



# **All-India Institute of Medical Sciences Ansari Nagar, New Delhi-29.**

## **(STORES SECTION (DO))**

Dated: 26.12.2016

Ref. No. XX-134/SO(DO)/Blood Bank (Main)/2016-17/FSC-I

**Subject:** Proposal for purchase of Fully automated individual unit NAT testing machine on buy back basis on Proprietary basis (PAC) for department of Blood Bank (Main) at AIIMS - Inviting comments thereon.

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The Institute is in the process to purchase Fully automated individual unit NAT testing machine on buy back basis on Proprietary basis (PAC) for department of Blood Bank (Main) at AIIMS, New Delhi-110 029 from M/s.Grifols (HK) Limited, USA (OEM) through their Indian Agent M/s.Hemogenomics Pvt. Ltd., Bangalore. The proposal submitted by M/s.Hemogenomics Pvt. Ltd., Bangalore, PAC certificate, quotation and other related documents are attached for ready reference.

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 giving reference **Ref. No.XX-134/SO(DO)/Blood Bank (Main)/2016-17/FSC-I**. The comments should be received by office of Sr. Stores Officer, Stores Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before **10.01.2017 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

**Encl:** Related documents enclosed.

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES  
Ansari Nagar New Delhi : 110029**

PROPRIETRY/ SPECIFICATION BRAND GOODS CERTIFICATE

Dated:- 29.11.2016

- |   |  |
|---|--|
| 1. Item/Type/Model No required along with specification   | : Fully automated individual unit NAT testing machine on buy back basis ((Procleix Panther System based on TMA technology) |
| 2. If the item a spare part attachment or accessory for an existing equipment.  | : Independent fully automated system   |
| 3. Name of the manufacture/supplier of the item proposed by the indenter.   | : M/s Grifols U.S.A. through M/s Hemogenomics  |
| 4. Are they sole manufacturer/sole distributor of the item  | : Yes M/s Grifols U.S.A is Sole manufacturer. and M/s Hemogenomics is sole distributor in India                            |
| 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   |
| 6. What were the efforts made to located alternative source   | : Global tender was floated only one firm M/s Hemogenomics is quoted   |
| 7. Why open/limited tender can't be resorted to for locating alternative source.  | : Global tender was floated only one firm M/s Hemogenomics is quoted   |
| 8. Are the proprietary items certifying that the rates are reasonable or not.   | : Rates are available with the tender Document.  |
| 9. Any other justification for procuring item from the single source.   | : Justification is attached  |

Prof. S. K. PANDA  
Head, Department of Pathology  
All India Institute of Medical Sciences  
Ansari Nagar, New Delhi-110029

Signature of Indenter  
(Demanding Officer)  
Dr. POORAM COSHIC  
Chief Medical Officer  
(for Blood Bank (Main))  
All India Institute of Medical Sciences  
Ansari Nagar, New Delhi-110029

Dr. Punit Kaur  
अध्यापक एवं अध्यक्ष / Professor & Head  
जैवभौतिकी विभाग / Deptt. of Biophysics  
अ.भा.आ.स. / A.I.I.M.S.  
आंसरी नगर, नई दिल्ली-29 / Ansari Nagar, New Delhi-29

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K Chatterjee

(Countersigned)  
(Head of the Department)  
Dr. KABITA CHATTERJEE  
आचार्य एवं प्रभारी आचार्य  
Prof. & Faculty incharge  
मुख्य रक्तकोष / Blood Bank (Main)  
अखिल भारतीय आयुर्विज्ञान संस्थान / A.I.I.M.S.  
नई दिल्ली-110029 / New Delhi-110029




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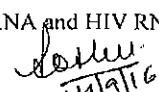
**Revised specification as advised in pre-bid meeting**  
**Specification for Fully Integrated and Fully Automated Walk away compact**  
**Individual Donor Nucleic acid testing (NAT) System**  
**As a Turnkey Project on Buy Back basis.**

