Annexure - A
Technical Specifications of Molecular Biology Lab

Item No. 1 Specifications of Real Time PCR

1. System & reagents both are CE-IVD & US-FDA certified
2. Light source is Broad spectrum high intensity Xenon arc Lamp
3. Simultaneous, scan –free detection of signals from all wells with telecentric optics & CCD Camera.
4. Block cycler unit is 96-well format including Therma- base
5. Peltier based heating /cooling from 37° C to 95°C, (20° C stating temperature to perform specific melting curve analysis)
6. Heating rate: 96-well block: 4.4°C & Cooling rate: 96-well block 2.2°C
7. Reaction volume is 10µl to 100µl
8. System offer full traceability: Date, time, lot numbers, QC checks, patient IDand test results captured ina single report.
9. System should have 2 platforms, one is laboratory/user-developed protocols or UDF & another is existing IVD-approved test menu.
10. System is 21 CFR Part 11 Compatible.
11. Maintenance & ROX calibration is not requiring for the system.
12. IVD approved cancer marker assays like KRAS, BRAF and EGFR mutation tests with the system.
13. The tests are able to reliably detect mutations in cell lines and clinical FFPET specimens at > 5% mutation levels
14. The KRAS mutation test offer broad mutation coverage of KRAS codons 12, 13 and 61 to identify colorectal cancer patients not likely to respond to anti-EGFR monoclonal antibody therapies
15. The BRAF mutation test detects BRAF V600 mutations in FFPET samples and should aid in selecting patients for treatment with Zelboraf
16. The EGFR mutation test detects andidentifies mutations in exons 18, 19, 20 and 21 of the EGFR gene from FFPET non-small cell lung cancer samples.
17. The system provides automate result interpretation
18. Up gradation option for HPV 16,HPV 18 & other high risk group screening & genotyping with automation.
19. Manufacturer should have standardized protocol & assay for H1N1 & Ebola
20. System should capable of multiplexing of 5 or more targets.

Item No. 2 Specifications of Bio Safety Cabinet A2

- The Bio safety cabinet should be Type A2 in which 70% Air should be re- circulated and 30% of the air should be exhausted
- The motor must automatically adjust the airflow speed without the use of a damper to ensure continuous safe working conditions, even without maintenance adjustments.

- In order to preserve safety to the user and the environment, the exhaust blower on the cabinet must continue operating when the supply blower stops working. If the exhaust blower should fail, the supply filter will also be turned off.

- In order to ensure consistent and reliable down flow velocity across the supply HEPA filter over the life of the cabinet, the cabinet must use a pressure sensor (rather than anemometer) to detect pressure drop across the supply filter, rather than in just one point across the down flow. The pressure sensor must be encased in order to protect the sensor from temperature, humidity and other environmental phenomena that can impact the sensor's performance.
- The microprocessor must display the inflow and down flow air velocities in real-time on an LED display to ensure the user knows whether or not the cabinet is working under safe operating conditions.
- The cabinet design should incorporate dual brushless DC motors, one each to independently monitor exhaust/Inflow and down flow.
- The front window must be a 10" sash opening and be made of laminated safety glass to ensure containment of potentially hazardous samples in the case of accidental glass breakage.
- All interior and exterior parts must be painted or smooth to ensure no risk of cuts to users or maintenance personnel.
- The front of the cabinet must be angled 10° to help minimize glare on the window to the user, and to ensure that the user's posture is comfortable during a working session. Inadequate user ergonomics in a safety cabinet may lead to excessive fatigue, unsafe working habits and harmful consequences to user safety or product contamination.
- The cabinet noise level must be less than 63 dB(A) for a 4 foot cabinet as measured in a sound proof room 12 inches in front of the cabinet and 15 inches above the work surface. Lower noise levels promote more comfortable and safer working habits of the user.
- The Biosafety Cabinet should have microprocessor controller and same must be located on a slanted front panel so it is easy to see and reach from a seated working position in front of the cabinet.
- The interior of the front window must be accessible for cleaning without requiring the user remove or support the window.
- The interior walls of the cabinet must be coated in white color to ensure that samples are easier to visualize and enhance user comfort.
- The biological safety cabinet must be capable of achieving current state-of-the-art in energy efficiency. A biological safety cabinet with lights on and fan at operating speed should consume less than 200 watts for a nominal four foot width and have a reduced energy mode for non-operational maintenance on containment in the work area.
- The cabinet must automatically reduce fan/blower motor speed to 30% when the front window sash is in closed position to ensure reduced energy consumption when the cabinet is not is use.
- In order to provide maximum effectiveness, efficiency and safety to laboratory Personnel, UV light must be programmable to allow for specific exposure times from 0 to 24 hours. The automatic shut off feature on the UV light saves money on replacement of the bulbs.
- The Cabinet should be provided with taps for Vacuum, Water and Non Combustible Gas.
- The Bio safety Cabinet should be NSF certified.
- The Bio safety cabinet should incorporate HEPA filter of the class H 14 EN 1822 or better and having efficiency of 99.995% at 0.3 μm particle size.

