate with the middleware to flawlessly perform all the analytical steps and transmit the results.
7	**STAT samples:** System should allow STAT sample loading with flexibility to fix any sample loading area for STAT during direct loading of samples on analytical modules.
8	**Reagent capacity:** It should have facility to load reagents for at least 45 refrigerated reagent positions for IA &at least 60 refrigerated reagent positions for CC on each module.
9	**Direct Sample loading:** System should allow continuous direct loading of samples on analytical modules. System should have a sample loading capacity of at least 120 tubes at a time on each IA analyzerand CC analyzer.
10	**Reagent loading:** It should have continuous access to reagent compartment for loading & unloading of reagents, while sample run is in progress.
11	**Reagent pack size:** For high volume IA parameters like T3, T4, TSH, the bidder should quote for bigger pack sizes also.
12	**Ready to use reagents:** IA reagent should be ready to use and there should not be any additional / ancillary reagent required to run the test.
13	**Calibration:** It should have facility to view and print calibration curves. The system should have

	calibration stability of minimum 28 days for majority of IA parameters & minimum 5 days for all CC parameters, to minimise repeated calibrations & to reduce reagent wastage.
14	**Multi-lot calibrators:** The calibrators should be used for multi-lot reagents to save the calibration cost.
15	Clot and bubble detection or similar technology to ensure proper aspiration of samples and reagents with alert to user.
16	The system should have mechanism to avoid the reagent wastage, due to sample clot / bubble issues.
17	**User safety:** It should have continuous access for reagents &consumables without safety hazard to user. It should have facility to accommodate liquid and solid waste separately.
18	**Quality Control on board storage:** System should preferably allow on-board storage of QCs and automatic QC testing at prescribed intervals defined by user.
19	**Quality of Results:** The system should have facility to measure results directly from disposable cuvettes at PMT for all immunoassay parameters to avoid any cross contamination or carry over.
20	**Chemistry module cuvettes:** The CC module should have quartz cuvette to minimize the consumables usage / plastic waste.
21	**Result storage:** System should be capable of result storage up to 200,000 on each integrated IA or CC module.
22	**Walk away capability:** It should have walk away capacity without any interruption or user intervention up to 3 hours or more.
23	**Quality standards:** Should provide valid US FDA certificates or CE certificate.
24	**Assay Quality:**The immunoassays should be free of Biotin-associated interference by having assay designs that**DO NOT** utilize biotin and streptavidin binding**OR** thatutilize a streptavidin-biotin complex bound in reagents before incubation with blood samples.
B.	**General Track Specifications**
1	The Total Lab Automation (TLA) system should be able to automate pre-analytical steps like sorting and de-capping before connecting with analytical modules.
2	The track should have modules like **Input Output and sorting module, Buffer Module and Decapper** unit with high flexibility to add or remove any of the modules to fit the requirements of the lab now and in the future.
3	The system should simultaneously support sample tube of diameters from 13mm to 16mm with barcodes in each of the modules.
4	TLA should support upgrades to connect more analysers to cover future increase in workload with minimal disruption of the workflow and with minimum downtime.
5	Sample tubes transportation should have built in redundancy and should provide minimum downtime. Sample Transportation should have the ability to adjust the variable speed at which sample can be transported depending on the priority of the sample.
6	The supplier should be able to design the track system within the space provided by the lab with flexibility to modify the design in future with no disruption to current operation.
7	Vendors should provide their electricity consumption units (in KW / BTU) for their track design including analytical modules quoted in the tender in a separate sheet.
8	The supplier must perform equipment calibrations as per manufacturer's recommendations to fulfil the requirements of the latest IS0 15189 and NABL 112 or as specified by NABL from time to time and the records of such calibration must be made available to the laboratory including certificate of calibration.
9	IQ, OQ & PQ of all the equipment must be provided to the laboratory at the time of installation.
10	The automation should be able to handle all barcodes as per CLSI AUTO2-A2.
11	All hardware and software required (including drivers, interfaces etc) to be included.
12	The TLA modules should work individually, for example if one module is down, the rest of the modules should function without any hassle.
13	If any civil works required in the lab to install and commission the Track, it shall be the responsibility of the vendor and cost should be borne by the vendor.
C.	**Track software and Middleware – Specifications**
1	There should be a single command system to monitor all the analysers attached on the middleware for sampling status, sample location, TAT monitoring, QC status and additional testing.
2	STAT sample handling by priority in both pre-analytical and analytical modules without interrupting the routine run.
3	System software should be smart enough to identify the STAT sample tubes.

