INDIAN INSTITUTE OF TECHNOLOGY BOMBAY

MATERIALS MANAGEMENT DIVISION

Powai, Mumbai 400076

PR No. 1000053937 **RFx. No. 6100002770**

TECHNICAL SPECIFICATION FOR Polymerase chain Reaction Machine (Multi-Block/Gradient/Droplet Digital/Real Time) (Qty. 1)

Sr. No	Detailed Technical Specification	Technical Compliance (Yes / No)	Additional Information (if any)
1.	**Purpose:** Absolute quantification for Copy Number Variations		
2.	I. Table-top modular system with latest state of the art technology and upgradable modalities in terms of automation and multiplexing capabilities, complying with norms of respective instrument placements in pre-amplification, amplification and post-amplification areas as recommended by accrediting agencies and complying with MIQE guidelines. II. Complete, ready to use setup should be quoted and supplied, which should include Droplet Generator, Droplet Reader, Plate Sealer, Gradient enabled Deep-Well Thermal Cycler, High configuration Computer System, Data analysis Software and all essential accessories.		
3	**System should be able to:** I. Detect rare DNA target copies with high sensitivity II. Determine SNP mutation with high sensitivity III. Perform absolute quantification of nucleic acids with high precision and sensitivitywithout the use of reference genes, standard curves or any kind of		

	passive reference dye, that involves normalization before data interpretation. IV. Determine copy number variation with high accuracy V. Measure gene expression level with high precision. VI. Perform NGS Validation and library quantification		
4	**Droplet Generator:** I. System should be based on water-oil emulsion droplet technology with microfluidics. II. System should be able to generate around 20000 uniform nanoliter droplets of each sample. III. Total reaction volume needed: 20 microliters IV. Sample capacity: Flexible, a min of 8 samples per cartridge to 96 samples per run. V. The Sample capacity should be easily scalable from 1 sample to 96 sample in a single run. VI. Droplet generator should be ready to use system, supplied with all standard and essential accessories, attachments, etc.		
5	**Droplet Reader:** I. Suitable for counting data from one droplet at a time and segregating PCR positive and PCR negative droplets. II. Reading capacity: System should be capable of reading and analyzing 1 to 96 samples in a single run. III. Compatible for 96- deep well plate. IV. Sample Illumination/Detection method: System should use two light emitting diodes for illumination and differentially detect emission using two filtered multipixel photon counter. V. Dynamic range: 4 orders or more VI. Two channel detection for FAM (Evagreen) and HEX (Vic) dyes.		

	VII. The equipment must be able to read and analyse multiplexing upto 4 targets/well with VIII. probe (FAM/HEX) based chemistry, as well as must be capable of performing multiplexing even with dye (Evagreen) based chemistry. IX. The reader must be able to read, analyse and represent fluorescence data from each single droplet individually, during the data capture step		
6	**Plate Sealer:** Plate Sealer suitable for sealing 96 well plate using heat-based sealing, along with support block, sealing frame and power chord.		
7	**Thermal Cycler:** I. Gradient enabled 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 II. Instrument with graphical touch screen and display should be provided		
8	**Software:** I. Software packages for Droplet Digital PCR data capturing and analysis, which should include features that: Provide total number of droplet counts per sample, fraction of negative droplets for each sample to fit to a Poisson algorithm, II. Display of fluorescence amplitude value per droplet for both channels {FAM and Hex(VIC)}, III. Show how multiplex data per sample can be calculated, for two channels, IV. Computes Absolute quantitation (copies/µl) for each sample		

	V. Performs copy number variation analysis, VI. Calculates fractional abundance of mutant target in wild-type background for mutation detection, VII. Allow setting automatic/manual threshold values for entire sample plate or for individual samples, VIII. Options for merging results from replicate wells, IX. Graphical and tabular representation of data, data acquisition and analysis, report generation, export results, etc. X. Software package used for digital PCR system should be latest one to be freely used in different computer system XI. The software should not require manual setting of exposure & camera gain for the optics bench during or after run set up to avoid inter/intra run variations, subjective data analysis and automated data interpretation without manual intervention. XII. The software should not require any reference dye to detect/normalize and count positive and negative droplets to avoid bias.		
9	**Computer:** I. Latest available and manufacturer's recommended high configuration 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. II. Computer system should have sufficient memory to store at least 1000 previous runs data III. Consumables required for installation and starter kit to run the instrument must be provided. IV. 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 (in form of Screening kits, individual mutation and CNV assays and Multiplexing kits) must be available for the mutation detection and CNVanalysis V. The vendor must have validated assays on digital PCR. VI. 3rd party validated Kits should also be available on the quoted platform.		
10	**Mandatory parameters:** I. Flexibility to take Time-breaks during workflow; droplet generation to PCR-Readouts II. Thermal cycler with gradient feature to be available in the system to run samples with different annealing temperatures and for easy assay optimizations, to incur lower sample running cost, save time and provide wider flexibility. III. The instrument/technology must have and option of recovering the samples after thermal cycling for any other downstream applications like NGS. IV. No Special temperature window for instrument operation V. Flexibility to use small (8) or high (96) number of samples throughput without wasting consumables VI. All Workflow components manufactured by same vendor for consistent performance delivery VII. The technology must have more than 10,000 Publications in reputed international journal as proof of technology.		
11	**Documents for regulatory compliance** I. Quality System and Electrical & Laboratory Equipment compliance II. CE/ISO Certification		
12	**After sales support/ service / application support:** Required by Local Engineer.		
13	**Training**		

	Application Training will be provided on site by supplier.		
14	**Others** I. Service: a certified service engineer should be easily accessible and available on demand within 48 hours of any problem in the instrument. Two compulsory visit per year for maintenance must be included apart from the installation. II. Spares: the supplier of the instrument must confirm in writing that the spares for the entire instrument will be available for a period of at least ten years after the installation of the instrument. III. Manual: one set of operating manual and service manual (in english) should be provided with the instrument		
15	**Warranty- 3 years**		