



Terms of Reference /Technical Specification Clauses

Item Name: Pooling Equipment for NAT Testing

I- Specifications:

Functional Requirements

- Must support pooling of 1 to 96 individual samples per run.
- Compatibility with Roche Cobas system for automated sample pooling and NAT (nucleic acid testing) in donor screening.
- Automated tracking and documentation of pool composition.
- Integration with LIS (Laboratory Information System) and NAT platforms.
- Closed-system liquid handling to avoid cross-contamination.
- Minimal hands-on time; user-friendly interface.

Technical Specifications

- Sample volume accuracy: $\pm 1\%$
- Multi-Probe Head (MPH) Technology:
 - Incorporation of CO-RE (Compressed O-Ring Expansion) 96- and 384-Multi-Probe Heads is preferred.
 - These heads enable simultaneous pipetting of full 96- or 384-well plates or selected sections for high-throughput and flexible sample pooling.
 - Equipped with Liquid Level Detection (LLD) technology to ensure accurate and contamination-free liquid handling, particularly critical when working with varying sample volumes or viscosities.
- Decontamination Features: Integrated UV or chemical cleaning between runs
- Cross-contamination risk: $< 0.1\%$
- Barcode reader for individual donor tube traceability
- Alarm for pooling errors (e.g., mislabeling, volume errors)
- Daily throughput capacity: ≥ 1000 samples/day
- CE-IVD, FDA, or equivalent approval

Data Management

- Secure export of pool map (CSV/XML)
- Audit trail compliant with 21 CFR Part 11
- Retention of pooling records for ≥ 10 year

Maintenance

- Preventive maintenance as per manufacturer guidelines
- Local support availability < 8 h response time



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- Spare parts availability

II- Training:

- Vendor-led hands-on training for lab personnel
- Competency assessment prior to independent operation
- Annual refresher sessions

III- Documents to be delivered:

- Equipment User Manual
- Certificate of Conformity and Calibration
- Installation Qualification (IQ) report
- Operational Qualification (OQ) report
- Preventive Maintenance Log
- Pooling SOPs and workflows
- Warranty
- **Completed LRC BTS Supplier Qualification Form:** The official form must be fully completed, signed, and stamped.

IV- Accessories required:

Any required accessories to be suggested and provided by the company.

V – Transport, installation, and setup

To be assured by the company.