

**All-India Institute of Medical Sciences  
Ansari Nagar, New Delhi-29  
Store Section (D.O.)**

Ref. No. 25/SO(DO)/Path/PAC/22-23/FSC-III

Dated:- 25.10.2023

**Subject:** Procurement of Real Time PCR (Rotor Gene Q-5 Plex) from M/s Bioteknika India Pvt. Ltd. (M/s Qiagen GmbH, Germany, OEM), from Deptt. of Pathology on proprietary article certificate basis - Inviting comments thereon.

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The request has been received from Department of Pathology for the purchase of Real time PCR from M/s Bioteknika India Pvt. Ltd. (M/s Qiagen GmbH, Germany, OEM) on proprietary basis along with Technical Specifications, OEM Proprietary Certificate and Departmental PAC certifications.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 15 days giving reference **No. 25/SO(DO)/Path/PAC/22-23/FSC-III**. The comments should reach to the office of Stores Officer (DO), Store Section (DO), 1<sup>st</sup> Floor, Animal house Building, Near Gate No. - 2 at AIIMS on or before 10/11/2023 **upto 04:00 P.M.**, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

**Encl: Related documents enclosed.**

1. PAC Certificates enclosed.
2. Technical Specification.

  
**MANOHAR ARYA**  
STORES OFFICER (DO)  
अखिल भारतीय आयुर्विज्ञान संस्थान  
All India Institute of Medical Sciences  
अंसारी नगर, नई दिल्ली/Ansari Nagar, New Delhi-29



### Proprietary Article Certificate

To WHOMSEVER IT MAY CONCERN

5<sup>th</sup> Jan 2023

This is to certify/Confirm That QIAGEN Product with Product code

Product code QIAGEN Rotor Gene Q 5 plex plus HRM along with RGAM software 42530881 Premium is exclusively manufactured & Sold by M/S QIAGEN GmbH, Str. 1,40724 Hilden Germany, QIAGEN CLC is in Proprietary in Nature and there is no firm/company manufacture/produce the same.

QIAGEN India Pvt Ltd is a fully owned subsidiary of QIAGEN GmbH. and exclusive legal entity authorized to sell and service QIAGEN CLC products, India.

All above information are true to the best of our knowledge

A handwritten signature in blue ink, appearing to read "Frank Schacherer".



5<sup>th</sup> Jan 2023

Frank Schacherer  
VP Discovery Genomics, QIAGEN Bioinformatics QIAGEN GmbH  
QIAGEN Str. 1  
40724 Hilden German


**ALL INDIA INSTITUTE OF MEDICAL SCIENCES**

**ANSARI NAGAR, NEW DELHI-110029**

**PROPRIETARY Article Certificate (PAC) (Machinery & Equipment)**

1.	The indented goods are Manufactured by M/s.	QIAGEN GMBH, Hilden, Germany
2.	Item Name	Real time PCR system
3.	Model No.	5PlexRGQ
4.	Vital Technical Performance Parameters Required which makes the requirement Proprietary	The equipment is used for FDA approved markers which is essentially done on QIAGEN RT PCR Rotor Gene 5 plex plus HRM for Oncology Testing PIK3CA, EGFR, KRAS, BRAF, IHD1/2 etc, It is a single system used to perform multiple critical care & oncology testing & system can be used for all other 3 <sup>rd</sup> party kits from any other vendor too which will help to plan out for any new Biological markers without requiring any additional cost.
5.	No other make or model is acceptable for the following reasons	No other company manufacturer same specifications companion diagnostics kits, which are FDA approved proprietary certificate along with FDA approval enclosed.

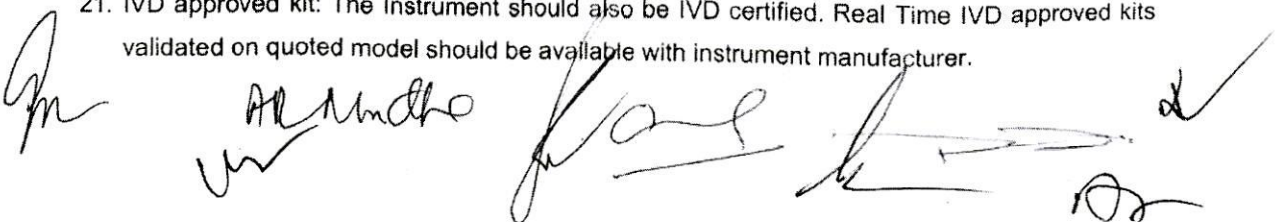
It is certified that market survey has done and found that no other manufacturer is manufacturing similar/equipment specifications which can fulfil the vital requirements of end user.

