

ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-29
STORES SECTION (DO)

Ref. No. 50/Stores(DO)/E&M/PAC/2019-20/FSC-I Dated-18/02/2020

Sub:- Purchase of "Chemistry Auto Analyzer – 01 No." for the Department of Endo & Metabolism at AIIMS, New Delhi-110029, on proprietary basis inviting comments thereon.

The Institute is in the process to purchase "Chemistry Auto Analyzer – 01 No." at AIIMS, New Delhi from M/s. Roche GmbH, Germany. The PAC Certifications by M/s. Roche GmbH, Germany as well as the user department are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within 15 day from the date of issue/uploading of the notification giving reference No. 50/Stores(DO)/E&M/PAC/2019-20/FSC. The comments should be received in office of Stores Officer (FSC), Store Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before 09/03/2020 upto 12.30 p.m. failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,


SR. STORES OFFICER (DO)

Encl: Related documents enclosed.

Dept. of Endo & Metabolism
All India Institute of Medical of Medical Science
Dept. of Endocrinology & Metabolism

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Dated :- 14th Feb 2020

Sub: Technical Specifications drawn by Technical Committee for the purchase of Chemistry Auto Analyzer

S No	Tender Specifications
1	Completely dedicated, discrete system for more accuracy & least batch to batch variation is essential. Fully automated, computer driven machine, capable in operating under Indian voltage condition.
2	All the technical points should be highlighted on the manufacturer's brochure (No data other than that highlighted brochure will be entertained). Any point missing in that brochure will be treated as not available category. No further enquiry will be conducted.
3	Reagent should come in compact, ready to use condition for hassle free use.
4	On board reagent cooling system for better storage of open vials.
5	System which will must use disposable cuvettes/tubes/cups will be preferred for minimal contamination & maximum accuracy.
6	Less sample requiring machines will be preferred. In any case more than 100 µl sample requiring machines will not be considered.
7	Instrument should have multi mode analyzing capacity like absorbance photometry for enzymes & substrates, fluorescence polarimetry, turbidimetry for specific proteins, Ion selective electrode for sodium, potassium, lithium, chloride etc measurement (must measure in direct method to avoid dilution & thus for accuracy). Single mode instruments will not be entertained.
8	Reagents should be available in pack sizes of 100 to about 800 tests.
9	Light source should be cheaper, common & easily available Like Halogen-Tungsten.
10	Clot detection facility with correction is a must for smooth running of the machine.
11	Should have capacity to read bar-code on reagent pack. The instrument must have flexibility to change reagent packs when running.
12	Instrument must have the capacity to run some essential tests like Triglycerides, LDL, HDL, cholesterol, serum creatinine, uric acid, urea bilirubin, HbA1C, Micro Albumin Urea, D-Dimer glucose, sodium, potassium, CRP, APO A, APO B & Drug Assays & vendor demonstrate the Physical running of these parameters on the machine.
13	HbA1c test must be perform from Whole Blood sample & the kit must be US FDA Approved. <i>Preferably for</i>
14	Instrument with less water requirement with not more than 2 liters water/hour in running condition will be preferred.
15	The instrument must have the facility to perform ISE tests through Direct & Indirect Methods
16	Assay throughput must be minimum 400 test per hour. Machines with lower capacity will not be considered.
17	Should be able to process at least 30 test per sample in a single run.
18	System must have 12 wave length options from 340-800nm. Identifies the electrolytes potassium, sodium, chloride, Lithium*.
19	Should have capacity to handle whole blood, serum, plasma, urine, cerebrospinal fluid etc.
20	Minimum sample loading capacity should be 75 OR more & the continuous sample loading facility is essential.
21	Sample dilution should be automatic & on board for greater accuracy.
22	The instrument must be able to support at least 140 applications.
23	Real time on Board inventory.
24	The instrument should come with the computer, monitor & laser printer.
25	Should provide the list of customers with the model quoted & the presence of that model in Northern part of India will be given preferences for obvious reasons of service personnel presence & expertise

Hack
सहायक आचार्य/Assistant Professor
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Foram
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26	In case of breakdown minimum time for response should be mentioned with the number of service engineer in the region (4)
27	The stability of the reagents on the analyzer must be at least 8-12 weeks.
28	The system must be capable of automatic dilution and repeatability of samples as well reading different types of sample's bar code. The storage of reagents are being held in refrigerated space.
29	System must have pressure sensors for sampling control and clot detection , with automatic removal.

