CORRIGENDUM

IGIB/2-1NC/250/2024-25(875)

28.10.2024

Subject : Biobanking and Archiving Equipment

Ref.:- CPPP Tender ID No. 2024_CSIR_211354_1 Dated 15.10.2024

With reference to the above tender this is to inform that after pre-bid meeting the technical specifications has been revised.

Bidders are requested to submit their bid as per the revised technical specification (enclosed with this corrigendum). All other terms and conditions of the tender documents will remain same.

Revised technical specifications encl.

Stores and Purchase Officer 28/10/200

Annexure 1

Biobanking and Archiving Equipment

The specifications are for biobanking and archiving equipment for sample storage, processing, and distribution. The equipment will be utilized for the long-term ultra-low temperature storage of biological specimens planned to be stored including plasma, serum, tissues, cells, DNA, RNA, and Peripheral Blood Mononuclear Cells (PBMCs). This will include the building of the site, commissioning, installation, and maintenance of the biobanking and archiving equipment at the site, which should have the following components and specifications:

- 1. A turn-key job to build, commission, install, and maintain a temperature-controlled, stabilized line facility that can house the biobank and archiving system. The storage facility should be designed to house the biobanking and archiving system to store sensitive biological samples at temperatures down to minus 80°C. The Ambient temperature of the facility should be maintained at $20 \pm 4^{\circ}$ C with safety and security controls. Please refer to Annexure A for detailed specifications of the turn-key job that must be met to build the facility.
- 2. Capacity The biobank system should have ultralow temperature freezers to hold at least 7000 microtube storage boxes (81-well) or at least 10 lakhs, 0.5 ml cryotubes. The ultralow temperature freezer can be divided across separate units to cater to the storage capacity. The cryo racks for storing at least half of the total capacity must be provided with ultralow temperature freezers. The units should be accessed controlled through a username and password control. The system should perform at a noise level below 65 dB.
- 3. **Security** The ultralow temperature freezer should come with HID/RFID access card/s for electronic door access control.
- 4. **Compressor** The system should have two number of -variable speed compressors to quickly adapt to the freezer requirements.
- 5. Liquid nitrogen (LN2) or equivalent Backup The system should have on-board integrated LN2 or equivalent Backup system to maintain the set temperature of ultralow temperature freezers in case of power failure, compressor failure, heat exchanger failure,

or other parts failure. The LN2 backup system must come with a LN2 tank of at least 200 liters of capacity and function without manual intervention or override.

- 6. **Wireless monitoring system -** The freezers must have on-board data or event logging connect with freezer that should be graphically displayed and log the temperature of the system parameters. The data log should be downloadable and displayed via a USB port.
- 7. Power management system should show incoming line voltage, indicate low or high line voltage, and provide voltage correction of up to +/- 10% of rating. The system must work online with a voltage of 200-240V/ 50Hz and have an instrument current rating of no more than 7 Amps. Suitable servo stabilizers should be provided to maintain the voltage with each unit.
- 8. Controlled thawing and freezing The system should come with a sample preparation and thawing unit with a temperature resolution of 0.5°C or less; an internal capacity of at least 45 liters or more with at least 4, 1.2/2.0 ml cryotube racks. The unit should have a standard temperature range of ambient + 10°C to -180°C. The equipment must be ISO/BIS accredited and should have the following features:
 - a. The 'sample preparation and thawing unit' should have a chamber freezing Rate of a minimum of 0.5°C / min or less to a maximum of 50°C / min or more over an operating temperature range. The chamber warming rate should be a minimum of 0.5°C / min or less to a maximum of 10.0°C / min or more.
 - b. The unit should have at least one hinged solid door and must have dual valve control for LN2 injection to maintain precise temperature control. The unit must incorporate an internal sensor for chamber temperature and sample temperature, independently. It must come with at least one LN2 supply tank of at least 200 liters or more.
 - **c.** The equipment should also have adjustable cold and warm alarms as well as audible and visual alarms. The equipment must have integrated touchscreen logs usage and events to support audit trail and traceability of usage with USB data export functionality and at least 3 levels of user accessibility for security. It should be connected to the cloud with onboard WiFi and have standard remote alarm terminals. The unit should have PC Interface companion software for the remote operation of the product.
- 9. Wireless data logger and asset management system The asset management and wireless data logger system should be connected to the ultra-low temperature freezers

supplied to maintain the record of health, temperature, event logs, and alarms in a single PC. The asset management system should have components like external sensor probes, communicating devices, and recording software. Each freezer or unit should be connected/have a sensor probe to record temperature data. The software should be able to send mail, SMS, and call alerts to the assigned persons in case of deviation from the setpoints. The software should have configurable storage for all the event logs and should have at least five levels of access control options. The software should be upgradable to 21CFR compliance. The manufacturer should have an installation base in a reputed academic/ research institution within India and be available for demo upon request.

