



JAWAHARLAL INSTITUTE OF POST-GRADUATE MEDICAL EDUCATION & RESEARCH
(Institution of National Importance Under Ministry of Health & Family Welfare, Government of India)
Dhanvantari Nagar, Puducherry-605 006

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PURCHASE SECTION

No. JIP/Pur. 12(Proprietary-CBNAAT)/2024

Dated: 23 JAN 2024

NOTE

Sub: Procurement of **CBNAAT with 16 modules** for the Department of **Microbiology**, JIPMER on proprietary basis – **Inviting comments thereon.**

This Institute intends to purchase a **CBNAAT with 16 module – 01 No** for the Department of **Microbiology**, JIPMER, manufactured by M/s. Cepheid, located at 904 Caribbean Drive, Sunnyvale CA 94089 U.S.A through their 100% subsidiary M/s. Cepheid India Pvt. Ltd. Tower B, Paras Twin Towers, Floor No.9, Revenue Estate, sector 54, Village Haiderpur Viran, Gurgaon, Haryana 122002, India, as having factory at USA and shipping through authorized distributor M/s. Vivek Enterprises, new # 40, Second Floor, 12th Avenue, Ashok Nagar, Chennai – 600 0083.

This purchase is intended to be made with the belief that this equipment is a proprietary product of its manufacturer and no other company manufacturer this equipment with the specifications laid down by the Institute (Annexure 1).

The documents on which this belief is based include:

1. A proposal submitted by M/s. Vivek Enterprises, Chennai on behalf of by M/s. Cepheid, Sunnyvale CA 94089 U.S.A
2. The Proprietary Article Certificate submitted by experts.
3. The Proprietary Article Certificate submitted by the manufacturer.
4. Technical Specifications.

The above documents are being uploaded with this announcement for open information. Objections and comments, if any, regarding the proprietary nature of the equipment are invited from manufacturers of equipment similar to the one referred to in this notice, giving reference and date of this communication. The comments should be sent by E-Mail to purchase.jipmer@gmail.com (Purchase Officer, Purchase Section, Administrative Block, JIPMER) within 30 days (i.e. on or before **23.FEB...2024** to 04.00 PM), failing which it will be presumed that no other manufacturer makes similar equipment and the Institute will proceed with purchase of the above equipment on proprietary basis.

R. S. S. S.

OFFICER IN-CHARGE OF PURCHASE

क्रय प्रभारी अधिकारी

Officer In-Charge of Purchase

जिपमेर / JIPMER

पुदुच्चेरी / Puducherry - 605 006

Encl.: As above

JAWAHARLAL INSTITUTE OF POST-GRADUATE MEDICAL EDUCATION & RESEARCH


DHANVANTARI NAGAR, PONDICHERRY- 605006

PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE


1. Item Type/Model No. required along with specification	Cartridge based nucleic acid amplification test (CBNAAT) system with 16 Modules. GeneXpert Dx system - Model: GXXVI-16-L-10C
2. Is the item a spare part attachment or accessory for an existing equipment	No
3. Name of the manufacturers/Supplier of the item proposed by the indenter	Manufacturer: Cepheid, Sunnyvale CA 94089, USA Indian office: M/s Cepheid India Private Limited, Gurugram, Haryana – 122002 Indian distributor: M/s Vivek Enterprises, Chennai
4. Are they sole manufacturers/ sold distributors of the item	Yes
5. What is the unique function that is performed by this equipment that equipment manufactured by other manufacturers cannot perform	The Cartridge based nucleic acid amplification test (CBNAAT) system with 16 Modules manufactured by Cepheid is the only system that can provide the user with a fully automated 10 color PCR, a single standardized solution, easy to use technology, on demand and random-access solution with integrated, single step automated workflow for nucleic acid extraction, amplification and detection. capability. The other manufacturers do not have a single unit with 16 modules and the single integrated automated workflow for nucleic acid extraction, amplification and detection.
6. Is 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 advantage/cost effectiveness of the recommended item from these offered by other.	No
7. What were the efforts made to locate alternative source of supply or use other substitutes	Through internet. No other alternative source for supply or other substitutes. In the GEM tender (GEM/2023/B/3759027) floated on 29/07/2023 also only one bid from M/s Vivek Enterprises, Chennai, India for the Cartridge based nucleic acid amplification test (CBNAAT) system with 16 Modules manufactured by Cepheid, USA was obtained.
8. Why open/limited tender can't be resorted to, for locating alternative source	This is a proprietary item manufactured by Cepheid, USA. One GEM tender yielded only one bid as mentioned above.
9. Are the proprietary items certified that the rates are reasonable or not.	Rate shall be compared with other Government purchases of this item.
10. Any other justification for procuring item from single source	This is a proprietary item manufactured by Cepheid, USA and this item is exempted for Make in India and included in the GTE approved list.