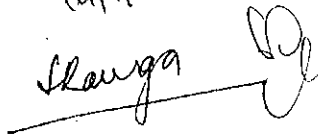
1. Individual Donor NAT System must be fully integrated and fully automated Walk away compact system.
2. Test Assay must be able to detect following in Individual Donor Nucleic Acid Testing(ID-NAT) format in initial screening as well as repeat testing by using Polymerase Chain Reaction(PCR)/Transcription Medicated Amplification (TMA) method.
  - HIV-1 (Group M, N, O)
  - HIV-2
  - HCV (genotypes 1, 2, 3, 4, 5, and 6.)
  - HBV (genotypes A, B, C, D, E, F, and G.)
3. Amplification process must not be inhibited by Heparin or any other anticoagulant.
4. System must perform automated nucleic acid target capture or nucleic acid extraction, amplification, and detection all in a single tube to minimize sample handling and any chances of contamination.
5. Multiplex Assay to detect HIV 1&2, HBV and HCV in plasma by running Nucleic Acid Amplification Test.
6. Test procedure must be able to target & amplify two separate regions of HIV-1 genome.
7. Internal control is added to each specimen in the first step of the assay to ensure assay integrity is maintained throughout the process.
8. The system must have throughput of minimum 300 samples in individual donor nucleic acid format (ID-NAT) in 8 to 12 hours
9. Test kit must consist of ready-to-use reagents and chemicals necessary for the whole NAT procedure. Each kit contain positive and negative calibrators, internal control samples, primers, probes, enzymes, reagent buffers and all other reagents needed for the target capture, amplification and detection of HBV DNA, HCV RNA and HIV RNA.

Punet Kar

  
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M.D., F.A.Sc.  
Head, Department of Pathology  
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Ansari Nagar, New Delhi-110029

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10. It must process and obtain on-demand results for high priority samples with stat testing ability.
11. It must provide programmable system maintenance and priming during lab's off hours.
12. The system must offer 24 hour calibrator stability.
13. The system must perform continuous processing of samples and continuous access of result with random access capability.
14. The system must have built-in process controls for sample and results integrity.
15. The system must have full sample traceability with positive sample identification through barcode and manual options
16. ID-NAT test procedure must be validated for highest available accuracy and precision of detection of HBV, HCV and HIV 1 & 2 Nucleic acid in donor plasma or serum either through European CE/IVD approved or US FDA approved NAT method licensed for blood donor screening.
17. Waste capacity of machine must be at least 600 tests.
18. The ID-NAT assay kits must have necessary approvals from CDSCO India.
19. The bidder is required to provide proven data on analytical sensitivity, specificity, reproducibility, repeatability and other relevant parameter of assay performance.
20. Quoted NAT machine must have proven installation base in India & must have at installations in at least five blood banks in India. The service support must be available within Delhi/NCR.
21. The sensitivity of assay at 95% LOD must be at least :
  - a. HIV – 1: 30 IU/ml
  - b. HCV – 8 IU/ml
  - c. HBV – 5 IU/ml
22. The specificity of the tests must be 100%
23. The cost of consumables must be quoted along with.
24. Original literature of equipment must be submitted.
25. European CE and/or FDA certification specific for the product must be mandatory.
26. Firm must supply the relevant calibration certificate for the equipment from NABL accredited Lab.

*Pratap Kumar*

*SS*  
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 Ansari Nagar, New Delhi-110029

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27. User's list must be provided with satisfactory report for the last three years from three licensed blood banks with contact details. However if a new /upgraded model is quoted with recent launch it will still be considered without 3 years satisfactory report.
28. Invalid test results will not be charged by the firm and in such case the firm has to bear the cost of tests and the kits as well.
29. Firm will have to supply the suitable UPS (with voltage stabilizing capability and back up supply for at least 2 hour with full load).
30. Demonstration of performance of equipment is compulsory in Delhi/NCR failing which the firm will not be considered for technical evaluation.
31. Up time & penalty for delays in repair & maintenance: the firm will ensure uptime of 345 days in a year during warranty period & CMC period.
32. Whenever there is breakdown the firm will carry out the repair within 24 hours of receipt of such information (either by telephone or by any other means). In case of system breakdown, the firm must bear the responsibility to test all the blood samples elsewhere on same platform and to provide the test results on the same day.
- If there is delay beyond 24 hours then the firm will be penalized at the rate of 1% of the cost of product per day.
- This financial penalty can be waived off on recommendation of the user dept. if the reasons of delay are genuine the same are recorded & endorsed by the concerned dept.
- If the down time is exceeded in a year from 20 days then the warranty shall stand extended by double the no. of days machine was out of order
33. Warranty: Comprehensive warranty for 5 years from the date of installation without any exclusion for both equipment and UPS with voltage stabilizing capacity. Next 5 years comprehensive maintenance contract for both equipment and UPS with voltage stabilizing capacity. The cost of warranty and CMC will be included in the total cost of the equipment for financial comparison
34. Electrical: The equipment must be able to run on the existing electrical provision. Any additional electrical requirement for the equipment must be supplied by the firm.