- Approximate Dimension
  Exterior 1500 H x 1300 W x 800 D; Interior 800 H x 1200 W x 500 D
- Ventilation System Exhaust and Inflow air volume approx 300-350 CFM
- Heat Emissions at 25°C should be approx 0.2 KW or lesser.
- The Bidders should provide details of Standard Warranty available
- The cabinet Should be provided with Microprocessor controller and large LED display for inflow and Down flow air velocity and hours of operation, Audible and visual Alarms for HEPA filter failure, blower failure, airflow speed failure, Incorrect window position.
- The cabinet should be provided with exhaust transition and appropriate ducting should be provided by the supplier
- The cabinet should be provided with sealing kit to carry out fumigation of the cabinet work space.
- The cabinet should be provided with fixed / adjustable Height Stand, UV Light and one set of detachable arms rest and one / two electrical outlet.

Item No. 3 <u>Specification of Water Bath</u>

- Capacity: minimum 10 Liters
- Temperature range: ambient to 100°C
- Temperature Stability: ±0.1°C
- Temperature Uniformity: ±0.2°C
- Temperature Presets: minimum 4
- It should have Icon-based graphical display for easy operation and monitoring
- Interior chamber should be seamless stainless-steel.
- Exterior should be epoxy powder-coated for outstanding chemical and corrosion resistance
- It should complete with clear polycarbonate gable cover, diffuser tray, drain hose and rubber duck
- It should have over-temperature safety to prevent thermal runaway; auto-on and auto-off timers to optimize operation schedules & audible alarms.
- Exterior dimensions (L x W x H): 15.5 x 15.1 x 9.2 in.
- Certifications: UL & CE are preferred
- Warranty: 2 years

Item No. 4 <u>Specification of Refrigerated Centrifuge:</u>

- Max Capacity: 4x400ml
- Temperature range: -10 °C to +40 °C
- Maximum Speed: Above 15000 RPM
- Maximum RCF : 25000 to 26000 xg
- The centrifuge should be CE, UL Certified and IVD Compliant, ISO 13485 international standard.
- The bucket lids for Swing out rotors must operate in a safe manner without spring clips or metal components. The buckets and rotor sealing lids must be certified for bio-containment by a 3rd party lab of worldwide recognition
- The centrifuge must be able to display both air/chamber temperature as well as temperature in the sample.
- Dual Timer mode- At Start and at Speed

- The centrifuge must have an option for automatic lid opening at the end of the run & also the facility of password protection for lid opening
- The centrifuge must have capability of password protection for the programs.
- The centrifuge must be able to display set parameters together with actual values,
- The centrifuge must have a minimum of 5 "direct recall" program keys, and capability for up to 99 programs.
- The centrifuge must be supplied with Swing out Rotor capable of running up to 76 x 5 ml or 7 ml blood collection tubes and 56 x 10 ml blood collection tubes in certified sealed conditions at 5000RPM & 4700xg. The buckets and rotor sealing lids must be certified for bio-containment by a 3rd party lab of worldwide recognition. The bucket lids for Swing out rotors must operate in a safe manner without spring clips or metal components.
- The centrifuge must be supplied with Fixed Angle light weight non corrosive Rotor capable of running a minimum of 8 x 50 ml & 8x15ml conical tubes at speeds of at least 24000 x g. The rotor should be warranted for 12 to 15 years. The rotor must be certified for bio-containment by a 3rd party lab of worldwide recognition
- The centrifuge must be supplied with Fixed Angle light weight non corrosive Rotor capable of running a minimum of 48 x 2 ml microtubes at speeds of at least 25000 x g. The rotor should be warranted for 12 to 15 years. The rotor must be certified for bio-containment by a 3rd party lab of worldwide recognition
- The centrifuge must be supplied with Microplate Rotor of capable of running of 6 microplates of standard footprint and height; the rotor must offer the possibility to accommodate the microplates in removable sealed containers, certified for biocontainment.
- Warranty: 2 Years on the machine

Item No. 5. Specification of Pipette

- The handle and the dispensing button of the Pipette should be made of an antimicrobial polymer containing silver ions as the active ingredient.
- The pipette should have **Advanced Volume Gearing mechanism**
- It should have facility of adjustable finger rest that can be adjusted 120° to the most ergonomic and comfortable position for pipetting and tip ejection.
- It should have features of super blow-out feature to ensure the delivery of micro-size drops.
- Pipette Ranges:
    1. Range: 0.2-2 µl ; Increment: 0.002 µl ; Accuracy µl: ±12.0-2.5%
    2. Range: 2-20 µl ; Increment: 0.02 µl ; Accuracy µl: ±3.0-1.0%
    3. Range: 20-200 µl ; Increment: 0.2 µl ; Accuracy µl: ±1.8-0.6%
    4. Range: 100-1000 µl ; Increment: 1 µl ; Accuracy µl: ±1.0-0.6%
- Warranty: 5 Years