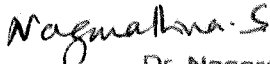
The above mentioned information is provided by the firm

We Certify that the item at/Sr.No.1 above is required to be pursued on single tender basis as the source of supply is definitely known/ ~~the specified brand proposed was advantages in meeting our functional requirements*~~ and limited/open tender system could be dispensed with as they would serve no useful purpose in this particular case. To the best of our knowledge there is only one manufacturer, as mentioned above of Cartridge based nucleic acid amplification test (CBNAAT) system with 16 Modules that can be used for single-step automated nucleic acid extraction, amplification and detection of MTB Complex and Extensive Drug Resistance TB (XDR TB), SARS-CoV-2, HIV-1 Viral Load, HBV Viral Load, HCV Viral Load, MTB/RIF, BCR-ABL, HPV, Carba-R, C. difficile, MRSA, FII&FIV, Flu/RSV, etc.


Signature of Head of Department
(Demanding/Indenting Officer)

Professor & Head
Dept of Microbiology,
JIPMER, Pondicherry


Signature of Expert
Dr. S. SIVA KUMAR, Ph.D.,
Scientist 'D' & H.O.D.,
Department of Bacteriology
National Institute for Research in Tuberculosis
Chetpet, Chennai-600 031.


Signature of Expert
Dr. Nagarathna. S
डा. नागरत्ना. एस
Professor / प्राध्यापक
Department of Neuromicrobiology
न्यूरोमैक्रोबायोलॉजी विभाग
NIMHANS, Bengaluru-560 029



WEB WWW.CEPHEID.COM
 MAIN 1.888.336.2743
 FAX 1.408.541.4192

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

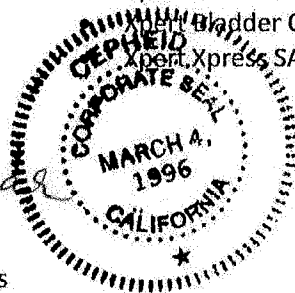
We confirm that we have control over the manufacture of our system and hold patent, license and trademark and other intellectual property rights for the technology and hardware in the GeneXpert system and tests as listed below:

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



h
 Professor & Head
 Dept of Microbiology,
 JIPMER, Puducherry-6.

25th Oct 2023

Proprietary Article Certificate from the manufacturer

To whomsoever it may concern

The GeneXpert Dx system manufactured by Cepheid can provide the user with a fully automated 10 color PCR, a single standardized solution, easy to use technology, on demand and random-access solution with integrated, single workflow for nucleic acid extraction, amplification and detection feature/ facility/ capability and this feature/ facility/ capability is a proprietary product of the GeneXpert/ Cepheid.

To the best of our knowledge GeneXpert is the only system/ equipment with the features mentioned above and Cepheid is the only manufacturer of such a commercially available system that offers this/these feature(s).

The following components/ parts/ accessories as mentioned in **Annexure-1** document are also proprietary products of the Cepheid and are essential for the system to function and no third-party substitute exists.