*Pratibha*

*SB*  
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14/9/16

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Justification & PAC documents to consider the case on single shortlisted /PAC basis.

The said tender has been participated by Hemogenomics with Procleix Panther System. Upon detailed evaluation, we have understood that the quoted product is proprietary in nature. The detailed Justification along with PAC document enclosed herewith:

#### 1. Individual Donor Nucleic Acid Testing (ID-NAT) by TMA :

Individual Donor NAT methodology is offered by only the participated bidder in India. Individual Donor NAT is preferred form for NAT testing of the blood donors, reasons as under:

##### Assay Sensitivity:

- In ID-NAT method of Nucleic Acid Testing, each individual donor sample is tested individually. Individual testing of the blood samples tested ensures the detection of true viral load, without any dilution effects. That means, the Analytical Sensitivity of the NAT testing and the Screening Sensitivity is the same.
- Better sensitivity and decreased chances of contamination or false positive results as no pooling (mixing of multiple donor samples) or any other external manipulation of the donor sample is required.

##### Use of patented technology

- Transcription Mediated Amplification (TMA) is a patented amplification technology of Grifols. TMA uses Isothermal exponential amplification process enabling faster amplification process and high throughput.
- No extra sample preparation like extraction, purification, ultracentrifugation required for TMA.

ID-NAT testing using TMA technology is a proven and accepted worldwide as the safest and most sensitive method for Nucleic Acid Testing of blood donors.

Other benefits available with the above said ID-NAT testing of the blood donor samples.

- **Operational Impact:** Operationally also ID-NAT ensure faster release of blood units, as in pooling one must quarantine all the samples in a pool in case of initial reactive pool. Initial reactive pool should retest all the samples individually adding extra step, manpower and time. Whereas, in ID-NAT method all non-reactive blood units can be immediately released for issuance without any need for pool resolution. This helps in proper inventory management and saves time in emergency situations.

**Screening Algorithm:** In ID-NAT method by Panther System, as soon as donor samples are available can be loaded to System for NAT screening. Whereas, in MP-NAT method firstly the blood bank needs to perform the serology testing then only the serology negative samples only

*[Handwritten signatures and stamps are present over the bottom half of the page, including names like Dr. Punit Kaur, Dr. Kabita Chatterjee, and various official stamps from the All India Institute of Medical Sciences and the Blood Bank.]*

can be tested for NAT. This increases the overall duration and time to complete the full infectious marker screening of a blood bank.

**2. Continuous loading and continuous release of reportable results:**

In Panther System, sample and reagents not only can be loaded continuously but also release of results in continuous. After 3.5 hours, the first results become available and thereafter 5 more results every five minutes. There is no need to wait to finish a batch to know results of all the samples.

**3. Shortest Turn Around Time - STAT:**

Priority samples can be processed at any given point of time and results can be obtained in shortest turnaround time without waiting for already loaded batch processing to finish. This will enable blood bank to test emergency samples on priority.

Blood transfusion services are emergency service where many times unplanned blood donations are required to meet the demand of blood in following cases.

- Emergency surgeries or unplanned surgeries.
- Trauma & accident cases, where patient may require multiple units of blood.
- Patients with negative or rare blood groups.
- Single Donor Platelet (SDP) required for Dengue patients and in Onco-surgeries.
- STAT will ensure early result of high priority samples thus life of many patients can be saved by providing ID-NAT tested blood.