 Signature

## Note: 1 : TSEC should clearly mention the vital functional parameters requirement which end user essentially require and are manufactured by only one manufacturer mentioned in serial no. 1

**Specification for Real-time PCR Instrument (Rotor Gene Q 5 plex) (Global tender relaxation list No. 101)**

1. Real-time PCR detection machine, capable of and post-PCR (end point) analysis
2. The thermal cycler mechanism in the PCR machine should have air-based heating and cooling mechanism for maximum uniformity with even heating and cooling
3. The sample layout should be flexible for the tube input volumes having capability of running 72 or more samples in rotary format.
4. Any additional step like centrifugation of tubes should **NOT** be there.
5. The machine should have uniform temperature distribution. It should maintain iso-optical detection in all wells for maximum uniformity and have minimum equilibration time. Temperature uniformity should be  $\pm 0.02^{\circ}\text{C}$ .
6. The machine should have a dedicated **HARDWARE** for HRM with integrated **SOFTWARE** HRM tool with statistical analysis software.
7. The instrument should have high resolution SNP screening capability.
8. The instrument should come with standard chemistries for gene expression, quantification, miRNA, mutation scanning, genotyping, methylation studies etc. with an open system for other kit suppliers.
9. The instrument should have fast ramping of  $5^{\circ}\text{C}$  to  $10^{\circ}\text{C}$
10. Temperature range: Up to  $99^{\circ}\text{C}$
11. Light source: There should be 5 to 6 different wavelengths with minimum cross-talks. (Literature should be attached to prove the same). **NO SINGLE** wavelength of light. There should be optional Optical Thermal Verification kit for the automatic instrument calibration. It should be able to detect all wells equally with same optical path length.
12. There should be a warranty on light source for a minimum of 20 years
13. The excitation plexing should be as less as 5 plex, up to 6-Plex. It should have capability of further increasing the multiplexing beyond 6-Plex.
14. The Photomultiplier Tube (PMT) in the detector should have higher sensitivity with sensitivity control.
15. The dynamic range should be of 10 orders of magnitude.
16. The reaction volume to be in a range of 10-100ul
17. The instrument should not require any passive reference dye like ROX
18. Tube format: There should be a provision to mark the caps of the tubes. There should be a flexible tube format. No capillaries should be required.
19. The instrument should come with Hot Start facility. It should also have facility for touch down and long-range PCR.
20. The instrument should come with unlimited user software license with maximum features should come absolutely free of cost for the life of the machine. DNA concentration measurement software as standard should be provided.
21. IVD approved kit: The Instrument should also be IVD certified. Real Time IVD approved kits validated on quoted model should be available with instrument manufacturer.



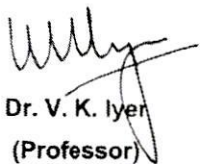
22. USB (fast) & LAN interphases should be there.
23. There should be a facility to store 800-1000 typical user-defined programs with the facility of unlimited USB flash drive expansion.
24. Power supply: Capable of working on 220-240 volts/ 50 Hz. An adapter should be supplied if needed. Compatible external adaptor and battery unit should be supplied with the instrument with attached hospital-grade Indian plugs.
25. UPS Backup: UPS backup which is suitable for supporting functions of the instrument of at least 4 hours should be provided with the instrument at no additional cost (at least 1KVA capacity). The CMC should also cover these third party supplied items if any.
26. The machine should be accompanied by a desktop computer/laptop, installed with licenced interface software. The software should have facility for programming, data analyses, pictorial report generation, data export and troubleshooting facilities.
27. Additionally, the machine should have LCD/ LED touch display for machine control and programming.
28. System should support applications including absolute quantitation, simultaneous analysis data for relative quantitation of Unlimited plates of 96 wells each, (up to 5 colour multiplexing), allelic discrimination (SNP), dissociation curve analysis as well as pathogen detection and plus/minus assay using internal positive control.

