

Admn/Prop/18/2020-AIIMS.JDH

Dated: 29th June, 2020.

Subject: Purchase of GeneXpert XVI for the department of Microbiology at AIIMS, Jodhpur on proprietary basis - <u>Inviting comments thereon.</u>

The Institute is in the purchase of GeneXpert XVI for the department of Microbiology at AIIMS, Jodhpur from M/s Cepheid, 904 Caribbean Drive, Sunnyvale CA 94089, USA on proprietary basis. The proposal submitted by M/s Cepheid, USA and PAC certification by user are attached.

The above document are being uploaded for open information to submit objection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/18/2020-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 20th July 2020 upto 03:00 PM 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,

Administrative Officer

Enclosed: Related documents enclosed.



All India Institute of Medical Sciences

Jodhpur

epheid.

TO WHOMSOEVER IT MAY CONCERN

WWW.CEPHEID.COM 1.888.336.2743 MAIN FAX 1.408.541.4192

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 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 RUO .
- **Xpert HBV Viral Load** .
- Xpert MTB/RIF Ultra •
- **Xpert HCV VL Fingerstick** .
- **Xpert Bladder Cancer Detection**
- Xpert Xpress SARS-COV-2 .
- Quakuman erom 0 Sowmya Arunkumar

Sr. Director- International Regulatory Affairs Cepheid April 3, 2020

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Specifications of Equipment GeneXpert XVI

- 1. System The System should be based on Automated Real Time PCR Technology including automated extraction and able to do Rapid ondemand Molecular tests such as MTB, HIV, HCV, HPV, EV, BCR/ABL etc.
- 2 Principle The System should be based on the Single Cartridge use and comprise of all major steps (Extraction, amplification and detection) within the cartridges.
- 3a. Application
 The System should have the cartridges for the Quantitative detection of HIV Viral Load, HCV viral load beside other markers.
- 4. TB detection The System should also have the cartridges, which can do TB detection from Pulmonary along with Rifampicin Sensitivity/ Resistance.
- 5. Accessories The System should be controlled through stand-alone laptop or Desktop PC
- 6. Modules The System should have 4 Active Modules with upgradation space of 16 module capacity. System can be independently used and controlled for any test cartridge.
- 7. Optical channel The System offer up to 5 to 6 Optical Channels that helps to cover wide assays.
- 8. Heater Cooler & Hach Active Module have Solid State heater and forced air cooling that makes system more robust and intact for PCR application
- 10. Certification FDA approval
- 12. Quality) control built-in (quality) control for all test steps
- 13 Demonstration The System should be able to performed on-demand and random access
- 14 Connectivity Can be connected with HIS if required

Haw Ohn DR. BIMAL DAS PROPESSOR MICROBIOLOGY