Considering the fact that the AIIMS Main Blood bank already has been screening the blood donor using ID-NAT since 2010 and subsequently Blood bank at CNC and JPNATC also are sending samples to the main blood bank for ID-NAT Screening. Main blood bank, Collectively performs over more than 80,000 donor samples per annum, so a system with very high throughput is required which can test and give result of at least 250 individual samples within 8 hours' time.

In Blood Bank operation, time is very precious. We need to process each blood unit very carefully and issue them within shortest possible time. Shortest time to process is offered by Panther, therefore it is more suitable.

AIIMS main blood bank has already evaluated the Panther system and finds the system meets the current and future throughput requirements. Thus, we want to procure the said system at PAC basis since the said system offers the latest and most advantageous features.

The PAC certificate of the said system that has TMA & ID-NAT in the certificate is enclosed herewith.

Dr. Poonam Kaur  
Head, Department of Pathology  
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डॉ. पूनम कौर/Dr. POONAM COSHIC  
मुख्य चिकित्सा अधिकारी  
Chief Medical Officer  
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Dr. KABITA CHATTERJEE  
आचार्य एवं प्रभारी अ.  
Prof. & Faculty  
मुख्य रक्तालय  
मुख्य भारतीय अकादमी  
नई दिल्ली-110029/New Delhi-110029

## **PROPRIETARY ARTICLE CERTIFICATE** **Procleix Panther System**

Tuesday, 9<sup>th</sup> February 2016

### **To Whom It May Concern:**

This is to certify and confirm that the Procleix Panther System, manufactured by M/s. Hologic, Inc., and marketed worldwide by Grifols Diagnostic Solutions, Inc, together with the system's associated reagents, are customized to meet applicable international regulatory requirements, such as the European Union's CE conformity route. The following items are unique and proprietary to this product:

1. Individual donor nucleic acid testing (ID-NAT) by Transcription Mediated Amplification (TMA) technology.
2. Continuous loading of samples and continuous access of results for ID-NAT blood donor screening
3. STAT features for ID-NAT blood donor screening.

We further confirm that as per the current information with us, there is no firm/company, that is manufacturing similar products, that have comparable specifications and features such as the Procleix Panther System and its reagents.

### **Acknowledgement**

Prof. S.K. PANDA  
M.D., F.A.S.C.  
Head, Department of  
S. C. Bha Institute of Medical  
Ansari Nagar, New Delhi-110029

**GRIFOLS DIAGNOSTIC SOLUTIONS INC.**

Signed by:

Name:

DIANE DAY

Title:

Vice President, Global Regulatory Affairs

Date:

09 FEB 2016

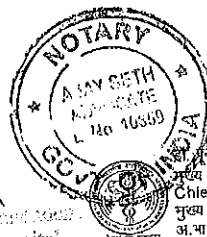


डॉ. पुनीत कौर / Dr. Pooja Kaur  
आचार्य एवं अध्यक्ष / Prof. & Head  
केन्द्रीय चिकित्सा विभाग / Dept. of Physics  
अ.च.आ.स. / A.I.I.M.S.  
अस्पताल, नई दिल्ली-29 / Ansari Nagar, New Delhi-29

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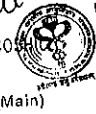
26 NOV 2016



Dr. Pooja Kaur  
Vardaan Hospital  
New Delhi-20

Medical Officer  
A.I.I.M.S. Hospital  
New Delhi-29

डॉ. पूनम कोशिक / Dr. POONAM KOSHIK  
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मुख्य रक्तबैंक / Blood Bank (Main)  
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NOTARY PUBLIC  
ACKNOWLEDGMENT

State of California  
County of Alameda ss.