Christian Borjesson
SVP/GM- Hospital & POC
Cepheid, Sunnyvale, USA

(Company Seal)



Specifications for CBNAAT with 16 Modules

Equipment Specifications

1. The System should be a fully integrated and automated Real Time PCR (RT-PCR) instrument which should include the extraction of nucleic acids, amplification and detection in a single step.
2. No human intervention is required in between any of the steps of including extraction of nucleic acid, amplification and detection.
3. The System should work on the self-contained test cartridge which carries all the necessary components and reagents to carry out extraction and RT-PCR test. The cartridges should be single-use disposable units.
4. The System should be controlled through a stand-alone desktop.
5. The System should have at least 16 active modules which can be independently used and controlled for different tests as available.
6. The System should have 10 Optics Channels for detection with the dye detection limit $<1nM$
7. The System should be capable of detecting 10 or more targets in a single PCR reaction
8. Each Active Module should have a Solid State heater and forced air cooling.
9. Ramp rate- Heating: $10^{\circ}C/sec$ or less from $50^{\circ}C$ to $95^{\circ}C$. Cooling: $2.5^{\circ}C/sec$ or less from $95^{\circ}C$ to $50^{\circ}C$
10. The System should be certified to be used for diagnostic use. Should provide CE certificate and IVD certificate (for TB diagnosis) and WHO endorsement (for TB diagnosis)
11. The System should include built-in (quality) control for all test steps.
12. The System should be able to perform on-demand test runs and should have random access.
13. The System should be easily connected to LIS/HIS if required.
14. The System should only require minimal expertise to operate and run. The system shall be space-saving design and low-power requirement so that it can be easily installed and operated.
15. The System should have different tests available to use, like- MTB Complex and Extensive Drug Resistance TB (XDR TB), SARS-CoV-2, HIV-1 Viral Load, HBV Viral Load, HCV

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Viral Load, MTB/RIF, BCR-ABL, HPV, Carba-R, C. difficile, MRSA, HII&FIV, Flu/RSV, CT/NG, etc.

16. Should be supplied with 5 KVA UPS with at least 2 hours back up

17. Should supply at least 30 tests of Extensive Drug Resistance TB (XDR TB)

Other specifications:

1. Warranty inclusive of annual calibration: 3 years
2. CAMC inclusive of annual calibration: 7 years
3. Warranty and CAMC should cover the desktop provided with the equipment including the software required for performing the tests.
4. Breakdown services should be provided within 48 hours.
5. The equipment should be supplied with IQ, OQ, PQ certificates

Terms and conditions for CAMC:

a. Unless mentioned otherwise, the comparison of the responsive tenders shall be carried out on Delivery Duty Paid (DDP) consignee-site basis. The quoted turnkey prices and CAMC or AMC (to be decided by the specification vetting committee before the item is tendered) prices will also be added for comparison/ranking purpose for evaluation. "Net Present value (NPV) of the Comprehensive Annual Maintenance charges (CAMC) or Annual Maintenance Contract (AMC) (to be decided by the specification vetting committee before the item is tendered) quoted for 5 or 7 years after the warranty period shall be added to the bid price for evaluation. The NPV will be calculated after discounting the quoted price by a discounting factor of 5% per annum."

b. Where the tender for an equipment asks for a mandatory AMC, the annual AMC amount used for price comparison will be 2% of the value of equipment before GST or the actual value of AMC quoted by the firm, whichever is higher. Similarly, when a mandatory CAMC is asked for, the annual CAMC amount will be 5% of the value of equipment before GST or the actual value of CAMC quoted by the firm, whichever is higher. The above-mentioned percentages are only for the purpose of price comparison, and for calculation of performance security for AMC/CAMC. The order for the AMC/CAMC will be at the actual price quoted in the bid in case

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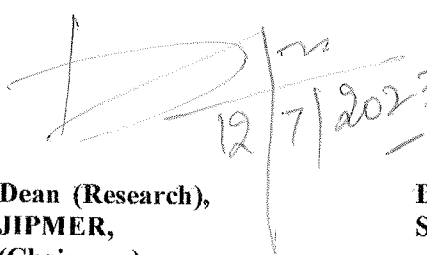
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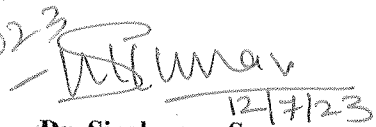
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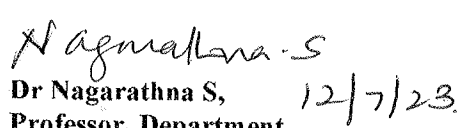
the contract is awarded to the bidder. Furthermore, the above mentioned method of price comparison is applicable only for those firms who have quoted the AMC/CAMC for the period as required in the tender conditions.

