Republic of the Philippines
DEPARTMENT OF HEALTH
Metro Manila Center for Health Development

BAGONG PILIPINAS

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB#2024-125
PROCUREMENT OF 24,545 PCS BLOOD BAG QUADRUPLE TOP AND BOTTOM

This Supplemental/Bid Bulletin No. 1 is being issued to revise provisions/specifications in the Bidding Documents for a forecited project:

1. Query during Pre-bidding Conference:

Technical Specifications	Query	Response of the End User Unit
6. Sample site computer design	6. Sample site coupler design	6. Sample site coupler design- GRANTED
b. Barrel of the ample site coupler must extend at least 20mm beyond the tip of the needle.	b. Barrel of the sample site coupler must extend at least 15mm to 20mm beyond the tip of the needle.	b. Barrel of the sample site coupler must extend at least 15mm to 20mm beyond the tip of the needle. - GRANTED
c. Provision of semi-annual preventive maintenance of six (6) units of semi-automatic leukoreduction machines until consumption of all blood bag with certificate and preventive maintenance sticker attached to each machine.	c. Provision of semi-annual preventive maintenance of six (6) units of semi-automatic leukoreduction machines until consumption of all blood bag with certificate and preventive maintenance sticker attached to each machine with provided 6 units machines	c. Provision of semi-annual preventive maintenance of six (6) units of semi-automatic leukoreduction machines until consumption of all blood bag with certificate and preventive maintenance sticker attached to each machine with provided 6 units machines- GRANTED
Shelf Life: Must be fresh commercial stocks with a shelf life of not less than twenty-four (24) months from the date of receipt by the end-user	Must be fresh commercial stocks with a shelf life of not less than eighteen (18) months from the date of receipt by the end-user	Must be fresh commercial stocks with a shelf life of not less than eighteen (18) months from the date of receipt by the end-user- GRANTED
Delivery Schedule 1st tranche: 15,000 pieces - Thirty (30) calendar days upon receipt of approved Notice to Proceed (NTP) 2nd tranche: 9,545 pieces – Sixty (60) calendar days after the first delivery	**Delivery Schedule** 1st tranche: 15,000 pieces - Sixty (60) calendar days upon receipt of approved Notice to Proceed (NTP) 2nd tranche: 9,545 pieces – Sixty (60) calendar days after the first deliver	**Delivery Schedule** 1st tranche: 15,000 pieces - Sixty (60) calendar days upon receipt of approved Notice to Proceed (NTP) GRANTED 2nd tranche: 9,545 pieces – Sixty (60) calendar days after the first delivery

Bidders are advised to use the **following attached forms and submit them together with all required documents for the submission of bids on the 7th day of August 2024, 9:00 AM:**

This Supplemental/Bid Bulletin No. 1 shall be integral to the Bidding Documents. All other provisions indicated in the bidding documents not affected by this Supplemental/Bid Bulletin No. 1 shall remain in effect.

For guidance and information of all concerned.

Issued this 31st day of July 2024 in MMCHD

Approved by:

JEREMIAS FRANCIS Y. CHAN, MD
Licensing Officer V / BAC Chairperson

TECHNICAL SPECIFICATIONS			
Item No. 1	**BLOOD BAG QUARUPLE TOP AND BOTTOM**	Qty./Unit	**24,545 Pieces**
Name of Manufacturer:			Country of Origin (if applicable)
Brand:			Model: (if applicable)
ABC: **26,999,500.00**			
PURCHASER'S SPECIFICATION			STATEMENT OF COMPLIANCE

Detailed Technical Specification

1. Quadruple Top Bottom Blood Bag with Tie-up Machine.

2. Volume: For the collection of 450ml of Whole Blood for Leukoreduction

3. Anticoagulant: CPD for primary bag and SAGM or its equivalent as the additive solution in the red cell transfer bag.

4. Blood Bag Orientation:

   a. Made up of PVC (Polyvinyl Chloride)

   b. Sterile and pyrogen-free

   c. With slits on both sides of the satellite bags

   d. With rounded corners to facilitate adequate mixing of blood and anticoagulant.

   a. With connector tube to allow smooth transfer of blood
   b. With non-erasable donor segment number markings at regular intervals.
   c. Base label must be tamper-evident.

