بسم الله الرحمن الرحيم

ADDU EQUATORIAL HOSPITAL
Addu Equatorial Hospital
Kanbihaa Magu | 19020 | Addu City | Maldives
info@aeh.gov.mv | +960 6885555

Tender Specifications – Transfusion Blood Bag Systems

1. General Requirements

1. All blood bag systems shall be sterile, pyrogen-free, non-toxic, and suitable for collection, processing, storage, and transfusion of human blood and components.
2. All bags and filters must comply with ISO 3826, WHO recommendations, and other relevant international and national regulatory requirements.
3. Each unit shall include tamper-proof closures, leak-proof seals, smooth tubing compatible with standard blood bank equipment, and labels that allow clear printing/barcoding and withstand refrigerated storage.
4. Shelf life at delivery must be not less than 24 months.
5. **Leukoreduction Standards:**
    - Inline leukoreduction filters (for WB or PRBC) must achieve a residual WBC count ≤ 1×10^6 per unit (≥ 3 $\log_{10}$ reduction).
    - Validation data must be provided by the supplier.
6. **Compatibility with Separation Methods:**
    - Preferred systems are those compatible with manual gravity separation using standard IV stands and clamps, without the need for automatic component extractors.
    - If a supplier's system mandates the use of a proprietary automatic component extractor (e.g., for proper functioning of leukoreduction filters), the supplier must provide such equipment on a free-of-charge loan/consignment basis for the duration of the contract. Please provide the rental payment plan with the proposal.
7. Systems must allow centrifugation and component separation on standard blood bank centrifuges.
8. All supplied blood bags must include necessary accessories such as break-off closures, sampling ports, and tubing compatible with heat sealing.
9. Supplier must provide certificates of sterility, biocompatibility, and (for leukoreduction systems) leukoreduction performance validation.

2. Capacity & Size Options

- Adult primary collection bag: 350 mL ±10% and/or 450 mL ±10%.
- Supplier shall quote all available size configurations (e.g., 350 mL with 4×30 mL, 450 mL with 4×50 mL, etc.).

3. Specification Schedule

Item No.	Blood Bag Type	Anticoagulant / Additive	Filter Type	Bag System	Intended Use	Clinical Use (Notes)
1	Single blood bag	CPDA-1	None	Single	Whole blood collection & transfusion	For emergency or massive transfusion when rapid volume replacement is required
2	Double blood bag	CPDA-1	None	Double	WB + PRBC preparation	Used for general transfusion needs where PRBC separation is required
3	Triple blood bag	CPDA-1	None	Triple	PRBC + Plasma + Platelets	Standard for component therapy (surgery, trauma, general medicine)
4	Quadruple blood bag	CPDA-1	None	Quad	PRBC + Plasma + Platelets + Cryo	For full component separation; supports multi-component therapy
5	Single blood bag with inline leukoreduction filter	CPDA-1	Inline filter (WB)	Single	Leukoreduced WB	For emergency use in situations where whole blood transfusion is required, but

						leukocyte reduction is also necessary. In chronic transfusion programs (thalassemia, oncology), leukoreduced PRBC in additive solution is preferred.
6	PRBC bag with additive solution + inline leukoreduction filter	SAGM	Inline filter (PRBC)	Double / Triple	Pre-storage leukoreduced PRBC	For thalassemia major, oncology, transplant, and chronically transfused patients
7	PRBC bag with additive solution (no filter)	SAGM	None	Double / Triple	PRBC with extended storage (42 days)	For general transfusion programs; standard use in routine patients
8	Bedside leukoreduction filter set	N/A	Bedside filter	External set	Post-storage leukoreduction	For use at bedside when pre-storage leukoreduction is not available or as contingency backup
9	Pediatric / small volume blood bag	CPDA-1	None	250–300 mL	Pediatric WB transfusion	For neonatal/pediatric emergencies requiring whole blood
10	Pediatric leukoreduction blood bag	SAGM	Inline filter	250–300 mL	Pediatric leukoreduced PRBC	For pediatric thalassemia, oncology, or critically ill neonates needing

						leukoreduced PRBC

4. Certificates & Documentation Requirements

1. **Mandatory certificates (must be provided for eligibility):**
    - ISO 3826 certification for the blood bag system.
    - Evidence of regulatory approval: **CE Mark (EU) or FDA .**
2. **Preferred (strongly encouraged, evaluated positively but not mandatory:**
    - ISO 13485 (Quality Management System for medical devices).
3. **Additional supporting documents (to be submitted if available, absence does not disqualify):**
    - GMP / manufacturing license.
    - Sterility validation (ISO 11137 / ISO 11135).
    - Biocompatibility testing (ISO 10993).
    - Leukoreduction validation data (for filter systems).
4. AEH reserves the right to request clarification, further documentation, or additional certifications prior to award to ensure product safety and compliance.

5. Disclaimer

This specification schedule is not brand-specific. Requirements are based on functional categories of blood bag systems necessary to meet patient care needs, including both thalassemia patients requiring leukodepleted transfusions and general transfusion patients. Evaluation will consider compliance with specifications, availability of quality certifications, and cost.