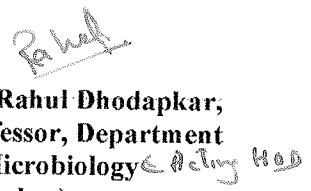
c. In case the bidder has not quoted for AMC/CAMC where it has been asked for or has quoted for a period less than that asked for in the tender conditions, the bid will be summarily rejected. If the value of AMC/CAMC exceeds Rupees one lakh per annum, a 'Performance security' for AMC/CAMC must be provided and only after that, the performance security paid for the purchase of the equipment will be refunded. If the value is up to this limit, the initial performance security provided at the time of supply shall extend till first-year AMC/CAMC has been successfully completed


d. No advance payments will be made towards AMC or CAMC.

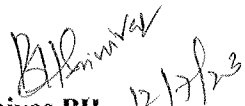

Dean (Research),
JIPMER,
(Chairman)


Dr. Sivakumar S,
Scientist D, Head
of Bacteriology,
NIRT, Chennai
(External Expert)


Dr. Nagarathna S,
Professor, Department
of Microbiology,
NIMHANS, Bangalore
(External Expert)


Dr. Rahul Dhodapkar,
Professor, Department
of Microbiology (Acting Head)
(Member)


Dr. Noyal Mariya Joseph,
Additional Professor,
Department of
Microbiology
(Member)


Dr. Srinivas BH,
Officer-in-charge,
Purchase Section,
(Member)

VIVEK ENTERPRISES

New # 40, Second Floor, 12th Avenue, Ashok Nagar, Chennai - 600 083.

Tel: 044 - 2371 7262 email : vivekenterprises14@yahoo.com

GSTIN: 33AFWPR0458Q1Z1

GeM Bid Ref. No.-: GEM/2023/B/3759027 Dated: 29.07.2023

Specification	Specification Name	Bid Requirement	
			Cepheid GeneXpert Model- GXXVI-16-L 10C
Technical Parameter	Number of Optics Channel	10	Yes. Technically Compliant
	Certification	CE-IVD, US-FDA	Yes. Technically Compliant
	Warranty	1, 2, 3, 4, 5 (year)	3 years warranty offered
	Test Available	SARS-CoV-2, HIV-1 Viral Load, HBV Viral Load, HCV Viral Load, MTB/RIF, BCR-ABL, HPV, Carba-R, C. difficile, MRSA, FII&FIV, Flu/RSV, CT/NG	Yes. Technically Compliant
	Number of Active Module	16	Yes. Technically Compliant
Additional Parameter	Features	Should be able to perform on demand test run and should have remand access, Should be easily connected to LIS/HIS, Should include built-in quality control for all test, Active module should have Solid State heater and forced air cooling, Cartridges should be single used disposable unit	Yes. Technically Compliant
Additional Specification Parameters - Cartridge Based Nucleic Acid Amplification Test (CBNAAT) (1 piece)			
Specification Parameter Name	Bid Requirement (Allowed Values)		Cepheid GeneXpert Model- GXXVI-16-L 10C
The System should be a fully integrated and automated Real Time PCR (RT-PCR) instrument which should include the extraction of nucleic acids, amplification and detection in a single step.	Yes		Yes. Technically Compliant
The System should be controlled through a standalone desktop	Yes		Yes. Technically Compliant
Should be supplied with 5 KVA UPS with at least 2 hours back up. Should supply at least 30 tests of Extensive Drug Resistance TB (XDR TB) (Free of cost)	Yes		We will provide a branded 5 KVA online UPS along with Machine of upto 45 minutes power back up
Warranty inclusive of annual calibration: 3 years; CAMC inclusive of annual calibration: 7 years; Warranty and CAMC should cover the desktop. The equipment should be supplied with IQ, OQ, PQ certificates.	Yes		3 year warranty offered. CAMC rates till 7 th year post warranty offered. IQ,OQ,PQ certificates will be provided
Terms and conditions for CAMC will be as per JIPMER norms. No advance payments will be made towards AMC or CAMC.	These terms and conditions are accepted		We accept payment terms as per the tender