General Clauses

1. Online Compatible UPS to be provided.
2. In-House Service Engineers from principal company/ or authorized agents should be available in India on one-week notice basis in case of emergency.
3. Rate list of Consumables / Spares should be provided.
4. Warranty: 5 years comprehensive (including spares and labor)
- 5.. 5 years CMC (6th - 10th year) after completion of warranty period with spares and labor
6. Standard Penalty Clauses apply
7. Important: The warranty (AMC/CMC) and maintenance of the computer and the UPS and its batteries should be the responsibility of the company which provides the Chemistry Auto Analyzer machine for the entire warranty period (5+5 years)

Dr. Nikhil Tandon

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(Representative of MS)
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Dr. Yashdeep Gupta

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ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR : NEW DELHI: 110029

PROPRIETRY/SPECIFICATION BRAND GOODS CERTIFICATE

Dated - 14th Feb 2020

1. Item/Type/Model No. required along with specification.

Chemistry Auto Analyzer with HbA1c whole Blood

2. If the item a spare part attachment or accessory for an existing equipment.

No, It is a machine.

3. Name of the manufacturer/supplier of the item proposed by the indenter.

M/s Roche Gmbh, Germany is sole manufacturer and M/s Roche Diagnostics India Pvt. Ltd. is authorized distributors for the same.

4. Are they sole manufacturer/sold distributor of the item

Yes - sole manufacturer

5. If there any other item with similar /equivalent specification available in the market to meet the job requirement envisaged. If the answer is yes, why the same can't be procured. Demanding officer should bring out comparative functional advantages /cost effectiveness of the recommended item from these offered by other.

No, as per our best knowledge Only M/s Roche Gmbh, Germany provide Chemistry Auto Analyzer with HbA1c whole Blood

6. What were the efforts made to located alternative source of supply or use other substitutes.

M/s Roche Gmbh, Germany is the sole manufacturer of this Instrument as per our best knowledge

7. Why open/limited tender can't be resorted to, for locating alternative source.

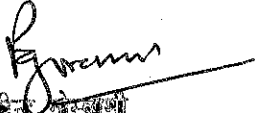
Because there is no other manufacture as per our best knowledge.

8. Are the proprietary items certifying that the rates are reasonable or not.

Yes proprietary items & the rates are reasonable.

9. Any other justification for procuring item from the single source.

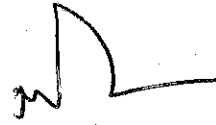
M/s Roche Gmbh, Germany is the sole manufacturer of this Instrument as per our best knowledge

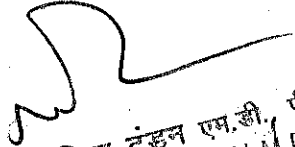

Dr. Ravinder Grewal
M.D., D.M. (Endo) (FAC), FRCR, FRCR
Signature of Indenter
(Demanding Office)

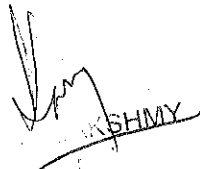
I certify that the item at Sr. No. 1 above is required to be procured on single tender basis as the source of supply is definitely known / the specified brand proposed was advantages in meeting our functional requirement and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

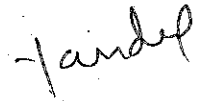
(strike out whichever is not applicable)

(Countersigned)
(Head of the Department)


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Ref. No.

August 5, 2019

To,

The Deptt. of Endocrinology & Metabolism

All India Institute of Medical Sciences

Ansari Nagar

New Delhi-110029

PROPRIETARY CERTIFICATE

We hereby confirm that Roche Fully Automated Clinical Chemistry Analyzer, Model: cobas Integra 400 Plus with below mentioned feature is our Proprietary item:

- 1). Disposable cuvettes for minimal contamination & maximum accuracy.
- 2). HbA1c Test from Whole Blood Sample & US FDA Approved.
- 3). The facility to perform ISE tests by Direct & Indirect Methods.

We further hereby confirm that the above said features to the best of our knowledge no company other than us manufacture this product anywhere else in the world.


Yours faithfully,
For Roche Diagnostics GmbH

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim


i.V. Andrea Weber
Manager Global Regulatory Affairs




IV. Christian Bovenkerk
Project Manager Regulatory Affairs


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TO WHOM IT MAY CONCERN

January 31, 2018

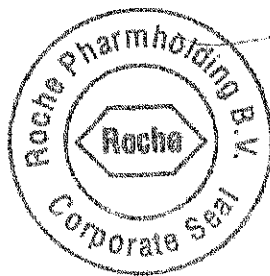
Roche Diagnostics India Pvt. Ltd. a company registered under the Indian Companies Act, 1956 is a wholly owned subsidiary of Roche Pharmholding B.V., The Netherlands. Further, Roche Pharmholding B.V. is a wholly owned subsidiary of Roche Finance Ltd., Switzerland, a company incorporated under laws of Switzerland.

Roche Diagnostics India Pvt. Ltd. is directly handling all business transactions in India for the Roche Diagnostics range of products.

Sincerely,

ROCHE PHARMHOLDING B.V.

Dieter F. Heinis
Director



Sheri L. Morin
Chairwoman of the Board

