I. Item: BD Vacutainer® EST Tubes / Art. no.: 143438 / EAN: 30382903627258

II. Background/ Purpose

The BD Vacutainer® EST tubes without additives are perfectly suited as a secondary tube for anticoagulated blood samples, for example for collecting plasma samples from blood bags. If required, they can also be used as discard tubes, but are not used to obtain a high-quality serum sample.

III. Objective / Scope of Work

The objective of this TOR is to procure BD Vacutainer® EST tubes without additives for component quality control.

IV. Detailed Specifications / Requirements

- Blood tubes without additives
- As a secondary tube for anticoagulated blood samples

- Perfect for collecting plasma samples from blood bags
- Can also be used as a disposable tube
- Does not serve to collect serum samples
- Volume: 3 ml
- Size: 13 x 75 mm
- Material: PET
- Without paper label
- With Hemogard™ closure
- Cap colour: transparent

V. Delivery / Execution Timeline

May 2026

VI. Submission Requirements

Suppliers shall submit:

- Technical datasheet and/or sample
- Declaration of compliance with this TOR
- Delivery timeline
- Financial quotation (clearly itemized)
- **Completed LRC BTS Supplier Qualification Form:** The official form must be fully completed, signed, and stamped.

I.Item: Malaria Antibody Confirmatory ELISA Kit for Blood Donors with Exposure Risk

II.Background/ Purpose

BTS currently screens at-risk blood donors for malaria exposure using the EUROIMMUN ELISA kit. As per best practice and regulatory recommendations (e.g., EDQM Guide, WHO Guidelines), positive/reactive results must be repeated using a validated malaria antibody detection kit (IgG/IgM) that is compatible with BTS's existing laboratory infrastructure, for confirmation of reactive donor samples.

III.Objective / Scope of Work

The objective of this TOR is to procure a validated malaria antibody (IgG/IgM) ELISA confirmatory kit for reactive/positive donor samples identified during malaria exposure screening.

IV.Detailed Specifications / Requirements

1. Assay Principle & Target

- Enzyme-Linked Immunosorbent Assay (ELISA) for qualitative and/or semi-quantitative detection of anti-Plasmodium antibodies (IgG and/or IgM) in human serum/plasma.
- Must detect antibodies raised against all four clinically relevant human Plasmodium species: P. falciparum, P. vivax, P. ovale, and P. malariae, covering multiple stages and species-specific epitopes.
- Assay intended for use as a second-line confirmatory test to the EUROIMMUN screening ELISA already in use at BTS.

2. Performance Criteria

- Clinical sensitivity $\geq$ 95% and specificity $\geq$ 95%, substantiated by independent evaluation, peer-reviewed publication, or manufacturer's validation dossier (data to be submitted with the offer).
- Positive predictive value (PPV) and negative predictive value (NPV) data to be provided for a low-prevalence donor population, where available.
- Low cross-reactivity/interference with antibodies to other parasitic and infectious diseases (e.g., leishmaniasis, toxoplasmosis, schistosomiasis, rheumatoid factor, ANA).
- Demonstrated ability to detect low-titre antibodies in asymptomatic/chronic carriers, supported by seroconversion panel or sensitivity-panel data.
- Traceability of cut-off/calibration to an international or WHO reference reagent/standard, where available.
- Inter-assay and intra-assay reproducibility (CV%) data to be provided.

3. Regulatory Compliance

- CE-marked under EU IVDR (or valid CE-IVD certification) and/or FDA-cleared/approved for the intended use.
- WHO prequalification is desirable and should be indicated where applicable.
- Certificate of Analysis (CoA)/batch release certificate to be supplied with each delivered lot.

- Declaration of Conformity, product Instructions for Use (IFU), and Safety Data Sheet (SDS) to be provided in English.

4. Kit Configuration

- Shelf life ≥ 12 months from the date of delivery, with lot number and expiry date clearly printed on primary and secondary packaging.
- Kit size/format (number of tests per kit) to be specified by the bidder, with pricing per test.
- Clear, validated, step-by-step procedure for sample preparation, assay run, and result interpretation (qualitative index/cut-off calculation), provided in the IFU.
- Reagents ready-to-use or requiring minimal on-site preparation; storage conditions (e.g., 2–8°C) and post-opening/in-use stability to be specified.
- Total assay turnaround time (incubation steps, hands-on time) to be specified by the bidder.