Rajesh Biswas
12/7/2023
ACTING HO
Department of Microbiology
JIPMER, Puducherry.
VIVEK ENTERPRISES
CHENNAI
600 083

Dashboard (https://mkp.gem.gov.in/dashboard)

Market (https://mkp.gem.gov.in/market)

Bids

Push Button Procurement (https://bestprice.gem.gov.in/login)

(https://gem.gov.in/)

Noyal Mariya Joseph

HOME (HTTPS://MKP.GEM.GOV.IN/DASHBOARD) / TECHNICAL EVALUATION

BID DETAILS

TECHNICAL EVALUATION

FINANCIAL EVALUATION

EVALUATION

BID AWARDED

Competent authority approval uploaded successfully

1. Bid Item(s) DETAILS

2. Technical Evaluation

List Of Sellers Participated

Download to Compare All (/download-compare-item/5104639)

View and Compare All (/compare-item/5104639/?detid=13784853)

B. Noyal Mariya Joseph
 21/12/2023

Dr. NOYAL MARIYA JOSEPH
 Additional Professor
 Department of Microbiology
 JIPMER, Puducherry-605 006.
 Regn. No: 76108

S. No.	Seller Name	Seller Rating	Offered Item	Participated On	EMD Status	MSE/MII Status	Status	Ve
1	Vivek Enterprises	☆☆☆	Make : GeneXpert Model : GX XVI-16-L-10C (View Product) (https://mkp.gem.gov.in/medical-equipment-accessories-supplies/genexpert-10c-xvi-16-l-system/p-5116877-36744395741-cat.html)	16-08-2023 18:03:02	EMD receipt (https://bidplus.gem.gov.in/show_EMDEpbg_rDocument_tech/1082260) <input type="button" value="Offline upload"/>	Verify Status	Qualified	Ver Doc & S Cla

डॉ. हिटेन्द्र गौतम
Dr. HITENDER GAUTAM, MD
 Additional Professor
 Department of Microbiology
 All India Institute of Medical Sciences, New Delhi-110029

Please Note:

- 1) No online verification of the status of MSE is being done at the GEM end because of the latest order granting benefits up to 3 years after the change of status. Buyers are requested to verify the status of the MSE at their end.
- 2) Verify all the products offered, technically evaluate the product specification offered by the seller to open financial Bid.
- 3) Please verify genuineness of any EMD receipt uploaded offline.
- 4) Buyers should disqualify any Sellers submitting incorrect MSE certificates or EMD Exemption document with respect to the Bid and may raise incidents for disablement of the Sellers furnishing wrong information.
- 5) As per para 7.3.5 on (Clarification of Bids/Shortfall Documents) of the Manual for Procurement of Goods 2017, issued by Ministry of Finance, Department of Expenditure, During evaluation and comparison of bids, the purchaser may, at his discretion, ask the bidder for clarifications on the bid. The request for clarification shall be given asking the tenderer to respond by a specified date. If the tenderer does not comply or respond by the date, his tender will be liable to be rejected. Depending on the outcome, such tenders are to be ignored or considered further. No change in prices or substance of the bid shall be sought, offered or permitted. No post bid clarification at the initiative of the bidder shall be entertained. The shortfall information / documents should be sought only in case of historical documents which pre-existed at the time of the tender opening and which have not undergone change since then. So far as the submission of documents is concerned with regard to qualification criteria, after submission of the tender, only related shortfall documents should be asked for and considered. For example, if the bidder has submitted a supply order without its completion / performance certificate, the certificate can be asked for and considered. However, no new supply order should be asked for so as to qualify the bidder.