



भारत सरकार/Government of India  
स्वास्थ्य और परिवार कल्याण मंत्रालय/ Ministry of Health and Family Welfare  
प्रधानमंत्री स्वास्थ्य सुरक्षा योजना/PMSY  
अखिल भारतीय आयुर्विज्ञान संस्थान/All India Institute of Medical Sciences  
मंगलगिरि, आंध्र प्रदेश/Mangalagiri, Andhra Pradesh

[www.aiismangalagiri.edu.in](http://www.aiismangalagiri.edu.in)

Ref: AIIMS/MG/Micro/Non DPR/CBNAAT- GeneXpert Consumables/2023-24/08

FTS: 3868

Date: 05-07-2024

### Call for Objection

**Subject:** Inviting comments/objection, if any before declaring proprietary article for procurement of “**Consumables for CBNAAT- GeneXpert Machine**” for the Department of Clinical Microbiology AIIMS Mangalagiri.

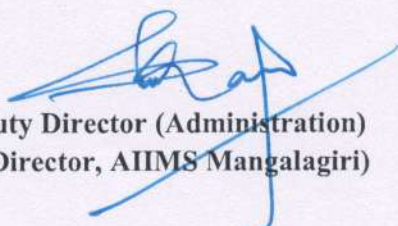
Clinical Microbiology Department, AIIMS Mangalagiri has to procure “**Consumables for CBNAAT- GeneXpert Machine**” through Proprietary Article basis.

The proposal submitted by M/s. Cepheid Inc. who is sole manufacturer sole dealer/agents of the sole manufacturer of this item along with Proprietary Article Certificate are attached & uploaded on Institute website.

The above documents are being uploaded for open information to submit objections, comments if any from any manufacturer/supplier before declaring proprietary article of the said equipment/items to be procured, within 10 days i.e., (15/07/2024) from the date of issuance/uploading of the notification.

The objection should be raised in the technical compliance sheet as enclosed in Annexure -I, if any Firm claiming suitability of their product with respect to specification mentioned.

The comments should be sent to the office of Procurement Cell, 2<sup>nd</sup> floor, Admin cum Library building at AIIMS Mangalagiri in a sealed envelope with above reference on or before (15/07/2024) up to 05:00 PM from the date of uploading on institutional website, failing which it will be presumed that any other manufacturer/vendor is having no comment to offer and case will be decided on merits.

  
Deputy Director (Administration)  
(for Director, AIIMS Mangalagiri)

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**PAC CERTIFICATE**

P-3 Form


(To be attached with P-2 form for Proprietary items)

AIIMS, Mangalagiri

**PROPRIETARY ARTICLE CERTIFICATE**

It is certified that the **CONSUMABLES AND REAGENTS** for **CBNAAT GeneXpert XVI-16 Module System** should be purchased from **M/s Cepheid Inc.** To the best of my knowledge **M/s Cepheid Inc.** are the sole Dealer/agents of the sole manufacturer of **CONSUMABLES AND REAGENTS** for **CBNAAT GeneXpert XVI Module System.**

Similar items manufactured by other firm(s) shall not be suitable for our purpose as it is a closed system. The consumables and reagents of same company has to be used to provide appropriate reliable results.

(Signature of Indenter)   
Date: 06.02.2021  
Designation: **DR. RAMAKRISHNA PAI J**  
**MD, MBA, PDCR**  
**Additional Professor**  
**Department of Clinical Microbiology**  
**All India Institute of Medical Sciences**  
Department: **Mangalagiri, Andhra Pradesh.**

  
**Dr. SUMIT RAI**  
**MD(Gold Medalist), PDCC(Infectious Diseases)**  
**Professor & Head**  
**Department of Clinical Microbiology**  
**All India Institute of Medical Sciences**  
**Mangalagiri (Andhra Pradesh)**

Signature of Head of Department /Section

N.B.: The indenter before recording the above certificate should satisfy himself that the article is genuinely of proprietary nature manufactured under patent laws.



WEB: WWW.CEPHEID.COM  
 MAIL: 1.888.336.2743  
 FAX: 1.408.561.4192

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**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 and  
 Cepheid Europe S.A.S., Vira Solelh, 81470 Maurens Scopont, France

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; and  
 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:**

- GeneXpert Dx System
- Xpert MTB/RIF
- Xpert MRSA/SA Blood Culture
- Xpert CT/NG
- Xpert TV
- Xpert Norovirus
- Xpert GBS LB
- Xpert Flu
- Xpert Flu/RSV XC
- Xpert Xpress Flu/RSV
- Xpert C. Difficile
- Xpert C. Difficile/Epi
- Xpert vanA
- Xpert vanA/vanB
- Xpert FII & FV
- Xpert Bladder Cancer Monitor
- Xpert Breast Cancer STRAT4
- Xpert Modules
- 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 HIV-1 Viral Load
- Xpert Carba-R
- Xpert BCR-ABL Ultra
- Xpert MTB/XDR
- Xpert HBV Viral Load
- Xpert MTB/RIF Ultra
- Xpert HCV VL Fingerstick
- Xpert Bladder Cancer Detection
- Xpert Xpress SARS-COV-2