5. Compatibility

- Fully compatible with BTS's existing open-system ELISA microplate reader(s) and washer(s).
- Compatible absorbance/wavelength requirements and standard 96-well microplate format matching existing equipment.
- If an incubator/shaker is required, this must be stated explicitly, including whether it is included in the kit or must be sourced separately.

6. Controls & Calibrators

- Positive and negative controls included in every kit, ready-to-use or requiring minimal dilution.
- Calibrator(s)/cut-off control(s) provided where applicable, sufficient for at least one full run of the supplied kit.
- Control/calibrator values and acceptable ranges clearly stated in the IFU or CoA to allow run validation.

7. Sample Requirements

- Compatible sample types specified (serum and/or plasma; anticoagulants accepted, e.g., EDTA, heparin).
- Minimum sample volume required per test to be specified.
- Stated sample stability/storage conditions (short-term at 2–8°C, long-term frozen) and freeze-thaw tolerance.

8. Training & Technical Support

- Supplier to provide on-site or remote training for laboratory staff on kit use, quality control, and troubleshooting prior to/at implementation.
- Availability of local or regional technical/after-sales support with a defined response time for technical queries or non-conformance investigations.
- Supplier to notify BTS promptly of any change in kit formulation, lot-to-lot variation, or field safety corrective actions.

9. Packaging, Labeling & Logistics

- Labeling in compliance with applicable regulations (lot number, expiry date, storage conditions, UDI where applicable).

- Cold-chain packaging and validated transport conditions to preserve reagent integrity from dispatch to receipt.
- Delivery lead time from order confirmation to be specified by the bidder.

V.Delivery / Execution Timeline

Maximum 1 week

VI.Submission Requirements

Suppliers shall submit:

- Technical datasheet, product insert (IFU), and/or sample
- Declaration of compliance with this TOR
- Copies of CE-IVD/FDA certification and, where applicable, WHO prequalification
- Supporting performance data (sensitivity/specificity, cross-reactivity, validation studies)
- Delivery timeline
- Financial quotation (clearly itemized)
- **Completed LRC BTS Supplier Qualification Form:** The official form must be fully completed, signed, and stamped.

VII. Evaluation Criteria & Scoring

Any vendor failing to comply with any technical, functional, or regulatory requirement specified in this Terms of Reference shall be directly excluded from the evaluation process, and its offer shall not proceed to financial evaluation.

I. Item: Surface & Equipment Disinfectant (Improved/Accelerated Hydrogen Peroxide)

II. Background / Purpose

The product shall be a ready-to-use hospital-grade surface disinfectant based on Improved (Accelerated) Hydrogen Peroxide (IHP/AHP) technology, intended for routine cleaning and disinfection of environmental surfaces and medical equipment in Blood Transfusion Services.

III. Objective / Scope of Work

The objective of this procurement is to acquire a hospital-grade surface disinfectant that is safe, effective, and compatible with laboratory and blood bank equipment for daily use within Blood Transfusion Services facilities.

IV. Detailed Specifications / Requirements

1. Active Ingredient

- Improved (Accelerated) Hydrogen Peroxide technology
- Hydrogen peroxide concentration approximately 0.5–1.5%
- Free from aldehydes (glutaraldehyde/formaldehyde)
- Free from phenolic compounds
- Chlorine free
- Low VOC formulation

2. Antimicrobial Efficacy

The disinfectant shall demonstrate efficacy against:

- Bacteria
- Mycobacteria
- Viruses

4. Material Compatibility

The disinfectant shall be compatible with:

- Stainless steel
- Polycarbonate
- Acrylic
- ABS plastic
- PVC
- Glass
- Aluminum
- Painted laboratory surfaces
- Blood bank analyzers
- Refrigerators
- Freezers

- Centrifuges
- Blood mixers
- Platelet agitators
- Computers and touch screens (when approved by equipment manufacturers)

The supplier shall provide a material compatibility statement. Accelerated hydrogen peroxide formulations have demonstrated compatibility with most common healthcare plastics and several metals.

