Blood Centre Main Hospital, AIIMS, New Delhi Department of Transfusion Medicine

Ref: No 1-BCMH/Store/NAT/PAC/24-25

Dated:- 18.04.2024

Sub:- Purchase of Procleix Ultrio Elite Assay Kit for Blood Centre Main Hospital Department of Transfusion Medicine, AIIMS New Delhi on proprietary basis --- reg.

The Institute is in the process to purchase of Procleix Ultrio Elite Assay Kit for the Blood Centre Main Hospital Department of Transfusion Medicine, AIIMS New Delhi on proprietary basis being close system. The proposal submitted by M/s Hemogenomics authorized distributor of M/s Grifols (HK) Limited. and PAC Certificates 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 issue of 15 days from the day of issue/uploading of the notification giving reference No 1-BCMH/Store/NAT/PAC/24-25. The comments should be received by office of HOD Dept. of Transfusion Medicine AIIMS, New Delhi on or **before 03.05.2024 up to 5.00 p.m.** failing which it will be presumed that any other vendor is having no comments to offer and case will be decided on merits.

Encl:- Related documents enclosed

Dr. Hem Chander Pandey
Head Department of Transfusion Medicine

AIIMS, New Delhi



Grifols Diagnostic Solutions Inc. 4560 Horton Street Emeryville, CA 94608-2916 USA

PROPRIETARY ARTICLE CERTIFICATE

Procleix Ultrio Elite Assay

To Whom It May Concerns

We herewith declare that the following IVD medical device is a proprietary product, covered by intellectual property rights (i.e. patents)

■ ID-Nucleic Acid Amplification Test (NAT) with Procleix Ultrio Elite Assay (for HIV-1, HIV-2, HBV, and HCV) using TMA technology.

The Procleix Ultrio Elite Assay is covered by the following US patents and their foreign equivalents:

US PATENT #	US PATENT A
7,097,979	6,074,816
6,870,045	5,780,219
6,649,749	5,714,596
6,623,920	5,696,251
6,245,519	

The above product is manufactured by Grifols Diagnostic Solutions Inc. (with business address at 4560 Horton Street, Emeryville, CA 94680, USA)

(NOTE: Grifols (HK) Ltd (with business address at Units 1505-07, Berkshire House, 25 Westlands Road, Quarry Bay, Hong Kong) is a subsidiary of Grifols Diagnostic Solutions Inc.)

Acknowledgement

GRIFOLS DIAGNOSTIC SOLUTIONS INC.

Signed by:

Alisha McReynolds

Title:

Name:

Alisha McKeyholds

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Director, Regulatory Affairs

Date:

2nd April 2024

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Blood Centre Main Hospital, AIIMS, New Delhi Department of Transfusion Medicine

Proprietary Article Certificate (PAC)

(for chemicals, spare parts, reagents, consumable etc)

- (iii) The indented goods are manufactured by M/s Grifols (HK) Limited appoint his distributer in India M/s Hemogenomics Pvt. Ltd.
- (ii) Item Name:- Pocleix Ultrio Elite Assy
- (xi) Model/part/catalogue:- Procleix Panther System
- (xii) Reasons/justification which makes the requirement proprietary: Closed System
- 9. It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfill the vital requirements of end user
- 10. It is certified that the purchase is proposed to be made on proprietary usage basis because any other material/equipment/instrument chemical, etc. If used will lead to deviation and affect the integrity/accuracy, validity or analysis of the assignment/patients care.

Signature of Fundamental Additional Professor & He

with Name, Designation, Department and Hospital/Institute/DGHS

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Blood Centre Main Hospital, AIIMS, New Delhi Department of Transfusion Medicine

CERTIFICATE OF REASONABILENESS OF PRICE

Reference ATE/LTE/STE/ PAC No

It is certified that the goods recommended for purchase against above referred ATE/LTE/STE from M/s...Hemogenomics Pvt. Ltd responsive bidder/single responsive bidder/proprietary bidder) are of requisite specification and quality, priced at the prevailing market rate and are reasonable.

The supplier recommended is reliable and competent to supply the goods in question

(Signature (S) if indenting/User Department all official Professor & Head

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Please strike out whichever is not applicable

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