



अखिल भारतीय आयुर्विज्ञान संस्थान राजकोट, गुजरात 360001
All India Institute of Medical Sciences, Rajkot, Gujarat 360001

Dated: 08 Sep 23

Subject: Proposal for Purchase of The QX200 Droplet Digital PCR System (DD-PCR) - 01 for the Department of Biochemistry on Proprietary basis at AIIMS Rajkot - Inviting Comments/Objection thereon.

The Institute is in the process for the purchase of above cited item from Bio-Rad Laboratories, Inc., Life Science Group, 2000 Alfred Nobel Drive, Hercules, California on a proprietary basis (PAC). The proprietary certificate submitted is attached & uploaded on website.

The above documents are being uploaded for open information to all principle manufacturers or their authorized distributors with the intention to invite objection/comments, if any with regard to proprietary nature of the above said system and accessories/consumables.

The comments/objections if any, should be received in the office of Stores, AIIMS Rajkot Khanderi, Para Pipaliya, Rajkot, Gujarat, INDIA, 360006, within 15 days from the date of notification, failing which it will be presumed that no other bidder/ manufacturer/ vendor is having any comments/objection against the proposition and the case shall be decided purely on merit.



Deputy Director (Admin.)

कमल पुनीत कुमार अरोरा,
Col. Puneet Kumar Arora,
उप निदेशक (प्रसा.)/Dy. Director (Admin),
एम्स राजकोट - 360 001, गुजरात.
AIIMS Rajkot - 360 001. Gujarat.

Enclosure: Related documents enclosed.

TECHNICAL SPECIFICATION OF DROPLET DIGITAL PCR SYSTEM	
	Droplet Digital PCR System, complete as per below mentioned configuration and specifications:-
1	Table top model with latest state of the art technology.
2	Complete, ready to use, setup should be quoted and supplied, which should include Droplet generator, droplet reader, necessary start-up kit and consumables, Gradient enabled Thermal Cycler, PC System, Software, all essential accessories, consumables, attachments etc.
3	System should be able to : <ul style="list-style-type: none"> • Detect rare DNA target copies with high sensitivity, • Determine SNP mutation with high sensitivity • Perform absolute quantification of nucleic acids with high precision and sensitivity without the use of reference genes as well as standard curves. • Determine copy number variation with high accuracy • Measure gene expression level with high precision. • Perform NGS Validation and library quantification
	Droplet Generator:
	1 No
4	System should be based on water-oil emulsion droplet technology with microfluidics.
5	System should be able to generate around 20000 uniform nanoliter droplets of each sample.
6	Sample volume should not be more 20 microliter
7	Sample capacity: Flexible ,a min of 8 samples per cartridge to 96 samples per run. The sample capacity should be easily scalable from 1 sample to 96 sample in a single run.
8	Droplet generator should be ready to use system, supplied with all standard and essential accessories, attachments, etc.
9	Droplet generation should not take more than 3 minutes for 5-10 samples.
	Droplet Reader:
	1 No
10	Suitable for counting PCR positive and PCR negative droplets
11	Reading capacity: System should be capable of analyzing 1 to 96 samples in one go.
12	Compatible for 96- deep well plate.
13	Sample illumination/Detection method: System should use two light emitting diodes for illumination and differentially detect emission using two filtered multipixel photon counter.
14	Dynamic range: 4 orders or more
15	Two channel detection for FAM (Evagreen) and HEX (Vic) dyes.
16	The equipment must be able to read multiplexing assays run with probe base as well as dye base chemistry
17	The reader must be able to read fluorescence data from each single droplet individually.
	Plate Sealer
	1 No
18	Plate Sealer suitable for 96 well plate, with support block, sealing frame and power chord.
19	One pack of 100 nos. of compatible seals should be supplied.
	Thermal Cycler:
	1 No
21	Gradient 96 deep-well PCR which can be used as a standalone PCR machine and having gradient range of 30-100°C with temperature differential range of 1-24°C
22	Model with graphical touch screen cum display should be provided
	Software
23	Software packages for droplet Digital PCR applications which may include features that provide fraction of negative droplets for each sample to fit to a Poisson algorithm; display of fluorescence amplitude value per droplet for both channels (FAM and Hex(VIC)), show multiplex data per droplet for two channels, Computes Absolute quantitation (copies/ μ l) for