5. Safety

The product shall:

- Be non-corrosive
- Leave no sticky residue
- Require no rinsing on non-food-contact surfaces
- Have low odor
- Be biodegradable
- Be suitable for daily use in healthcare facilities
- Be supplied with a Safety Data Sheet (SDS)

6. Packaging

Acceptable packaging:

- Ready-to-use spray bottles (500–1000 mL)

Each container shall clearly indicate:

- Batch number
- Manufacturing date
- Expiry date
- Storage conditions

7. Shelf Life

- Minimum shelf life upon delivery: 24 months

V. Deliverables

The supplier shall provide:

- Product Technical Data Sheet
- Safety Data Sheet (SDS)
- Instructions for Use (IFU)
- Evidence of hospital-grade registration (EPA, CE, or equivalent)

VI. Delivery / Execution Timeline

Depends on the availability in the local Lebanese market

VII. Submission Requirements

Suppliers shall submit:

- Technical datasheet and brochure
- Declaration of compliance with this TOR
- Warranty and after-sales service details
- Delivery timeline
- Financial quotation (clearly itemized)
- References from similar installations (if available)
- Completed LRC BTS Supplier Qualification Form: The official form must be fully completed, signed, and stamped.

VIII. Evaluation Criteria

Any vendor failing to comply with any technical, functional, or regulatory requirement specified in this Terms of Reference shall be directly excluded from the evaluation process, and its offer shall not proceed to financial evaluation.

I.Procurement Title:

Blood Component Irradiation Indicator Tags — Self-Adhesive, Writeable

II.Background / Purpose

The Lebanese Red Cross Blood Transfusion Services (LRC-BTS) irradiates cellular blood components using an X-ray blood irradiator.
Each blood component requires an irradiation indicator tag applied before irradiation.
The tag provides irreversible visual confirmation that the blood component has been exposed to the validated irradiation process and forms part of the product traceability documentation.

III.Objective / Scope of Work

Supply of blood component irradiation indicator tags meeting the specifications below.

IV.Detailed Specifications / Requirements

Parameter	Requirement
Product	Blood Component Irradiation Indicator Tag (Rad-Sure® or equivalent)
Intended Use	Visual process indicator confirming that a blood component has been exposed to irradiation using an X-ray blood irradiator.
Radiation Compatibility	Compatible and validated for use with X-ray blood irradiators.
Dose Performance	Indicator shall demonstrate an irreversible and permanent color change following exposure within the validated irradiation dose range of **25–50 Gy**.
Writable Area	Mandatory dedicated writable surface to write Operator Initials and Irradiation Date (DD/MM/YYYY).
Format	Single-piece self-adhesive label requiring no assembly.
Adhesive	Pressure-sensitive adhesive compatible with blood bag PVC. Shall remain securely attached during irradiation, transport and storage without peeling, lifting or leaving residue.
Label Compatibility	Shall not cover or interfere with ISBT-128 labels, product identification or barcodes.
Material	Polyester or equivalent durable synthetic substrate incorporating radiochromic technology. Latex-free.
Shelf Life	Minimum 24 months from date of manufacture and at least 18 months remaining upon delivery.
Storage Conditions	Store at 15–25°C,
Traceability	Lot number and expiry date shall appear on each package or dispenser.
Regulatory Compliance	CE marked (or equivalent acceptable regulatory approval) and manufactured under an ISO 13485 certified Quality Management System.
Quality Documentation	Certificate of Analysis shall accompany each supplied lot.

V.Deliverables

- Tags delivered in original manufacturer packaging; ≥18 months remaining shelf life.
- Certificate of Analysis per lot.

Delivery within 4 weeks of purchase order. Supplier to notify immediately if lead time cannot be met.

VI.Submission Requirements

Suppliers shall submit:

- Technical datasheet and/or sample
- Declaration of compliance with this TOR
- Delivery timeline
- Financial quotation (clearly itemized)
- **Completed LRC BTS Supplier Qualification Form:** The official form must be fully completed, signed, and stamped.

VII.Evaluation Criteria

Any vendor failing to comply with any technical, functional, or regulatory requirement specified in this Terms of Reference shall be directly excluded from the evaluation process, and its offer shall not proceed to financial evaluation.

I.Procurement Title:

BD Vacutainer® Blood Collection Tubes — Serum Separator (SST™ II Advance) and K_2EDTA (Lavender)

II.Background / Purpose

The Lebanese Red Cross Blood Transfusion Service (LRC-BTS) requires a reliable, validated and standardized supply of pre-analytical blood collection tubes for routine donor screening and laboratory testing. The two tube types specified in this document are foundational consumables used across serology, haematology, blood grouping, and molecular (NAT) workflows.

III.Objective / Scope of Work

Supply of the following CE-IVD marked BD Vacutainer® blood collection tubes to the LRC-BTS, in the quantities and to the specifications detailed below:

- BD Vacutainer® SST™ II Advance — 5 mL Serum Separator Tube (Catalog No. BD 367955)
- BD Vacutainer® K_2EDTA — 4 mL Lavender Tube (Catalog No. BD 367861)

IV.Detailed Specifications / Requirements

A- Goods (Medical Consumables)

All tubes shall conform to the technical specifications below. Substitution of equivalent products requires prior written approval from the LRC-BTS QA team and re-validation of pre-analytical parameters.

