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अखिल भारतीय आयुर्विज्ञान संस्थान (एम्स) कल्याणी
All India Institute of Medical Sciences (AIIMS) Kalyani
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के तत्वावधान में एक सांविधिकनिकाय)
(A Statutory Body under the Aegis of Ministry of Health and Family Welfare, GOI)
राष्ट्रीय राजमार्ग - 34, बसन्तपुर, सागूना, कल्याणी, ज़िला - नदिया, पश्चिम बंगाल - 741245
NH-34 Connector, Basantapur, Saguna, Kalyani, District Nadia, West Bengal 741245

WEB CHALLENGE NOTICE

Ref.No: 298 /M-11011/1/24-25(IM)/MICROBIOLOGY/CONS/894 Dated: 20.09.2024

The notice is being uploaded on the web site www.aiimskalyani.edu.in, e-wizard and CPPP.

Sub: Verification and Justification of proprietary nature of the items through 21 days WEB Challenge on the official website of AIIMS Kalyani, e-wizard and CPPP before Procurement of "Cartridge Based Nucleic Acid Amplification Test (CBNAAT) HIV-1 Viral Load Kit (Cepheid Xpert)" for the Dept. of Microbiology, AIIMS, Kalyani against proprietary article certificate of the Original Equipment Manufacturer (O.E.M.) Inviting Comments thereon.

Department of Microbiology, AIIMS Kalyani intends to buy "Cartridge Based Nucleic Acid Amplification Test (CBNAAT) HIV-1 Viral Load Kit (Cepheid Xpert)" make by M/s Cepheid India Private Limited (Address: 9th Floor, Tower B, Paras Twin Towers, Golf Course Road, Sector-54, Gurugram, Haryana - 122002, India).

M/s Cepheid (Address: 904 Caribbean Drive, Sunnyvale CA 94089 USA) designated M/s Cepheid India Private Limited (Address: Plot No. 37/2, Survey No. 198, Block Nos 55,56,57,60 and 61, Hitech, Magadevakodigehalli village, Hobli Jala Taluka, Bengaluru North Urban, Karnataka, 562149, India) as the official manufacturer of Cepheid Products and authorized M/s Cepheid India Private Limited (Address: 9th Floor, Tower B, Paras Twin Towers, Golf Course Road, Sector-54, Gurugram, Haryana - 122002, India) to bid, negotiate and conclude the contract in regard to the business across India for "Cartridge Based Nucleic Acid Amplification Test (CBNAAT) HIV-1 Viral Load Kit (Cepheid Xpert)". The same may be purchased from M/s Cepheid India Private Limited (Address: 9th Floor, Tower B, Paras Twin Towers, Golf Course Road, Sector-54, Gurugram, Haryana - 122002, India).

The Original Equipment Manufacturer (OEM) (Namely M/s Cepheid (Address: 904 Caribbean Drive, Sunnyvale CA 94089 USA), has been declared in the Proprietary Certificate provided in their company's letter head that they are the sole manufacturer of the "Cartridge Based Nucleic Acid Amplification Test (CBNAAT) HIV-1 Viral Load Kit (Cepheid Xpert)".

The notice is being uploaded for general information of prospective Manufacturer/ Authorized Distributor/Dealer to submit their objection/ comments, if any, on proprietorship of the "Cartridge Based Nucleic Acid Amplification Test (CBNAAT) HIV-1 Viral Load Kit (Cepheid Xpert)", Make: M/s Cepheid India Private Limited (Address: 9th Floor, Tower B, Paras Twin Towers, Golf Course Road, Sector-54, Gurugram, Haryana - 122002, India) they may submit their proposal along with specifications, supported by all documentary evidence and a price quotation for the above said items.





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(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के तत्वावधान में एक सांविधिकनिकाय)
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NH-34 Connector, Basantapur, Saguna, Kalyani, District Nadia, West Bengal 741245

Continued from Page...01

The objection/proposal/comments, if any should be sent in sealed cover to the Office of the Chairperson, Procurement Cell, AIIMS, Kalyani, P.O.- Ghoragacha, NH-34 Connector, Basantapur, Saguna, Kalyani, District-Nadia, West Bengal- 741245. Or through email to web_challenge@aiimskalyani.edu.in, so as to reach on or before 21 days from the web published date (before 5:00 pm) failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The "Ref No. **298** /M-11011/1/24-25(IM)/MICROBIOLOGY/CONS/894 on or before 21 days from the web published date (before 5:00 p.m.) should be superscripted on sealed envelope.

