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

Ref. No. 44/Stores (DO)/Gastro/PAC/2017-18/FSC

Dated-24/02/2018

Sub:- Purchase of "Fully automated analyser for fecal calprotectin and Tissue Transglutaminase IgA, IgG, DGP, IgE" for the Department of Gastroenterology & HNU, (AIIMS), New Delhi-110029, on proprietary basis <u>Inviting comments</u> thereon.

The Institute is in the process to purchase Fully automated analyser for fecal calprotectin and Tissue Transglutaminase IgA, IgG, DGP, IgE for the department of Gastroenterology & HNU, (AIIMS), New Delhi from M/s Thermo Fisher scientific Upasla, Sweden, through M/s. Biochrom International Pvt. Ltd. Delhi The PAC Certifications by M/s Thermo Fisher scientific Upasla, Sweden, 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. 44/Stores(DO)/Gastro/PAC/2017-18/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 14/03/2018 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.

STORES OFFICER (FSC)

Encl: Related documents enclosed.

Specifications – analyser for fecal Calprotectin and tissue transglutaminase IgA, IgG, DGP, IgE Assay

- 1. Fully automated immunodiagnostic system based on fluoro-enzyme immuno technology.
- 2. System should be fast, integrated, automated and single unit to determine values for autoimmune disease parameters specific for faecal calprotectin, tissue transglutaminase IgA, , tissue transglutaminase IgG, Deaminated gliadin peptide (DGP) and IgE antibodies in human serum.
- 3. Should have an inbuilt/external barcode reader to read multiple barcode types on samples, standards and reagents.
- 4. Should have capability to do assay in stat and random assay mode.
- 5. Should be calibrated to international standards for sensitivity and specificity of high level. It should have a broad range of standards for calprotectin preferably up to 5000mg/kg.
- 6. Should have a capacity to run as low as a single sample to high throughput of up to 300 tests at minimum running cost.
- 7. Should have facility for clot detection and in-adequacy of sample.
- 8. Should be able to analyze sample volume of less than 100uL depending on the analyte.
- 9. Should have separate probes for sample and reagent dispensing.
- 10. Should have facility for onboard auto dilution and reflex testing for high and abnormal samples.
- 11. Should have effective wash technique to prevent intermixing with last sample processed.
- 12. Should provide access for loading and unloading reagents without interrupting analyzer processing.

13. Should have controlled temperature (ambient) system for long on-board stability of reagents. Moreover the reagents (kept in stock) should not require special or extreme storage requirements.

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- 14. Should have in built QC system for monitoring of obtained results and error recovery system.
- 15. Results should be available both test-wise and patient-wise in numerical with storage of 5000 results.
- 16. The instrument software should be user friendly for calibrations, measurements etc.
- 17. Should be compatible with Laboratory Information Management System (LIMS) / e-Hospital for online computerization of patient reports.
- 18. Should be CE-IVD, ISO approved for safety reasons.
- 19. Should have an onboard touch screen monitor for instructions to the machine.
- 20. Should come with PC compatible with machine and a printer of reputable make.
- 21. Should have troubleshooting assistance
- 22. System should come with comprehensive warranty as per protocol.

Osfor/2018

(Dr. Hjay Hadda)

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(Dr. Vineet Alaya)

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(Dr. Roban Malik)

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

PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE

01.	Item /Type/Model No. required alongwith specification	PHADIA 250
02.	Is the item a spare part attachment or accessory for an an existing equipment	Automated analyser No
03.	Name of the manufacturer/supplier of the item proposed by the indentor	Thermo Scientific
04.	Are they sole manufacturers/ sole distributors of the item.	Yes, authorization certificate enclosed.
05.	Is 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 the other.	No. The fecal calprotectin, tissue transglutaminase IgA & IgG, Deaminated gladin peptide (DGP), IgE levels can be assayed in a single unit.
06.	What are the efforts made to locate alternative source of supply or use other substitutes.	No other machine can perform all assays.
07.	Why open/limited tender can't be restored to for locating alternative source.	NA, Proprietary
08.	Are the proprietary items certifying that the rates are reasonable or not?	Yes, certificate enclosed
09.	Any other justification for procuring item from single source.	Good feedback from elsewhere in the country.

Signature of Indentor (Demanding Officer)

COUNTERSIGNED (Head of the department)

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

(Strike out whichever is not applicable)

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Thermofisher SCIENTIFIC

Uppsala, February 23, 2017

To Whom It May Concern

Ref: DociD 631376

Confirmation of proprietary of ImmunoCAP Products

This is to confirm that ImmunoCAP is a proprietary product, based on FEIA technology, exclusively manufactured by Phadia AB, Rapsgatan 7P, P.O. Box 6460, 751 73, Uppsala, Sweden and marketed exclusively by authorized distributors & subsidiaries.

The complete range of ImmunoCAP Products are available in India via Thermo Fisher Scientific India Pvt. Ltd (ImmunoDiagnostics Division), Unit No.07, 10 &11, ground floor, Splendor forum, plot no 03, Jasola, District Centre, NEW DELHI-110025, India.

Sincerely,

Ulf Karlberg
Regulatory Affairs Manager
Regulatory Affairs

ImmunoDiagnostics

Phadia AB

Phadia AB

Rapsgatan 7P, P.O. Box 6460 751 37 Uppsala, Sweden

Ulf Karlberg Regulatory Affairs Manager

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Date- 7th Dec 2017

TO WHOM SO EVER IT MAY CONCERN

We at Thermo Fisher Scientific India Pvt. Ltd. having office at Unit No. 7, 10, 11, ground floor, Splendor Forum, Jasola District Centre, New Delhi-110025, being importer of Phadia Laboratory Instrument and Consumables, hereby authorize BIOCHROM INTERNATIONAL, PLOT NO:9, FIRST FLOOR-120, SIKKA GALAXY, SHRESTHA VIHAR, NEW DELHI-110092, as an authorized distributor of the company.

They are sole authorized distributor to quote, supply and collect payments for Phadia-250 range of products (ImmunoCAP & EliA) in Dept. Of Gastroenterology, All India Institute of Medical Science, Delhi.

Thanking you,

Sincerely yours,

Authorized signatory

Thermo Fisher Scientific India Pvt. Ltd.

Perpentaged Officer:

Unit No. 7, 10 & 11, Spheciar Forum. Flect 3. Obstrict Contac, Japans

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