1. BD Vacutainer® SST™ II Advance — 5 mL Serum Separator Tube

BD 367955 — 5 mL SST™ II Advance (Serum Separator Tube)	
Parameter	Specification
Catalog Number	BD 367955
Full Product Name	BD Vacutainer® SST™ II Advance Tube
Intended Use	Serum collection for chemistry, immunology, and serology testing
Draw Volume	5.0 mL (nominal)
Tube Material	Polyethylene terephthalate (PET) plastic
Tube Dimensions	13 × 100 mm
Closure / Stopper Color	Gold / Yellow
Additive	Clot activator (silica particles) + polymer gel separator
Gel Separator	Thixotropic polymer gel — forms a stable barrier between serum and clot after centrifugation
Anticoagulant	None (serum tube)

Clot Formation Time	Minimum 30 minutes at room temperature before centrifugation
Label / Color Coding	Gold label with yellow ring — internationally recognized serum separator color
Sterility	Sterile; single use only
Shelf Life	12 months from manufacture date (per labeling)
Regulatory Status	CE-IVD marked; FDA 510(k) cleared for in vitro diagnostic use
Latex Content	Latex-free
Safety Features	BD Hemogard™ closure (needle-shield); reduces splash risk on opening
Compatible Analyzers	Universal compatibility with major clinical chemistry and immunoassay platforms (Alinity)

2. BD Vacutainer® K_2EDTA — 4 mL Lavender Tube

BD 367861 — 4 mL K_2EDTA Lavender Tube	
Parameter	Specification
Catalog Number	BD 367861 (4 mL K_2EDTA, lavender)
Full Product Name	BD Vacutainer® K_2EDTA Tube — Lavender
Intended Use	Whole blood collection for haematology (CBC/diff), blood grouping, crossmatch, and molecular / NAT testing
Draw Volume	4.0 mL (nominal)
Tube Material	Polyethylene terephthalate (PET) plastic
Tube Dimensions	13 × 75 mm
Closure / Stopper Color	Lavender (purple)
Additive	K_2EDTA (dipotassium ethylenediaminetetraacetic acid) — spray-dried onto tube wall
Anticoagulant Mechanism	Chelates calcium ions — prevents coagulation cascade activation and preserves cell morphology
Gel Separator	None
Specimen Type Produced	Whole blood (primary); EDTA plasma (post-centrifugation)

Stability — Haematology	CBC: stable up to 24 hours at room temperature (18–25°C) or up to 48 hours at 2–8°C
Label / Color Coding	Lavender label — internationally recognized anticoagulated haematology/molecular tube color
Sterility	Sterile; single use only
Shelf Life	12 months from manufacture date (per labeling)
Regulatory Status	CE-IVD marked; FDA 510(k) cleared for in vitro diagnostic use
Latex Content	Latex-free
Safety Features	BD Hemogard™ closure; reduces aerosol and splash risk on opening
Storage Conditions	4–25°C; away from direct sunlight; do not freeze
Compatible Analyzers	Universal compatibility with haematology analyzers (Sysmex) and immunohematology (IH-500)

B- Services

Not applicable for this consumable supply procurement.

V.Deliverables

The following must be delivered with each order:

- Tubes delivered to LRC-BTS warehouse in original, undamaged manufacturer packaging.
- Remaining shelf life at time of delivery: minimum 9 months.
- Certificate of Analysis (CoA) per lot, including draw volume verification, sterility, and shelf-life data.
- Notification of any change in formulation, materials, or regulatory status ≥ 30 days in advance.

Delivery / Execution Timeline

Delivery within 4 weeks of purchase order confirmation. Partial deliveries accepted provided the BTS is notified in advance.

VI.Submission Requirements

Suppliers shall submit:

- Technical datasheet and/or sample
- Declaration of compliance with this TOR
- Delivery timeline
- Financial quotation (clearly itemized)
- **Completed LRC BTS Supplier Qualification Form:** The official form must be fully completed, signed, and stamped.

VII.Evaluation Criteria & Scoring

Any vendor failing to comply with any technical, functional, or regulatory requirement specified in this Terms of Reference shall be **directly excluded from the evaluation process**, and its offer shall not proceed to financial evaluation.