



Terms of Reference / Technical Specification Clauses

Item Name: Freezer for Plasma Storage

I- Specifications:

- Temperature controller with a built-in audio visual alarm. It features an LED digital temperature display, programmable high temperature alarms, manual alarm checks, and a programmable operating range
- Microprocessor temperature controller with built-in alarm/monitor
 - o Temperature Display Unit at 0.1 °C graduation.
 - o Continuous Temperature Recorder: build in seven-day chart with battery back-up.
 - o Roll-out type of drawers or trays. (Included)
 - o Availability of alarm test.
 - o Interface for Remote Temperature Monitoring.
 - o Casters for easy movement of the equipment.
 - o Stainless steel construction.
- Full-color touchscreen monitor with downloading,
- Maximum temperature uniformity.
- Operating temperature range from -20°C to -40°C
- Performances: -30°C to the core within 60 minutes
- Bacteria-resistant powder coated interior and exterior for added security
- Sure-Seal self-closing door with magnetic closure to eliminate broken door latches
- Program up to 4 daily defrost events to run during low use periods for greater efficiency
- Meets AABB and/or FDA and/or EU Blood Directive
- Offers a temperature validation package that will certify the temperature performance of the Freezer.
- A multiple point temperature recorder will map the temperature inside the freezer chamber and a document with the data will be provided. Includes documentation of the chamber temperature and certificate of calibration for the test instrument.
- Storage trays Simplify and organize storage needs. Each tray comes with dividers and rails to customize individual storage areas. (Included)
- Storage options: Solid stainless steel drawers
- Capacity: ~ 650 L and/or 1400 L
- The company should support in validating the equipment according to BTS LRC policy.

II- Training:

The supplier will train LRC blood bank technologists on site.



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III- Documents to be delivered:

- The supplier will provide the LRC with FDA/AABB/EU approval.
- Certificate of validation: Certifies that monitor was calibrated with traceable thermometer before it left manufacturer facility.
- Validation: The Equipment Validation Guide for Refrigerators provides documentation for Installation Qualification and Operational Qualification (IQ/OQ), as well as an outline of suggested topics for performance qualification (PQ).

- Technical manual with
 - clear instructions for use
 - Safety measures
 - Programming

- Maintenance manual with:
 - Technical specifications
 - Electrical design,
 - Instructions for installation,
 - Maintenance schedule with operations to be done and frequency.
 - Instructions for first level maintenance and repair.
 - Catalogue or list of accessories and its references,

IV- Accessories required:

- Chart recorder papers
- Stylus ink pen
- Drawers' dividers.

Their provision must be guaranteed for a period of ten years as of the date of installation of the devices.

V – Transport, installation, and setup

The supplier will perform the installation qualification of the equipment.