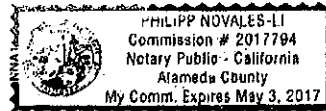
A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document, to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

On 09 FEB 2016 before me, PHILIPP NOVALES-LI, Notary Public, personally appeared DIANE DAY, who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

  
Signature



(scal)

OPTIONAL INFORMATION

Date of Document 09 Feb 2016 Thumbprint of Signer

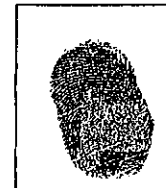
Type or Title of Document Proprietary Article Certificate

Number of Pages In Document One (1)

Document in a Foreign Language N/A

Type of Satisfactory Evidence:  
☐ Personally Known with Paper Identification  
☒ Paper Identification  
☐ Credible Witness(es)

Capacity of Signer:  
☐ Trustee  
☐ Power of Attorney  
☐ CEO / CFO / COO  
☐ President / Vice-President / Secretary / Treasurer  
☒ Other: Grifols Diagnostic Solutions, Inc.



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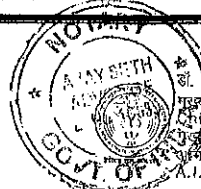
Other Information: N/A

Prof. S.K. PANIDA  
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रक्तसंचयन (Blood Bank)  
आचार्य (एन.एस.), आ.आई.एम.एस.,  
आ.आई.एम.एस., New Delhi

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आचार्य (एन.एस.)  
आचार्य (एन.एस.)

NOTARY PUBLIC  
ACKNOWLEDGMENT

State of California  
County of Alameda ss.

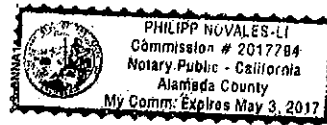
A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document, to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

On 09 FEB 2016 before me, PHILIPP NOVALES-LI, Notary Public, personally appeared DIANE DAY, who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

[Signature]  
Signature



(seal)

OPTIONAL INFORMATION

Date of Document 09 Feb 2016

Thumbprint of Signer

Type or Title of Document Proprietary Article Certificate

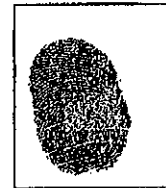
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Document in a Foreign Language N/A

Type of Satisfactory Evidence:  
☒ Personally Known with Paper Identification  
☒ Paper Identification  
☐ Credible Witness(es)

Capacity of Signer:  
☐ Trustee  
☐ Power of Attorney  
☐ CEO / CFO / COO  
☐ President / Vice-President / Secretary / Treasurer  
☒ Other: Grifols Diagnostic Solutions, Inc.

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A.I.I.M.S., New Delhi  
Dr. Kabita Chatterjee  
Prof. & Faculty  
A.I.I.M.S., New Delhi

## SECTION - XIV MANUFACTURER'S AUTHORISATION FORM

The 'Director'  
All India Institute of Medical Sciences  
Ansari Nagar  
New Delhi - 29  
India.

Dear Sirs,

Ref: Your TE document No XX-134/SO(DO)/B.B.(Main)/2016-17/FSC-1, dated 04 August 2016

We, Grifols (HK) Limited (Formerly Novartis Vaccines and Diagnostics (HK) Limited), who are proven and reputable manufacturers/License Holders of the Procleix Panther System and Procleix Ultrio Elite Assay, hereby authorize Messrs Hemogenomics Pvt. Ltd., located at 3rd Floor, Site No. 26, New BEL Road, Opp. Indian Oil Petrol Bunk, Near M.S Ramalah Hospital, Bangalore-560054, to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We further confirm that no supplier or firm or individual other than Messrs Hemogenomics Pvt. Ltd., located at 3rd Floor, Site No. 26, Opp. Indian Oil Petrol Bunk, New BEL Road, Near M.S Ramalah Hospital, Bangalore 560054 is authorized to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us. We also hereby extend our full warranty, CMC as applicable as per clause 15 of the General Conditions of Contract, read with modification if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

Yours Faithfully

Name: Electra  
Title: Director  
Date: 26 October 2016

For and on behalf of Grifols (HK) Limited  
Units 1505-07 Berkshire House 25 Westlands Road  
Quarry Bay  
Hong Kong

Prof. S. P. ANDA  
M.D., F.R.S.  
Head, Department of Biophysics  
All India Institute of Medical Sciences  
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Dr. Punit Kaur / Dr. Punit Kaur  
Professor & Head  
Dept. of Biophysics  
A.I.I.M.S.  
Ansari Nagar, New Delhi-29



Dr. POONAM CSHIC  
मुख्य चिकित्सा अधिकारी  
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