Enclosures:

- 1) Proprietary Article Certificate (PAC) of Manufacturer M/s Cepheid (Address: 904 Caribbean Drive, Sunnyvale CA 94089 USA) and in India Manufacturer by M/s Cepheid India Private Limited (Address: Plot No. 37/2, Survey No 198, Hitech, Defence and Aerospace Park Industrial Park, Industrial Area, Mahadevakodigehalli Village, Hobli Jala Taluka, Bengaluru North Urban, Karnataka, 562149, India).
- 2) Authorization Certificate provided by the OEM to M/s Cepheid India Private Limited (Address: 9th Floor, Tower B, Paras Twin Towers, Golf Course Road, Sector-54, Gurugram, Haryana - 122002, India).
- 3) Specification Copy

Copy to:

1. PS to ED : For kind information please
2. PS to DDA : For kind information please
3. FIC Website : For kind information please.
4. Administrative Officer : For kind information please.
5. FIC, Finance : For kind information please.
6. Indenting Officer : For kind information please

Moh
20/9/24
Dr. Mahuya Chattopadhyay
Chairperson Procurement Cell



7 August 2023

PROPRIETARY ARTICLE CERTIFICATE

We, Cepheid, located at 904 Caribbean Drive, Sunnyvale CA 94089 U.S.A., having facilities and/or offices at

- Cepheid 904 Caribbean Drive, Sunnyvale CA USA 94089,
- Cepheid AB, Rontgenavagen 5, SE-171 54 Solna, Sweden,
- Cepheid Europe S.A.S., Vira Solelh, 81470 Maurens Scopont, France; and
- Cepheid India Private Limited, Plot No-37/2, Survey No 198, Block Nos-55,56,57,60 and 61, Hitech, Defence and Aerospace Park Industrial Area, Mahadevakodigehalli Village, Hobli Jala Taluka, Bengaluru North (Bangalore) Urban, Karnataka, 562149, India,

hereby confirm that one of the above facilities is designated as the official manufacturer of record for the molecular diagnostics system identified below ("Cepheid Products").

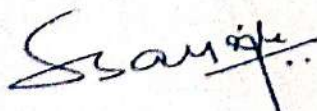
Cepheid is the owner of the following subsidiary companies in the Europe:

- Cepheid AB, Located at Rontgenavagen 5, SE-171 54 Solna, Sweden;
- Cepheid Europe S.A.S., with registered office at Vira Solelh, 81470 Maurens Scopont, France

We confirm that we have control over the manufacture of our system and hold patent, license and trademark and other intellectual property rights for the technology and hardware in the GeneXpert system and tests as listed below:

Cepheid Products and Accessories:

- | | | |
|---|-----------------------------------|----------------------------------|
| • GeneXpert Dx System | • Xpert MRSA/SA SSTI | • Xpert MTB/RIF Ultra |
| • GeneXpert Infinity System (Infinity48-48) | • Xpert SA Nasal Complete | • Xpert HCV VL Fingerstick |
| • GeneXpert Edge System (GXI-EDGE-L) | • Xpert MRSA | • Xpert Bladder Cancer Detection |
| • Xpert MTB/RIF | • Xpert MRSA NxG | • Xpert Xpress SARS-COV-2 |
| • Xpert MRSA/SA Blood Culture | • Xpert GBS | • Xpert HIV-1 Viral Load |
| • Xpert CT/NG | • Xpert HPV | • Xpert Carba-R |
| • Xpert Norovirus | • Xpert HCV Viral Load | • Xpert BCR-ABL Ultra |
| • Xpert Flu | • Xpert HIV-1 Qual | • Xpert MTB/XDR |
| • Xpert Flu/RSV XC | • Xpert C. Difficile | • Xpert HBV Viral Load |
| • Xpert Xpress Flu/RSV | • Xpert C. Difficile/Epi | • Xpert Breast Cancer STRAT4 |
| • Xpert FII & FV | • Xpert vanA | • Xpert Modules |
| • Xpert Xpress SARS-COV-2 Plus | • Xpert vanA/vanB | |
| | • Xpert Xpress CoV-2/Flu/RSV Plus | |
| | • Xpert Bladder Cancer Monitor | |