	each sample; performs copy number variation analysis, Calculates fractional abundance of mutant target in wild-type background for mutation detection; setting automatic/manual threshold values for entire sample plate or for individual samples, merging results from replicate wells, graphical and tabular representation of data, Data acquisition and analysis, report generation, export results, etc.	
24	Latest available, Licensed version of the software should be supplied	
25	The software should not require manual setting of exposure & camera gain for the optics bench during run set up to avoid run to run variation.	
26	The Software should not use any reference dye to detect and count positive and negative droplets to avoid bias	
	Computer	
27	Latest available and factory recommended computer workstations should be provided for control, acquisition+analysis, etc. Computer system should be inclusive of all required hardware, drivers, adequate storage and RAM modules, etc.	1 No
28	Computer system should have sufficient memory to store at least 1000 previous runs data	
	Consumables:	
29	Consumables Sufficient to run at least 200 samples should be provided.	
30	The vendor must have comprehensive portfolio* of Assays and Kits across different Applications- Mutation Detection, Copy Number Determination, Genome Edit Detection, Gene Expression, Residual DNA Quantification and Library Quantification. Wet Lab Validated Assays must be available for the mutation detection and CNV analysis of more than 200 Oncology gene markers.	
	Preferred parameters	
31	Flexibility to take Time-breaks during workflow; droplet generation-PCR-Readout	
32	No Special temperature window for instrument operation	
33	Flexibility to use small or high number of samples throughput without wasting consumables	
34	All Workflow components manufactured by same vendor for consistent performance delivery	
35	More than 6000 Publications in reputed international journal as proof of technology	
36	More than 50 installations in India of the Product quoted with more than 15 in clinical setup	
37	<ul style="list-style-type: none"> The company needs to provide 3-year warranty and 5 years spare parts availability. The equipment must have easily replaceable parts and a list of necessary maintenance spares and consumables for a period of five years must be attached and supplied with the machine. Supply must undertake to provide comprehensive maintenance for further 5 years after expiry of the essential initial warranty period of 36 months after installation. During warranty frequent periodic services should be given. Periods of breakdown of machine will be excluded from warranty period. 	

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 जीव रसायन विभाग / DEPARTMENT OF BIOCHEMISTRY
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 ALL INDIA INSTITUTE OF MEDICAL SCIENCES, RAJKOT



**Bio-Rad
Laboratories**

Life Science Group
2000 Alfred Nobel Drive
Hercules, California 94547
Telephone: 510-741-1000
Facsimile: 510-741-5800

Annexure-III

Proprietary Article Certificate (PAC) from the firm

Proprietary Article Certificate is provided by the Bio-Rad Laboratories, Inc., Life Science Group, 2000 Alfred Nobel Drive, Hercules, California 94547, OEM before procuring the goods from a single source under the provision of sub Rule 166 (i) and 166 (iii) as applicable.