Item No. 6. Specification of Vortex Mixer

- Speed Range: 0-3000rpm
- Operating Mode: Continuous / Touch
- Minimum Load: 0.5Kg
- Built-in safety features regarding current overload
- Wide variety of optional accessories to accommodate different vessel types

Item No. 7. Specification of LN2 Tank:

- Capacity: 600 of 2ml vials
- Applications: Portable Sample Storage Vessel
- At least 6 no. of canister should be supplied
- Neck Diameter: 3.5 inch
- Static Evaporation Rate should not be more than 0.18 L / Day.
- Static Holding Time should be at least 193 Days

Item No. 8. Specification of Ultra Pure Water Purification System

1. Reverse Osmosis, Ultra pure Ion Exchange System with UV Photo-oxidation
2. Pretreatment system with Activated Carbon Filter, Hardness Stabilizer, Filter Insert, 5µm, 1µm, 0.5µm of 10" cartridge
3. Micro-processor based table top model with Reverse Osmosis, Ultra pure water System, re-circulation pump to generate ASTM Type II and ASTM Type I quality water for molecular biology applications and HPLC, ICPMS, TOC, etc.
4. RO Permeate Output capacity 6 ltrs/hr
5. Ultra pure water capacity 1.0ltr/min
6. Ultra pure water Conductivity 0.055µS/cm
7. TOC value 1 - 5 ppb
8. UV Photo-Oxidation with 185 and 254nm
9. Ultra filtration Module, should be internal and not external
10. Endotoxines < 0.01 EU/ml
11. Integrated tank capacity 6 ltr with vent filter, conical bottom and food grade polyethylene
12. Tank water should be re circulated through ultrapure cartridge after fixed interval
13. 99% Retention of bacteria
14. 99% Retention of particles
15. Low-noise recirculation pump
16. Digital microprocessor control
17. LCD display for monitoring the conductivity of output ultra pure water
18. Limiting switch to ensure quality of water
19. Keypad for entering start and flow of operations
20. RS232 interface for external data print

Item No. 9 Specification for the Nanodrop Microplate Spectrophotometer

- A UV-visible spectrophotometer with microplate reading option.
- A monochromator based UV/Vis spectrophotometer with Xenon Flash lamp as light source and photo multiplier tube (PMT) as detector, for better performance.
- The system is able to read 96 & 384 well plates. Should have the facility of 16 samples analysis in 2ul quantity at a time.
- Instrument is able to provide the wavelength range from 200nm to 1000nm with 1 nm steps.
- It should have spectral scanning option for standardizing new assays.The applications include nucleic acid quantification, protein assays, enzyme kinetic assays, immunoassays (ELISA) , cell toxicity assays, apoptosis and reporter gene assays.

- The instrument has inbuilt incubation and linear shaking options for ELISA, enzyme kinetic assays etc.
- Incubation temperature: from ambient +4 ^{0}C to +45 ^{0}C.
- Measurement speed should be 6 sec. for 96 well and 10 sec. for 384 well plate
- It should be an open system and able to accommodate any consumables from any manufacturer.
- Instrument has an option for pathlength corrections to correlate the microplate data to cuvette, in case of nucleic acid quantification performed on microplate.
- It has Power Save function for reduced energy consumption when the instrument is 'on' but not in use.
- It should run in stand-alone mode OR with computer & software controlled.
- The instrument has a memory of 100 inbuilt protocols in stand-alone mode and has color display for better visualization.
- Analysis software should be supplied with the instrument and has unlimited user system license.
- The instrument has USB port for the easy data transfer.
- It should have a self diagnostics option to give a guaranteed high quality data.

Item No. 10 Specification of pH meter

- Range pH : -2.00 to 20.00
- 0.001 pH resolution and ±0.002 pH accuracy
- Machine should show up to 5 different slopes with offset
- Temp Compensation: Automatic or manual (0 to 100 °C / 32 to 212 °F)
- Easy-to-understand prompts
- Graphic display with adjustable backlight
- Calibrate with custom pH buffer values
- Date and Time to meet GLP
- Password protection
- Optional calibration reminder & high/low alarm
- 500 point memory – log manually or at intervals
- Easily view calibration data
- pH meter should be supplied along with TRIS compatible pH/ATC electrode , electrode arm, RS-232 & USB cables, 100/240 V power supply, and manual
- Warranty: 2 Years

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