Technical specifications for Department of Microbiology (FY 2025-2026)

CBNAAT

1. The System should be fully integrated and automated Real Time PCR instrument which should include the extraction of nucleic acids, amplification and detection in a single step.
2. No human intervention required in between any of the PCR step of extraction of nucleic acid, amplification and detection.
3. The System should work on the self-contained test cartridge which carries all the necessary components to carry out the PCR test. The cartridges should be single-use disposable units.
4. The System should be controlled through stand-alone laptop or desktop.
5. The System should have at least 8 active module which can be independently used and controlled for any test cartridge.
6. The System should have 10 Optics Channels for detection with the dye detection limit.
7. The System should be capable to detect 10 or more targets in a single PCR reaction.
8. Each Active Module should have Solid State heater and forced air cooling.
9. Ramp rate- Heating: 10°C/sec from 50°C to 95°C. Cooling: 2.5°C/sec from 95°C to 50°C.
10. The System should be certified to be used for diagnostic use.
11. The System should include built-in (quality) control for all test steps.
12. The System should be able to perform on-demand test run 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, run and to report the results.
15. The system shall be space-saving design and low-power requirement, so that it can be easily installed and operated at multiple healthcare settings.
16. 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 Viral Load, MTB/RIF, BCR-ABL, HPV, Carba-R, C. difficile, MRSA, FII, Flu/RSV, CT/NG, etc.
17. Warranty: 5 years from date of installation.
18. Suitable UPS/stabilizer to be provided with minimum 5 years warranty.
19. All consumables to install and perform initial 100 reactions of MTB/RIF & HPV to be supplied with equipment.
20. All consumables and accessories required to run the platform should be mentioned in the tender.
21. System to be provided with suitable laptop/desktop with printer.

JDMM KSSSCI	FIC, Microbiology KSSSCI	FO/Nominee KSSSCI	Nominee of Director KSSSCI	External Expert KSSSCI

Dr. MRIDEEP SEN
Professor
Department of Microbiology

Kalyan Singh Super Specialty Cancer Institute

कल्याण सिंह अति विशिष्ट कैंसर संस्थान

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(An Autonomous Institute of the Govt. of Uttar Pradesh)

(उत्तर प्रदेश सरकार का स्वायत्तशासी संस्थान)

GeneXpert

~~CBNAAT~~

Email: procurement.ksssci@gmail.com

Proprietary Article Certificate (PAC) for Items/Goods

(1) The indented goods are manufactured by M/s. CEPHEID

(2) No other make or model is acceptable for the following reasons:

a) only VSFDA ANICI POC. TB PCR standalone system

b) .....

c) .....

Mamatha

.....

(Signature of Indentor)

Mamatha

.....

(Signature of HOD)

Gmail **Kalyan Singh Super Specialty Cancer Institute <procurement.ksssci@gmail.com>**

PAC CBNAAT

Dr Manisha Gupta <clinicalresearcher.manisha@gmail.com> Mon, Jun 2, 2025 at 12:20 PM
To: Kalyan Singh Super Specialty Cancer Institute <procurement.ksssci@gmail.com>, Finance Officer SSCI&H <fo.sscih@gmail.com>

PFA

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Best Regards
Dr. Manisha Gupta
MD, DNB, MNAMS, FRSPH(UK), DipRCPath, PDCC Infectious Diseases
AP(Microbiology)
Member Secretary Hospital infection control committee
Kalyan Singh Super Specialty Cancer Institute
Lucknow

Proprietary Article Certificate.pdf
273K

Jagrati
02.06.2025

Super Speciality Cancer Institute & Hospital (Stores Sec.)
Receipt date 02/06/25
No 7114 Initials Kamal

Cepheid.
A better way.

5 June 2024

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
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

T 1.888.336.2743
P 1.408.541.4191
F 1.408.541.4192

904 Caribbean Drive
Sunnyvale, CA 94089 USA

www.Cepheid.com

danaher.

Cepheid.
A better way.

The machine, spare parts, software, kits, and consumables are proprietary products of M/s. Cepheid. Sales and service are provided only by Original Equipment Manufacturer, M/s. Cepheid.

We also hereby declare that only M/s. Cepheid India Pvt. Ltd. located at 9th Floor, Tower B, Paras Twin Towers, Golf Course Road, Sector 54, Gurugram, Haryana – 122002 is responsible for providing the onsite service/remote support, repair, troubleshooting, Maintenance, and additional support to our user/customer as per our agreement and standard operating procedure in India.