4	Should perform automatic balancing of workload and number of sample tubes, reagent and calibration status, sample programming information and dynamic instrument test menu and status etc.
5	Should have automatic communication of sample test status to properly handle storage or rerun of the sample.
6	Should have automatic retrieval of samples for re-run, reflex and add-on testing.
7	Should have automatic recognition of errors in any of the modules connected and notification to the user.
8	Should provide alerts to control station & monitoring screens.
9	Should allow user to search sample information via Sample or Sample History.
10	Should have manual rerun ability to accommodate request for a sample tube previously run on TLA.
11	Should allow automatic routing of samples for testing based on tests ordered, test menu of the available Connected analysers, load balancing across analysers with common test menus to optimize throughput and best fit sort destinations.
12	There should be automatic sample tracking including sample arrival (date/time recording), sample location while on the automation line and time of sample removal from the system.
13	System should be provided with all the necessary controlling devices and monitoring screens to provide real time information about status of samples & turn-around time.
D.	**Modules to be connected on the track**
	All the modules shall be pre-assembled with uniform user interface to benefit the users with ease of use and quick learning.
	1. Input Output Module
a	It should have a throughput of minimum 800 tubes per hour.
b	It should have STAT / Priority sample handling facility.
c	It should be able to recognize tube type using cap colour detection.
d	It should have the ability to rerun / reflux samples to allow re-introduction of previously processed sample tubes for routing to and from the storage.
e	IOM module should be able to sort samples into sample racks of 3rd party analysers for track sampling.
f	Capacity of loading area for input / output to be at least 500 tubes.
g	It should support offline archiving of samples by identification of sample position in Archive using middleware, if the Archive / storage module off the track.
	2. Decapper:
a	It should be able to De-Cap sample tubes with common tube types including push and screw caps.
b	Should have a De-Capping capacity of minimum 500 tubes per hour.
	3. Buffer Module or Similar Technology:
a	Should have a throughput of minimum 800 tubes capacity.
b	Reduce Redundancy: It should hold the samples in case the sample has missing test order or analyser overload, or output module is overloaded or samples requiring re-distribution to another instrument etc.
c	It should release samples from buffers the moment they are needed to improve individual patient result delivery and improve analytical Turn Around Time (TAT).
	4. Sample Transport System:
a	The sample carrier should have a capability to attain differential speed for improved TAT.
b	The Track should have parallel lanes for priority sampling and better management of redundancy.
c	Point in space sample aspiration – It should enable direct Track Sample aspiration while the sample tube remains on the track without the need to remove the sample from the Track to improve the TAT and reduce the incidents of batching.
d	Analysers should be able to work independently when the track is not functioning/ not connected.

Table-3: Format for price of kits

Name of the Assay	Pack Size	Cost of Kit	Tax	Final Total Cost of Kit	Cost per Test
1.	2.	3.	4.	5.	6.

Table-4: Format for price of controls, calibrators, consumables etc.

Name of the Assay	Calibrator			Control		Other Consumables	
	Cost	Pack Size	Onboard Stability (in days)	Cost	Pack Size	Cost	Pack Size
1.	2.	3.	4.	5.	6.	7.	8.

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Note: -

1. **Rate of Calibrator, Control and Other consumable may be quoted separately, if the rates/item not included in the kit itself.**
2. **Test load as indicated in Technical specifications may be taken into account for quoting rates for kit, calibrator, control & other consumable.**