

REGIONAL CANCER CENTRE

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Sub:- Purchase of Fully automate Real Time PCR system for detection of Tuberculosis and Rifampicin Resistance from M/s. Cepheid HBDC SAS France, on proprietary basis

Regional Cancer centre, Thiruvananthapuram, Kerala is in the process to purchase one Fully automate Real Time PCR system for detection of Tuberculosis and Rifampicin Resistance from M/s. Cepheid HBDC SAS France, on proprietary basis for our Microbiology Division.

(Detailed technical specification and Proprietary Certificate are also attached) This matter is being published for open information to submit objections, comments, if any from any vendor regarding the proprietary nature of the equipment. If any vendors have objection for purchasing of this equipment directly from M/s. Cepheid HBDC SAS France on a proprietary basis, that may please be intimated to the undersigned on or before 30/01/2018 failing which, it will be presumed that any other vendor is having no objection/comment to offer and RCC will proceed with the purchase.

Trivandrum
16/01/2018

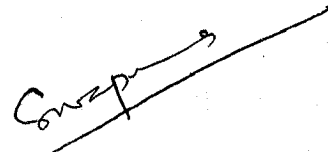
Sd/
DIRECTOR

6. Specification for Fully Automated RT-PCR

- The System should be based on Automated Real Time PCR Technology including automated extraction and able to do rapid molecular tests especially, mycobacterium tuberculosis.
- The System should be based on the single cartridge use, thus eliminating the problem of bio-hazards (cartridge based nucleic acid amplification test).
- The System should have the cartridges for TB detection from pulmonary as well as extra pulmonary samples along with detection of drug resistance especially Rifampicin resistance if any.
- The System should be controlled through stand-alone laptop or Desktop PC
- The System should have at-least 2 Active Modules which are independently used and controlled for any test cartridge.
- The System should have the endorsement of WHO.
- The system should include built-in (quality) control for all test steps.
- The System should be able to performed on-demand and random access.
- The system should be easily connected to LIS/HIS if required
- The System should require no special (lab or PCR) environment to operate effectively.
- It should have a dedicated program for precision study. Vendor must provide QC software to manage QC data of the laboratory as per NABH/NABL requirements.
- Complete service manual & circuit diagrams, operating manual must be provided. Supplier must provide original documentary proof of the date and place of manufacturing of supplied equipments.
- Comprehensive and full training of all users by supplier for operating equipment and trouble free maintenance at installation point.
- Supplier must undertake to provide comprehensive maintenance for further 7 years after expiry of the essential initial warranty period of 36 months after installation. CMC cost per years must be quoted.


SHYMA K BABU
Biomedical Engineer
Cancer Centre





- Vendor must have Kerala based service engineer and have to give written assurance & undertaking that they have an Instrument specialist who will attend machine related problems within 24 hours.
- The quoted system with exact model shall be demonstrated in working conditions to the technical experts and also have to show acceptable quality.
- Equipment manufacturer must bear valid FDA in addition of CE/ISO certification as well as other all certification as per NABL accreditation requirement.

Swaz

[Signature]

SHYMA K BABU
Biomedical Engineer
Regional Cancer Centre

[Signature]



Cepheid HBDC s.a.s
 Vira Solelh
 81470 Maurens-Scopont
 France
 Tel : +33 563 82 53 00
 Fax : +33 563 82 53 01

Maurens-Scopont, January 19th 2016

Manufacturer's Proprietary Certificate

To whom it may concern:

We, Cepheid, who are proven and reputable manufacturers having factories at *904 Caribbean Drive, Sunnyvale, CA94089, USA* and *Röntgenvägen 5, SE-171 54 Solna, Sweden* and registered office at *Vira Solelh, 81470 Maurens-Scopont, France* further confirm that we are the exclusive manufacturers and hold all patent or license rights and Trade marks for the technology and hardware in the GeneXpert system and Xpert MTB/RIF tests.

Eric Salle
 Quality Systems Manager

P/O Sophie Naiting

Cepheid HBDC SAS
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 Fax : +33 5 63 82 53 01
 SIRET : 512 057 993 00010 - APE 4646Z
 VAT : FR26 512 057 993

5th February, 2014

To whom it may concern

We hereby certify that Cepheid is the owner of the inventions describe here after:

- Cepheid's GeneXpert® System, patent number WO2013163424 A1
- Cepheid's Xpert® CGX/MTB, patent number WO2011138765 A1

I remain at your disposal for any further information you need.

Sincerely yours,


Eric SALLE
~~Senior EMEA Regulatory Compliance / Quality Systems Manager~~

CORPORATE HEADQUARTERS

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5th February, 2014

Manufacturer's Proprietary Form

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We confirm that we are the exclusive manufacturers and hold all patent or license rights and Trade marks for the technology and hardware in the GeneXpert system and Xpert MTB/RIF tests:

- Cepheid's GeneXpert® System, patent number WO2013163424 A1
- Cepheid's Xpert® CGX/MTB, patent number WO2011138765 A1

Sincerely yours,


Eric SALLE
Senior EMEA Regulatory Compliance / Quality Systems Manager

Société Anonyme Simplifiée
au capital de 37 000 000 €

APE: 4646Z
N° TVA FR26 512 057 993
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Maurens -Scopont, 5th February 2014

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