**29. Accessories:**

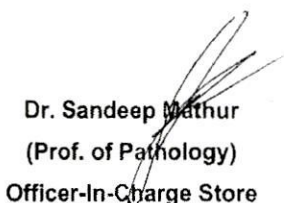
- i) All other accessories needed to install and make the instrument functional should be provided by the supplier at no additional cost. The calibration kits for PCR protocols available in the instrument (Absolute Quantification, Relative Quantification, Endpoint Genotyping, Melting Curve Analysis) should be supplied during the supply of the instrument. All essential electrical parts, extension cords, multipoint plugs, calibration kits, spare set to unlock the thermo-block, etc, should be provided by the supplier at no extra cost to the user.
  - ii) Along with the machine the following consumables (1000 pack each) should be supplied with the instrument at free of cost:
    - a) PCR tubes (0.2ml), b) PCR strips with cap (0.1ml). Quotations for these items should be separately provided, the cost of which will be fixed for next 10 years for use in the laboratory.
  - iii) Compatible USB dongle for dedicated use with the machine.
30. On-site Training at the user laboratory would be the responsibility of the supplier, which includes demo run and software training at no extra cost. During use, if required by the user, technical support should be given on-site installation. The vendor will be responsible for calibration of all applications available with the instrument at no extra cost to the user.
31. The machine should be certified by multiple national & international regulatory bodies, and should be certified for real-time PCR amplification for diagnostic use. Calibration certificates must be provided along with complete user manual in English language.

*[Handwritten signatures and initials]*

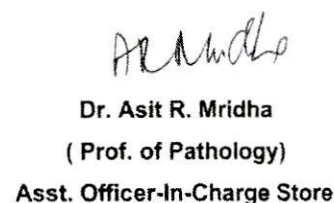
32. Systems with licensed full version software for primer and probe design with comprehensive assay design and development guidelines for quantitative and qualitative real-time assays will be preferred.
33. **Warranty:** 5 years comprehensive warranty on all components including the third party supplied items as UPS backup is must. Mandatory AMC quotation for another 5 years/ life-time of the instrument should be given with the original quotation including all third party supplied items.
34. **Penalty Clause:**
- Up-time-95% or more-In no case instrument should remain in non-working condition for more than 7 days, beyond which a penalty of 2% of machine cost will be charged per day.
  - If not repaired within 2 months, the machine should be replaced.
  - If anytime the machine is needed to be taken to the workshop, a similar demo machine should be provided to the user as a backup.
35. Undertaking from the specification committee stating that the specifications are broad-based, general in respect to the requirement and not suit to any particular firm/brand.
36. The machine should be certified by European-CE & ISO or US-FDA.



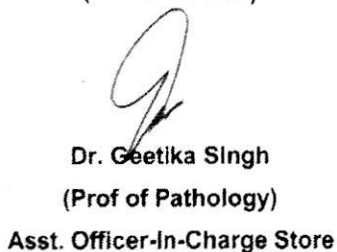
Dr. V. K. Iyer  
(Professor)  
Head of Dept. of Pathology  
(and Chairman)



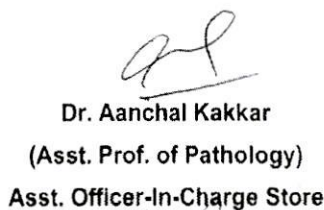
Dr. Sandeep Mathur  
(Prof. of Pathology)  
Officer-In-Charge Store



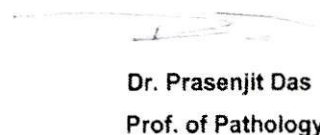
Dr. Asit R. Mridha  
( Prof. of Pathology)  
Asst. Officer-In-Charge Store



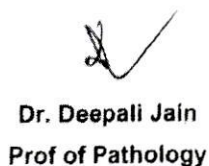
Dr. Geetika Singh  
(Prof of Pathology)  
Asst. Officer-In-Charge Store



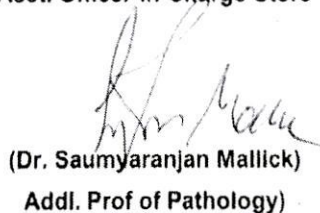
Dr. Aanchal Kakkar  
(Asst. Prof. of Pathology)  
Asst. Officer-In-Charge Store



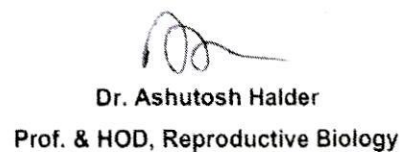
Dr. Prasenjit Das  
Prof. of Pathology



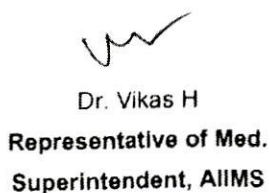
Dr. Deepali Jain  
Prof of Pathology



(Dr. Saumyaranjan Mallick)  
Addl. Prof of Pathology)



Dr. Ashutosh Halder  
Prof. & HOD, Reproductive Biology



Dr. Vikas H  
Representative of Med.  
Superintendent, AIIMS