Charles Mwangi

Charles Mwangi (Jun 5, 2024 22:31 PDT)

Charles Mwangi
SVP and Chief Financial Officer
Sunnyvale, USA
(Company Seal)

Technical specifications for Department of Microbiology (FY 2025-2026)

Fully automated TMA based Molecular testing system (Proprietary)

1. Fully integrated and fully automated molecular system
2. System should be compact, all-in-one single chamber system for performing all the testing steps
3. System should perform automated nucleic acid target capture, amplification, and detection all in a single tube
4. System should Perform nucleic acid amplification by using transcription mediated amplification (TMA)Technology
5. System should facilitate consistency and accuracy of system results with built-in process controls
6. System should have proactive system maintenance through intuitive software
7. System should have Continuous Testing and reporting of samples
8. System should offer random access capability
9. System should be capable of running multiple assays on the same patient sample
10. System should have Bi-directional LIS interface for streamlined data management.
11. System should have 24-hour calibrator/ control stability and On-Board reagent stability of 72 hours
12. System should have RFID labelled Fluid bottles with automated system scanning facility
13. System should have intuitive software with touchscreen facility
14. System should provide real-time guidance and status updates throughout all functions
15. System should provide both visual and audio assistance through task-driven interface
16. System should have In-process checks, which reduce operator and system errors.
17. System should offers real-time inventory supply updates and status messages throughout the day
18. Provides programmable system maintenance and priming during lab's off hours
19. System should have automated Liquid-level detection and reagent dispense verification.
20. System should report results within 3.5 hours of any sample loading individually without wait for batch processing.
21. Processes and obtains on-demand results for high priority samples with STAT testing ability.
22. System should be capable of testing at least 275 samples in 8 hours and 1000 samples in 24hrs
23. System should have minimum 700 tests onboard waste capacity
24. The HPV assay should be able to target and detect highly conserved regions of virus such as E6/E7 genes.
25. The sample collection specimen should be able to directly be loaded in the system without preheating/pre warming step.
26. System should process qualitative assays like HPV, HPV-GT and quantitative assays like HIV, HCV & HBV on the same system
27. System should be supplied with an IVD Dx RT PCR for cross validation and quality assurance
28. System should be supplied with all accessories to run the equipment.
29. System should be supplied with all kits and consumables for 1000 initial HPV mRNA and 300 HPV GT assay.
30. System should have a small footprint
31. Should have warranty of 5 years.

DMM	FIC, Microbiology	FO/Nominee	Nominee of Director	External Expert	External Expert
KSSSCI	KSSSCI	KSSSCI	KSSSCI	KSSSCI	KSSSCI

Kalyan Singh Super Specialty Cancer Institute

कल्याण सिंह अति विशिष्ट कैंसर संस्थान

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(An Autonomous Institute of the Govt. of Uttar Pradesh)

(उत्तर प्रदेश सरकार का स्वायत्तशासी संस्थान)

fully automated TMA based molecular testing system

Email: procurement.kssscl@gmail.com

Proprietary Article Certificate (PAC) for Items/Goods

(1) The indented goods are manufactured by M/s HOLOGIC INC

(2) No other make or model is acceptable for the following reasons:

a) only IVD FDA approved mRNA based HPV testing system

b) .....

c) .....

.....
Mamta
.....
(Signature of Indentor)

.....
.....
(Signature of HOD)

HOLOGIC®

PROPRIETARY ARTICLE CERTIFICATE
Hologic Panther System

Wednesday, 23rd July 2024

TO WHOM IT MAY CONCERN

On behalf of Hologic, Inc., located at 10210 Genetic Center Drive, San Diego, California 92121 USA, I herewith declare that the following IVD medical device and its related assays are a proprietary product, covered by intellectual property rights (i.e. patents):

- Hologic Panther System
- Aptima HPV assay
- Aptima HPV 16, 18/45 Genotype Assay
- Aptima HIV-1 Quant Dx assay
- Aptima HCV Quant Dx
- Aptima HBV Quant assay

The Hologic Panther System is covered by the following US patents and their foreign equivalents:

US PATENT# FOR PANTHER SYSTEM
US PATENT# FOR APTIMA HPV ASSAY
US PATENT# FOR APTIMA HPV 16, 18/45 GENOTYPE ASSAY
US PATENT# FOR APTIMA HIV-1 QUANT DX ASSAY
US PATENT# FOR APTIMA HCV QUANT DX
US PATENT# FOR APTIMA HBV QUANT ASSAY

Hologic, Inc. located at 10210 Genetic Center Drive, San Diego, California 92121 USA is the legal manufacturer and the owner of the intellectual property of the above-mentioned proprietary articles.

Sincerely,

Jeff Zinza
VP, Global Regulatory Affairs
Hologic, Inc.

Multiplex Protein analyte system

System should have-

1. Multiplexing capability: Up to 500 individual analytes in 96/384 well format.
2. ≥ 5.5 decades of detection (verified with beads dyed with a high concentration oforganic dye).
3. Input Voltage Range should be 100–120 V, 6.0 A, 50/60 Hz or 200-240 V, 3.0 A, 50/60 Hz
4. Operating Temperature should be 15 to 30°C (59 to 86°F)
5. Operating Humidity should be 20 to 80%, non-condensing.
6. System warmup time should be 30min.
7. System Initialization should be<45 min (including laser warmup and weekly calibration)
8. System Verification should be 5min.
9. Temperature Control should be Samples are maintained at a constant temperature when using the heater block (from 35 to 60°C (95 to 131°F), +/- 1°C of set point)
10. Plate Run Time should be ~20 min in 96-well plate in and ~75 min in 384-well plate.
11. System should have latest OEM software (xMAP® INTELLIFLEX Software) for operation and data acquisition.
12. Additional analysis Immunoassay Software should be provided with curve optimization Wizard. 4pl, 5pl and Robust fits and parallelism analysis.
13. The analysis software should allow a minimum of four types of curves fitting function.