- (i) Bio-Rad Laboratories, Inc., Life Science Group, 2000 Alfred Nobel Drive, Hercules, California 94547 is the sole manufacturer of the indented goods; QX200 Droplet Digital PCR System & accessories .
- (ii) The QX200 Droplet Digital PCR System is unique for the following reasons:-
 - 1) The QX200 Droplet Digital PCR System –1864001 (including the QX200 Droplet Generator-1864002 and the QX200 Droplet Reader-1864003) and the QX200 AutoDG Droplet Digital PCR System-1864100 (including the QX200 Automated Droplet Generator-1864101 and the QX200 Droplet Reader-1864003) with accessories are provided by the single vendor only, Bio-Rad Laboratories, Inc., Life Science Group, 2000 Alfred Nobel Drive, Hercules, California 94547 U.S.A.
 - 2) QX200 Droplet Digital PCR System includes dynamic partitioning method which offers randomized distribution of DNA/RNA samples withing droplets .
 - 3) Highest number of recorded publications across more than 15 application areas (5900 as of Dec 2021).
 - 4) U.S. FDA-approved IVD kits are available for selected IVD clinical applications with a pipeline of future kits
 - 5) QX200 Droplet Digital PCR System offers flexible sample throughput, ranging from 1 sample to 96 sample/ run
 - 6) Post PCR, droplet-based amplification products can be recovered for other orthogonal testing
 - 7) QX200 Droplet Digital PCR System can easily scale to quantify target concentrations as low as one out of 1,000,000 (0.0001%) total copies
 - 8) QX200 is the only droplet digital PCR system which allows reading every single droplet individually to improves data quality. This is unique feature in QX200 Droplet Digital PCR System, where as other digital PCR technologies do data acquisition by imaging all partitions simultaneously.
 - 9) Only QX200 Droplet Digital PCR System workflow allows integrating a deep well gradient PCR which is essential for assay optimization in the QX200 Droplet Digital PCR workflow.

The above tangible benefits contributed by the Bio-Rad's QX200 Droplet Digital PCR Systems and processes are protected by the following U.S. patents: US9156010, US9417190, US9216392, US9126160, US9598725, US9500664, US9132394, US9089844, and US9764322.



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The QX200 Droplet Digital PCR System and the QX200 AutoDG Droplet Digital PCR Systems, with unique features as mentioned through para B, No. 1 to 9 are covered by the patents mentioned above. No other companies in the world are manufacturing the QX200 Droplet Digital PCR System or the QX200 AutoDG Droplet Digital PCR System.

- (iii) Concurrence of finance wing of the OEM: Bio-Rad Laboratories, Inc., Life Science Group, 2000 Alfred Nobel Drive, Hercules, California 94547 to the proposal vide Ref. No. BRH/RA/PG/2022/003. Dated: January 14, 2022. for issuing this PAC.
- (iv) Approval of the component authority of the OEM: Bio-Rad Laboratories, Inc., Life Science Group, 2000 Alfred Nobel Drive, Hercules, California 94547.

Authorized Signature:

Name: Patricia Gee Job Title: Regulatory Affairs, Representative

Signature:  Date: January 14, 2022

**All India Institute of Medical Sciences
Rajkot**

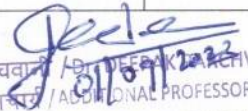
***** 398/2023

Ref No.- O.W.No /AIIMS.Rajkot /Biochemistry/ Dated: - 01-09-2023


Subject: Procurement of QX200 Droplet Digital PCR System on PAC basis

DD (Admin.)
I.No 5748 Date 07-09 Sign, BK
O.No _____ Date _____ Sign.


Description	Encis No
1. It is proposed to procure QX200 Droplet Digital PCR System for Department of Biochemistry, AIIMS Rajkot.	
2. The equipment is available on GeM . Technical specifications of the equipment are enclosed.	1
3. The item is to be procured on PAC basis. The proprietary certificate submitted by OEM is enclosed.	2
4. The equipment is also purchased by other AIIMS on PAC basis	3
5. Draft notice required to be published on the institute website inviting comments/objections thereon from any manufacturer regarding proprietary nature of the item is enclosed.	4
5. Approval may please be accorded to publish the notice and thereafter proceed with tender on GeM.	


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 ALL INDIA INSTITUTE OF MEDICAL SCIENCES, RAJKOT

- A/o i) AS per Ret N.S-01
- ii) Non-DPR item for Biochemistry Department
- iii) indent received from department on PAC base.
- iv) P.U for approval.


 21/9/23

Ao(Acc): (i) AS per ref. N.S-01
 (ii) P.U. for approval


 02/09/2023

DO (AS): on leave

ED Sir :


 02/9/23