*Sowmya Arunkumar*

Sowmya Arunkumar  
 Sr. Director- International Regulatory Affairs  
 Cepheid  
 Nov 02, 2020



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**Technical Specification for GeneXpert – Consumables & Reagents**

S.No	Name of the test	Description
1.	Xpert MRSA/SA BC (Blood & Other Samples)	<p>Reaction Time : 60-80 minutes Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system – Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test)</p> <p>Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : To detect methicillin resistant staphylococcus aureus DNA from blood &amp; other samples Sample types : Blood &amp; other Samples Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius Maximum Operating temperature : 18 degrees Celsius Product Certifications : CE-IVD</p>
2.	Xpert MRSA/SA SSTI (Exudate)	<p>Reaction Time : 60-80 minutes Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system – Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test)</p> <p>Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : To detect methicillin resistant staphylococcus aureus DNA from exudate &amp; other samples Sample types : Exudate Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius Maximum Operating temperature : 18 degrees Celsius Product Certifications : CE-IVD</p>
3.	Xpert <i>C. difficile</i> BT (Stool and Other Samples)	<p>Reaction Time : 45 -60 minute Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system – Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test)</p> <p>Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : To detect <i>C. difficile</i> DNA</p> <p>Sample types : Stool &amp; other Samples</p>

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Department of Clinical Microbiology

		<p>Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius Maximum Operating temperature : 18 degrees Celsius Product Certifications : CE-IVD</p>
4.	Xpert HPV (Genital Secretions & other Samples)	<p>Reaction Time : 60-80 minutes Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system - Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test) Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : To detect HPV DNA. Sample types : Genital Secretions &amp; other samples Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius Maximum Operating temperature : 18 degrees Celsius Product Certifications : CE-IVD</p>
5.	Xpert Xpress GBS (Vaginal swab & other Samples)	<p>Reaction Time : 30-45 minutes Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system - Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test) Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : To detect Group B Streptococcus Sample types : Vaginal swab &amp; other Samples Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius Maximum Operating temperature : 18 degrees Celsius Product Certifications : CE-IVD</p>
6.	Xpert HBV Viral Load (Blood, Plasma, Serum)	<p>Reaction Time : 60-80 minutes Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system - Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test) Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : To detect Hepatitis B virus load. Sample types : Blood, Plasma, Serum Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius</p>



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		Maximum Operating temperature : 18 degrees Celsius Product Certifications : CE-IVD
7.	Xpert HCV Viral Load (Blood, Plasma, Serum)	Reaction Time : 100-120 minutes Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system – Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test) Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : To detect Hepatitis C virus load. Sample types : Blood, Plasma, Serum Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius Maximum Operating temperature : 18 degrees Celsius Product Certifications : CE-IVD
8.	Xpert HIV – 1 Viral Load XC (Blood, Plasma, Serum)	Reaction Time : 90-100 minutes Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system – Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test) Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : To detect HIV load Sample types : Blood, Plasma, Serum Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius Maximum Operating temperature : 18 degrees Celsius Product Certifications : CE-IVD
9.	Xpert MTB/RIF Ultra (Sputum & other Samples)	Reaction Time : 80-100 minutes Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system – Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test) Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : Mycobacterium Tuberculosis (MTB) complex DNA along with Rifampicin Resistance from the Single step. Sample types : Sputum & other Samples Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius

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		Maximum Operating temperature : 18 degrees Celsius Product Certifications : CE-IVD
10.	Xpert MTB/XDR (Sputum & other Samples)	Reaction Time : 80-100 minutes Sample Extraction : Automated Test Requirement : Cepheid's GeneXpert system – Real Time PCR CBNAAT (Cartridge based nucleic acid amplification Test) Kit box size : 40 centimeter Cartridge types : Self contained Number of tests in single kit : 50 Packing type : Cartridge Application : To detect XDR MTB. Sample types : Sputum & other Samples Shell life from the date of manufacture (months) : 12 months Minimum Storage Temperature : 2 degrees Celsius

1. Sensitivity should be  $\geq 98\%$ , Specificity should be  $\geq 98\%$ .
2. Cold chain indicator to be provided with the kits.
3. A cumulative time/temperature indicator prequalified by WHO which indicates the exposure to temperature in the range of 2–8 degree C is to be provided on every pack of kits.
4. The supplier should ensure maintenance of cold chain during transportation of kits at 2° C to 8° C.
5. Original kit literature in English/Hindi (not photocopy) provided with each kit in English mentioning the principle, components, methodologies, validity, criteria, performance characteristics, bio-safety, limitations of assay, storage condition, manufacturing and expiry dates and methods of disposal provided.
6. Kit should be approved from the statutory in its country of origin.
7. Kit should be CE-IVD approved
8. Manufacture shall submit all necessary certifications, license and test reports to the buyer along with supplies.
9. Kit should have 3/4<sup>th</sup> of shelf life from the mentioned date of expiry when received by the department.
10. Supplier should agree to provide advance sample of the kit for buyer's approval before commencement of bulk supply.

  
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**SPECIFICATIONS**

**Objection should be submitted in following format:**

<b>S. no</b>	<b>Item specification as given</b>	<b>Specification offered by firm</b>	<b>Deviation if any</b>	<b>Remarks</b>