Optics

14. Classification Laser should be 638 nm, nominal output 30 mW, diode: mode of operation, continuous wave (CW)
15. Classification Detector should be Avalanche photodiodes with temperature compensation.
16. Reporter Channel Detection should be A/D resolution 16 bits.
17. Reporter Channel Dynamic Range (RP1) - ≥5.5 decades of detection (verified with beads dyed with a high concentration of organic dye)
18. Reporter Laser (RP1) should be 532 nm diode-pumped solid-state laser (DPSS): mode of operation, continuous wave (CW); output power varies based on mode with maximum output power of 50 mW
19. Reporter Detector (RP1) should be Photomultiplier tube, detection bandwidth of 565 to 585 nm
20. Doublet Discrimination Detector - Avalanche photodiodes with temperature compensation

Fluidics

21. Cuvette should be 200 µm square flow channel.
22. Sample Injection Rate should be 2 µL/sec
23. Sample Uptake Volume should be 10 to 200 µL
24. Sheath Flow Rate should be 7.9 ± 0.9 mL/min, temperature viscosity compensated.
25. Sheath Pressure should be 8 to 13 psi for normal operations; 15 psi maximum
26. Piercing Probe Capability should be available in system.
27. Auto-Adjusting Capability should be there in the system.

Microspheres

28. System should be able to distinguish 1 to 500 unique xMAP® Microspheres in a single sample.
29. Classification of xMAP® Microspheres should be ≥80%.
30. Total System Misclassification of xMAP® Microspheres should be ≤2%.
31. Well-to-Well Carryover should be<4%
32. **Additional Requirements**
33. USB for data transfer and connection to optional peripherals (keyboard, mouse, and/or printer)
34. Installation Category should be II - As defined in IEC 61010-1:2017
35. Pollution Degree should be II - As defined in IEC 61010-1:2017
36. Ports - USB – 1 port on front of system, 4 ports in rear. Ethernet – 1 port in rear of system (CAT5 10/100/1,000 Mbps)
37. Operating System should be Microsoft® Windows® 10 IoT Enterprise LTSC
38. Screen Resolution should be 1,366 x 768 pixels.
39. Screen Size should be 39.6 cm (15.6 in.)
40. System should have Barcode Reader for importing target values from the xMAP ® INTELLIFLEX Calibration and Performance Verification Kits

JDM&M KSSSCI	FIC, Microbiology KSSSCI	FO/Nominee KSSSCI	Nominee of Director KSSSCI	External Expert KSSSCI	External Expert KSSSCI

Dr. MANODEEP SEN
Professor
Department of Microbiology
Dr. R.M.L.I.M.S., Lucknow

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(उत्तर प्रदेश सरकार का स्वायत्तशासी संस्थान)

MULTIPLEX PROTEIN ANALYTE SYSTEM

Email: procurement.kssscl@gmail.com

Proprietary Article Certificate (PAC) for Items/Goods

(1) The indented goods are manufactured by M/s LUMINEX CORPORATION

(2) No other make or model is acceptable for the following reasons:

a) multiplex detection of >115 protein biomarkers and

b) analytes

c)

.....

Manohar

(Signature of Indentor)

.....

Manohar

(Signature of HOD)

30/4/2025

To,

To Whom It May Concern

We hereby certify that the integration of the xMAP® INTELLIFLEX® instrument, Belysa™ data analysis software, and the MILLIPLEX® PLEXpedition™ screening panel constitutes a proprietary solution offered exclusively by our organization. This unique combination is not available from any competitor in the market.

This advanced solution combines:

xMAP® INTELLIFLEX®, known for its high throughput multiplexing capabilities,

Belysa™ - Robust data analysis platform

MILLIPLEX® PLEXpedition™- A comprehensive high-content screening panel.

Together, they deliver unmatched performance, streamlined workflows, and enhanced sensitivity for multiplex immunoassays.

Belysa™:

- Belysa™ is multiplatform that can analyse data from: Luminex™, ELISA & SMCxPRO™
- Robust auto-flagging and data hygiene features
- Supports Parallelism Analysis with Statistical Comparison of Slopes

MILLIPLEX® PLEXpedition:

- Saves sample, time, and money by enabling detection of 115 proteins at one time
- 115 targets including cytokines, chemokines, growth factors, matrix metalloproteinases (MMPs), and biomarkers of bone health, metabolism, and cardiovascular disease.

Manufacturer:
MilliporeSigma, 400 Summit Drive, Burlington, MA 01803
MilliporeSigma is the U.S. and Canada Life Science business of **Merck KGaA, Darmstadt, Germany**

xMAP® INTELLIFLEX®
Luminex corporation: 12212 Technology Blvd Austin, TX 78727, USA