



अखिलभारतीयआयुर्विज्ञानसंस्थान, राजकोट, गुजरात
अभिलभारतीयआयुर्विज्ञानसंस्था, राजकोट, गुजरात
ALL INDIA INSTITUTE OF MEDICAL SCIENCES,
RAJKOT, GUJARAT

Ref. No.: AIIMS/Rajkot/Micro/5.3/2023/248

Dated: 20/09/2023

Subject: Proposal for procurement of "Genexpert IV-2-L-10C on PROPRIETARY BASIS - Invitation of comments/objections w.r.t. proprietary nature of the equipment if any, thereof.

All India Institute of Medical Sciences, Rajkot is in the process of procurement of "Genexpert IV-2-L-10C. i.e. Automated Cartridge based Nucleic Acid Amplification System (CBNAAT) Genexpert with 02 Modules– quantity 01 No. from M/s Cepheid, 904 Caribbean Drive, Sunnyvale CA 94089, USA for Department of Microbiology on PAC Basis. The proprietary article certificate (PAC) from the M/s Cepheid, USA is attached.

The above documents are being uploaded for open information to all principal manufacturers or their authorised distributor with the intention to invite objections/comments, if any with regard to proprietary nature of the said product.

The comments/objections if any, should be received in the office of Stores Officer, Store Section, Room No.:310, 3rd Floor, OPD complex, All India Institute of Medical Sciences (AIIMS), Village : Khandheri, Tahesil : Paddhari, District : Rajkot, Gujarat. 360110 within 15 days from the date of notification, failing which it will be presumed that no other bidder/ manufacturer/ vendor is having any comments/objection against the proposition and the case shall be decided purely on merit.



Deputy Director (Admin)
AIIMS, Rajkot.

कर्मल पुनीत कुमार अरोरा,
Col. Puneet Kumar Arora,
उप निदेशक (प्रसा.)/Dy. Director (Admin),
एम्स राजकोट - 360 001, गुजरात.
AIIMS Rajkot - 360 001. Gujarat.

Enclosures:

- In Principle approval from The Director, AIIMS
- Detailed specifications duly signed by User Department.
- Proprietary Article Certificate from the Principal M/s. Cepheid, USA.
- Performa Invoice/Quotation & previous supply order copies from other institute for rate reasonability

Automated Cartridge based Nucleic Acid Amplification System


Technical Specification


- 1 Self-contained, single-use cartridges, Real-time PCR instrument fully integrates and automates the three processes required for real-time PCR based molecular testing: sample preparation, amplification, and detection, all in one cartridge.
- 2 It should have complete, independent, temperature-controlled fluorimeter for performing and continuously monitoring chemical reactions such as real-time PCR.
- 3 The temperature of the sample should be controlled rapidly and precisely, allowing faster reactions and more accurate results.
- 4 The System should have at least 2 active modules which can be independently used and controlled for any test cartridge.
5. The System should have 10 Optics Channels for detection with the dye detection limit $<1nM$
6. The System should be capable to detect 10 or more targets in a single PCR reaction
7. Sample analysis should be performed using much less power than traditional methods. Performing all the complex steps of DNA or RNA extraction in its advanced micro fluidic cartridges.
- 8 Each unit should be operated and controlled independently.
- 9 It should be fast, accurate and simplified molecular testing requiring no specialized skills to operate, enabling round the-clock testing 24 hours a day, samples should be processed immediately, delivering rapid, actionable test results.
10. The modules should continuously monitor the chemical reactions in each cartridge in order to quickly create enough copies of the sample nucleic acid for reliable measurement. Each of the modules should work independently so that it can be used to conduct different tests simultaneously.

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- 11 The System should be controlled through stand-alone laptop or Desktop.
12. System should be easy to operate with little human intervention or specialized knowledge.
13. The system should be space saving and should be installed and operated at any indoor setting without a need for special molecular setting.
14. The equipment should be BIS/European CE IVD/US FDA approved
15. The system should include built-in (quality) control for all test steps.
16. The System should be able to perform on-demand and random access.
17. The system should be easily connected to LIS/HIS if required.
18. It should be provided with suitable UPS with back up time of at least 30 min.
19. The system should be provided with Laptop and Barcode reader.
20. The System should have different tests available to use, like- MTB Complex , MTB/RIF and Extensive Drug Resistance TB (XDR TB), SARS-CoV-2, HIV-1 Viral Load, HBV Viral Load, HCV Viral Load, , BCR-ABL, HPV, Carba-R, C. difficile, MRSA, FII&FIV, Flu/RSV, CT/NG, etc.
21. On site training should be provided to all staff.
22. There should be 5 years manufacturer warranty followed by 5 years of CMC.


डॉ. अनिल चौधरी / Dr. Anil Chaudhary
सहायक आचार्य / Assistant Professor
माइक्रोबायोलॉजी विभाग
Department of Microbiology
अखिल भारतीय आयुर्विज्ञान संस्थान राजकोट, भारत
All India Institute of Medical Sciences, Rajkot, India


डॉ. (को) अश्विनी आगरवाल / डॉ. (कोल) अश्विनी अग्रवाल
Professor and Head / प्रोफेसर और निदेशक
Department of Microbiology / सूक्ष्म जीव विज्ञान विभाग
All India Institute of Medical Sciences, Rajkot, India
अखिल भारतीय आयुर्विज्ञान संस्थान, राजकोट, भारत.



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





WEB WWW.CEPHEID.COM
MAIN 1.888.336.2743
FAX 1.408.541.4192

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)



Note Sheet1

All India Institute of Medical Sciences
Rajkot


Ref No.-AIIMS/Rajkot/Micro/5.3/2023/248

Dated: - 12/09/2023

Subject: Procurement of Cartridge based nucleic acid amplification system (CBNAAT) for Department of Microbiology on PAC basis


Description	Encls No
1. It is proposed to procure Cartridge based nucleic acid amplification system (CBNAAT) for Department of Microbiology, AIIMS Rajkot.	
2. The equipment is a non DPR item and available on GeM. Technical specifications of the equipment are enclosed.	1
3. The item is exempted from MII clause vide MoHFW OM No. F4/1/2023-PPD dated 03 April 2023 (Sr no. 131).	2
4. The item is to be procured on PAC basis as it is manufactured by only one firm- M/s Cepheid. The proprietary certificate submitted by OEM is enclosed.	3
5. Approximate cost of the item for 2 module model as per the budgetary quote submitted by OEM is Rs <u>16,07,891/-</u> .	4
6. Draft notice required to be published on the institute website inviting comments/objections thereon from any manufacturer regarding proprietary nature of the item is enclosed.	5
7. The equipment is also purchased by other AIIMS on PAC basis	6
8. Approval may please be accorded to publish the notice and thereafter proceed with tender on GeM to procure the item under provisions of Rule 166 of the GFR 2017 on PAC basis	

O.No _____ Date _____ Sign. _____
DD (Admin.)
I.No 6086 Date 13/9 Sign. B/L


Dr. Ashwini Agarwal
Professor
Department of Microbiology

A/o i) AS per Ref N.5-01
ii) AS per proposed by microbiology department
PAC item
iii) P.U for consideration.


14/09/23

Accepted: (i) P.U. for consideration 
14/09/2023 (P.T.O.)