- 10. **Gassed incubators -** The system should come with one unit of at least 200 L of chamber capacity carbon dioxide incubator equipped with CO₂ sensors, precise microprocessor controls, humidity control, HEPA air filtration, high-temperature decontamination capability that maintains at least 140 degrees celsius or more for at least 12 hours or more, and an alarm system to check temperature and % of CO₂ variations. The chamber material must be polished stainless steel and have at least two or more racks.
- 11. **Biosafety cabinet:** The system should come with one unit of class II, type A2 with approximately 70% recirculation that should have at least 4 feet of working area and must include dual DC motor configuration or equivalent and dual pressure sensor to control the inflow and exhaust air. The cabinet should be microprocessor controlled and must display the inflow and downflow air velocities in real-time on an LED display to ensure the user knows whether the cabinet is working under safe operating conditions. The Bio-safety cabinet should be NSF/ANSI49 certified with listing on the NSF website.
- 12. **Benchtop refrigerated centrifuge:** The system should come with one unit of refrigerated centrifuge that should be microprocessor controlled, direct, brushless induction low profile motor. It should attain a speed of at least 15,000 RPM & 25,000Xg or more. The centrifuge should have safety features like the ease in a change of rotors while switching between applications, certified biocontainment/aerosol-proof lids, Imbalance detection, finger-pinch prevention, and crash-proof construction. The rotors provided should be as per below:
 - a. The centrifuge should be provided with one unit of swing bucket rotor that is capable of handling 5/7mL vacutainer tubes (180 tubes or more), 50ml conical tubes (40 tubes

or more), 15ml conical tubes (80 tubes or more) and Microplates (20 plates or more) using adapters. The rotor should be able to attain speeds of 4000 RPM or more.

- b. The centrifuge must be supplied with one unit of fixed angle rotor for micro-centrifuge tubes with a capacity of at least 30 tubes. The rotor should attain speeds of 15,000 RPM & 25,000Xg or more.
- c. The centrifuge must also have user management and access control via passwords to maintain and access records that should be downloadable through a USB port. The software should be upgradable as per GMP/GLP standards.
- d. The centrifuge should have electrical safety certificate available with the equipment, biocontainment/aerosol proof certification, and IVD certification.
- 13. **Micropipette sets** The package should also provide one set of 8-channel micropipette. A set of micropipette should have space adjustable tip cones and should have different volume ranges that can cover $0.5-10 \ \mu$ L; $2-20 \ \mu$ L; $10-100 \ \mu$ L; $20-200 \ \mu$ L; $100-1000 \ \mu$ L or $50-1250 \ \mu$ L with electronic index finger pipetting action and adjustable finger rest. The micropipette should come with lithium-ion battery for quick recharge and at least two years warranty.
- 14. **Controlled-rate cryogenic freezer system** An automatic LN2-based controlled-rate cryogenic storage unit supplied with at least one pressurized LN2 cylinder of 200 Liters or more with vacuum insulation. The system must be compatible with both liquid and vapor phase storage. The system should have a sample capacity of at least 35,000 vials for 2 ml or 60,000 vials for 1.2 ml. The unit must incorporate a temperature sensor under the lid, which notifies high-temperature conditions by indicating the highest temperature reading at the top of the rack. It should also display liquid level and digital temperature simultaneously. Also, it should have a front-mounted cabinet key lock for sample security along with a key lock on the controller for temperature and alarm set-point security to avoid unauthorized people changing the controller parameters. The unit must continuously display the actual liquid level and high-level/low-level set points. The unit must prevent ice build-up and provide added user safety around the lid opening. The unit should have heavy-duty casters to provide mobility within the lab.
- 15. Liquid Nitrogen storage system with racks A liquid nitrogen container with 6 racks or more for sample storage. Storage temperature should always be below -180 degrees and

the capacity of the vessel should be 180L or more, with sample capacity of 6000 or more tubes of 2mL. The static evaporation should not be more than 0.99L per day. The container should be provided with accessory wheeled cart for easy transport during re-filling. The container should have advanced vacuum insulation to minimize liquid nitrogen evaporation and reduces operating costs. The unit must be CE, CSA certified.

- 16. Computer Workstation The system should have a dedicated computer with CPU: Intel Xeon Silver or Gold series (12 core) processor or equivalent and RAM: 64 GB DDR5 or higher for managing sample inventory. The system should be provided with an SSD storage system of at least 1 TB storage or more.
- 17. **Warranty** The system must have a five-year warranty for the complete system, including all accessories, and a minimum of ten years' warranty on the compressor for reliable quality. Five years comprehensive maintenance charges post warranty should be quoted. However, this will not be a part of the price or bid evaluation.

<u>Annexure- "A"</u> <u>Details of turnkey Project</u>

- 1. The facility to be developed is roughly 2000 square feet area. The existing level of the Ground is to be raised by 2 feet over which the facility is to be developed. The 2 feet-wide passage all around the perimeter of the facility is to be made Pucca by placing paver blocks.
- A structure of size roughly 40 feet X 50 feet to be built on the site. The walls of the outer structure, as well as the inner walls of the internal rooms, should made of at least 50 mm thick PUF Panel/SS panels/Other material of heat and weather resistant property and must be fire resistant.
- 3. The roof of the facility is to be provided with a proper drainage facility for rainwater (Preferably sloping). This drainage is to be connected with the nearest drain line.
- 4. The doors of the facility should have door closers with a security system for authorized entry. There must be at least two double-leaf doors for entry and exit of deep freezers and a single door for emergency exit. A glass window is also to be provided for an inside view. Ramps are to be provided for both entry and exit doors.
- 5. The facility should have a single entry partition to avoid AC loss.
- 6. The minimum room temperature to be maintained is 20±4°C. Hence, a suitable air conditioning system, VRF/VRV, can house the biobanking and archiving system to store sensitive biological samples at temperatures down to minus 80 degrees Celsius.
- 7. Adjustable stools 5 in number minimum. Lab working tables 4 in number minimum with provision for the electrical raceway. Stainless steel cabinet 1 in number and sample carry trolley-One number minimum.
- 8. LED lighting for the entire facility with the UPS of at least 10 KVA or more/backup electrical facility for the small equipment in the facility.
- 9. Fixing of MCP, smoke & heat detector with fire panel & extinguisher and as per fire safety norms.