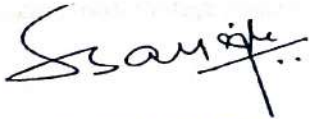
Sayan Banerjee
MBBS, MD, DNB, DipACPath (UK) / FRCPath (UK)
DNB (Infectious Diseases) (AIIMS Delhi)
Associate Professor, Department of Microbiology
AIIMS (All India Institute of Medical Sciences)
Karyool, West Bengal, India
Phone No 93379 (WBAC)

904 Caribbean Drive, Sunnyvale, CA 94089 USA WWW.CEPHEID.COM

The machine, spare parts, software, kits, and consumables are proprietary products of Cepheid. Sales and service support are provided by the Original Equipment Manufacturer, Cepheid. We further declare that Cepheid India Pvt. Ltd. located at 9th Floor, Tower B, Paras Twin Towers, Golf Course Road, Sector 54, Gurugram, Haryana – 122002 shall be responsible for providing the onsite service/remote support, repair, troubleshooting, maintenance, and additional support to our user/customer as per a valid agreement in place and standard operating procedure in India.



Christian Borjesson
SVP/GM- Hospital & POC
Sunnyvale, USA
(Company Seal)



Sayantan Banerjee
MBBS, MD, DNB, DipRCPath (UK), FRSPH (UK)
DM (Infectious Diseases) (AIIMS Delhi)
Associate Professor, Department of Microbiology
AIIMS (All India Institute of Medical Sciences)
Kalyani, West Bengal, India
Regn. No. 63576 (WBMCI)



C-13



30th July 2024

TO WHOM SOEVER IT MAY CONCERN

We Cepheid, located at 904 Caribbean Drive Sunnyvale, CA 94089 USA, who are established and reputable manufacturer of molecular diagnostics systems (In vitro diagnostic reagents/kits, GeneXpert System and associated accessories) having factories at Cepheid Caribbean Drive Sunnyvale, CA 94089 USA, Cepheid AB, Rontgenvagen 2, SE-171 54 Solna, Sweden and Cepheid Europe SAS, Vira Soleh, 81470 Maurens-Scopont, France hereby confirm that M/s Cepheid India Private Limited having registered office at 9th Floor, Tower B, Paras Twin Towers, Golf Course Road, Sector -54, Gurugram, Haryana-122002, India is the only affiliate to bid, negotiate and conclude the contract in regard to the business across India.

We confirm that we are the exclusive manufacturer and hold all patent or license rights and trademarks for the technology and hardware in the GeneXpert System and associated accessories.

Yours faithfully
For and on Behalf of Cepheid, USA

Kathryne G Reeves
Kathryne G Reeves (Aug 15, 2024 08:13 CDT)

Kathryne Reeves
SVP, Global Strategy, Product Management & Marketing
Sunnyvale, USA
(Company Seal)



T 1.888.336.2743
P 1.408.541.4191
C 1.408.541.4192

904 Caribbean Drive
Sunnyvale, CA 94089 USA

www.Cepheid.com



Specifications of Cartridge Based Nucleic Acid Amplification Test (CBNAAT) Kit for Quantification of HIV-1 Viral Load

1. The assay should enable accurate quantification of HIV-1 Group M: A-D, F-H, J, K, CRFA/B, CRF-A/E, CRF-A/G, CRF-BC, CRF06 Group O, Group N and Group P.
2. The entire process from nucleic acid extraction to viral load quantification should be fully automated.
3. The linear range of the cartridges should cover concentrations from 20 to 10,000,000 copies/ml.
4. The limit of detection (LoD) of the assay should be 20 cp/ml or less in general , while for HIV-1 group M subtype the LoD should be 13.6 cp/ml or less.
5. The assay should be preferably compatible with plasma as well as whole blood.
6. The turn around time of the assay should be less than 2 hours.
7. The product should be CE-IVD/ CDSCO-IVD compliant.
8. Adequate documents detailing the principle, assay procedure, performance characteristics, result interpretations, limitations and expiry should be provided with each kit.
9. The cartridges should have minimum remaining shelf-life of 5/6th or 12 months (whichever is more) at the port of discharge of consignees.
10. The vendor must be able to offer Telephone Technical Support and Field Applications/ Sales/ Service Support to help solve chemistry and instrumentation problems encountered with the reverse transcriptase quantitative PCR.



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