

Admn/Prop/14/2021-AIIMS.JDH

Dated: 19th May 2021

Subject: Purchase of Fully Automated Real Time PCR with Automated Extraction System for the

department of Microbiology at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.** 

The Institute is in the purchase of Fully Automated Real Time PCR with Automated

Extraction System for the department of Microbiology at AIIMS, Jodhpur from M/s Abbott

Molecular Inc. 1300 East Plaines Illinois 60018, United State of America on proprietary basis. The

proposal submitted by M/s Abbott Health Care Pvt. Ltd., New Delhi 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/14/2021-AIIMS.JDH. The comments should be

received by office of Deputy Director (Admin), Medical College at AIIMS, Jodhpur on or before

09th June 2021 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,

**Deputy Director (Admin)** 

**Enclosed: Related documents enclosed.** 





Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines Illinois 60018 United States of America

Dated: February 8, 2021

#### **Proprietary Article Certificate**

This to certify that "Abbott m2000sp - E Series and Abbott m2000rt " products and List Numbers listed below are proprietary to Abbott Molecular Inc, IL USA.

#### **List of Products:**

S.No	List Number	Product Description	
1	09K14-02	Abbott m2000sp - E Series	
2	9K15-01	Abbott m2000rt	

This is to confirm that Abbott Molecular Inc, 1300, East Touhy Avenue, IL 60018 USA is the only singular and original Legal Manufacturer in the world for the above products and country of origin being Singapore. Switzerland and United States of America.

To the best of our knowledge, no other company distributes these products, without being under contract with Abbott Molecular Inc.

Thanking you,

For Abbott Molecular Inc

Nenuska Key

Associate Director Regulatory Affairs

Abbott Molecular, Inc.

CHOOSE TRANSFORMATION

Dr. Ashwini Agar val अतिराज्य आजाय Additional Profession सूक्षा जीवांत्रका किला

**Abbott** 

Jodhpur





January 29, 2021

Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA Phone: 224-361-7000 Fax: 847-775-6777

India

### Manufacturer Declaration

To Whom it May concern,

Abbott Molecular Inc. located at 1300 East Touhy Avenue, Des Plaines, Illinois, USA; declare that 60018 is an authorized manufacturer / distributor having its manufacturing at 1300 East Touhy Avenue, Des Plaines, IL USA 60018 for the following product as per details below.

- m2000sp Instrument E-series (Extraction unit)
- 2. m2000rt Instrument system (Amplification unit)
- Abbott RealTime HIV-1 Amplification Reagent Kit
- Abbott RealTime HIV DBS Amplification Reagent Kit
- 5. Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit
- Abbott RealTime HIV-1 Calibrator Kit 6.
- 7. Abbott RealTime HIV-1 Control Kit
- 8. Abbott RealTime HBV Amplification Reagent Kit
- Abbott RealTime HBV Calibrator Kit
- 10. Abbott RealTime HBV Control Kit
- 11. Abbott RealTime HCV Amplification Reagent Kit
- 12. Abbott RealTime HCV DBS Amplification Reagent Kit
- 13. Abbott RealTime HCV Genotyping II Amplification Reagent Kit
- 14. Abbott RealTime HCV Genotyping II Control Kit
- 15. Abbott RealTime HCV Calibrator Kit
- 16. Abbott RealTime HCV Control Kit
- 17. Abbott RealTime CMV Amplification Reagent Kit
- 18. Abbott RealTime CMV Calibrator Kit
- 19. Abbott RealTime CMV Control Kit
- 20. Abbott RealTime EBV Amplification Reagent Kit
- 21. Abbott RealTime EBV Calibrator Kit
- 22. Abbott RealTime EBV Control Kit
- 23. Abbott RealTime High Risk HPV Amplification Reagent Kit
- 24. Abbott RealTime High Risk HPV Control Kit
- 25. Abbott RealTime CT/NG Amplification Reagent Kit
- 26. Abbott RealTime CT/NG Control Kit
- 27. Abbott RealTime MTB Amplification Reagent Kit
- 28. Abbott RealTime MTB Control Kit
- 29. Abbott RealTime MTB Amplification Reagent Kit
- 30. Abbott RealTime MTB RIF/INH Resistance Amplification Reagent Kit
- 31. Abbott RealTime MTB RIF/INH Resistance Control Kit
- 32. Abbott RealTime SARS CoV-2 Amplification Reagent Kit
- 33. Abbott Real Time SARS CoV-2 Control Kit

Sincerely,

Nenuska Key Associate Director Regulatory Affairs.

Abbott Molecular Inc.

डॉ. अश्विनी अग्रवाल Dr. Ashwini Agarwal अतिरिक्त आचार्य Additional Professor



# Technical specifications for fully automated Real Time PCR system with Automated Extraction System

- . The system should be CE-IVD and US-FDA approved and assays should be WHO Prequalified. Instrument should have fully automated, integrated system for extraction, assay set (Master mix
- The system should offer a high throughput capability of maximal 96 samples per run at a time
- System should have flexibility-to extract nucleic acid from whole Blood, Serum/Plasma, Urine, swabs, semen, Biopsy, Surgical fluids, Liquid based cytology, BAL, breast milk, sputum, Bone
- Protocols Preloaded and pre-optimized for different assays
- The system should be compatible for running CE\_IVD, US-FDA, EUO US-FDA approved assays for COVID-19, CTNG, HPV Genotyping, HBV, HCV, HIV, CMV viral loads and HCV
- All the assay should have non competitive internal controls feature to monitor the complete process starting from extraction to amplification and detection
- System should contain integrated barcode reader for patient sample tube, reagent tracking including the controls and reagents, entire test record should be traceable from end to end.
- The extraction system should use magnetic bead-based technology for all the assays
- The extraction system should have the flexibility to accept primary tubes to minimise the hands-
- System should have a flexibility to perform even smaller batch size of 24,48 and 72 including
- System should display step to step progress of extraction process including real time visibility The system should ensure contamination control providing Aerosol barrier tips, unidirectional
- process flow, optimize pipetting algorithm (Air gap technology after each aspiration step) System should provide open mode extraction protocols up to 140 for different customized
- 96 well Real time PCR system should be a high-end compact system with latest, fast and high
- System should be capable of performing two parameters (e.g. HIV -HCV and HBV-CMV) simultaneously Heating block of the RT PCR system should be Peltier based
- The RT PCR system should have 5 excitation and 5 emission filters providing the multiplexing The system should have less down time due to minimal maintenance
- The system should support LIS capability
- The system should offer automate data analysis software for quantitative and qualitative assays Remote monitoring of the system should be available to provide trouble shoot
- The bidder should provide compatible US FDA assay compatible from same manufacturer

Dr. Pratima Gupta, M.D. Professor & Head

Department of Microbiology All India Institute of Medical Sciences

Rishikesh

श्रॉ, अणिवनी अग्रवाल Dr Ashani Agarwal

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