5. Needle Assembly

   a. 16-gauge ultra-thin wall siliconized needle,

   b. Must be sharp for smooth insertion.

   c. With a built-in needle safety guard with an irreversible locking mechanism.

6. Sample site coupler design

   a. Sample site coupler must be fitted with a safety cap in situ.

   b. *Barrel of the sample site coupler must extend at least 15mm to 20mm beyond the tip of the needle.*

   c. Compatible with 10 ml red top evacuated tubes that perfectly fits into

the tube holder. 7. Terms and Condition for the Machine tie-up: a. Provision of at least two (2) leukoreduction machines to be returned after total consumption of the blood bags. b. Provision of two (2) units of blood collection monitors to provide smooth and gentle rocking movement to facilitate homogeneous missing of blood with anticoagulant to be returned after total consumption of all blood bags. c. *Provision of semi-annual preventive maintenance of six (6) units of semi-automatic leukoreduction machines until consumption of all blood bag with certificate and preventive maintenance sticker attached to each machine with provided 6 units machines-* . d. Provision of technical support on 24/7 assistance engineers and/or product specialists. 8. Certification that the bidder will provide the following: a. Actual demonstration and adequate training such as use of leukoreduction machine and phlebotomy training for all technical staff with Certificate to be issued upon completion of training. b. Two (2) hard copies and a soft copy of the operation and service manual in English. Machine with technical assistance from the winning bidder preferably a Product Specialist. 9. Technical Specification for Machine Tie-up: a. With three (3) integrated scale. b. Color graphical screen, effective and step by step guide. c. At least five (5) clamps with sealing head o easy blood tag loading. d. At least eight (8) optical detectors/sensors for accurate component separation. e. With quiet/silent stepper motor. f. With automatic air removal and weighing of the plasma bag. g. With automatic breaking of cannulas, h. Adjustable for a variety of blood bags ang flexible for all	

component preparation methods

i. With self-check/test routine at start-up for ful device diagnostics and functionality checks.

Type of Contract

1, Supply of items

2. Machine tie-up with lease of equipment supplied for use until

consumable are all utilized.

Shelf Life

Must be fresh commercial stocks with a shelf life of not less than eighteen (18) months from date of receipt by the end-ser

Package Instructions:

Standard packaging of the Manufacturer as approved by PFDA.

Labeling instructions

a. Each primary packaging, the following shall be imprinted or stickered with non- removable or permanent sticker or label that is binding, and with residue and tearing. If removed;

"Philippine Government Property Department of Health NOT FOR SALES"

b. On each small/bigger box/corrugated carton, the following should be imprinted or stickered with non-removable or permanent sticker or label that is binding, and with residue and tearing, if removed;

"Philippine Government Property Department of Health NOT FOR SALES"

Date of Manufacture: _____

Date of Expiry; _____

Batch/Lot no. _____

Recall and Replacement

1. The Supplier must ensure the quality of products and if there will be problems in the quality, the Supplier will recall and replace the products

distributed in the regions, hospital/treatment/ hubs/RHU/HC/BHSs, FDA Circular No. 2016-012 2. In instance of he product recalls due to failures of suppliers and manufacturers to comply with standard of safety and quality the cost of associated with proper disposal/destruction, handling or pull out from health facilities where these products have already been distributed shall be borne by the supplier (subject to the latest policy for disposal) DOH Administrative Order (AO) No. 2019-0041). 3. Replacement of stocks with approved shorter shelf life. 4. If the item approved is with shorter shelf life, replacement for fresh stocks shall be issued when returned three (3) months before expiry date. **Replacement Instructions** Replacement for fresh stocks shall be issued when returned three (3) months before expiry date **Additional Technical Documents** A. With valid and current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration issued by the Philippine Food and Drug Administration (PFDA) B. Valid and current License to operate (LTO) as Medical Device Importer/Wholesaler issued by the Philippine Food and Drug Administration (PFDA) C. The bidder shall submit any of the following whichever is applicable; a) If the bidder is the manufacturer, certify that the bidder manufactures the bidder manufactures the products/items or b) If the bidder is an exclusive/Authorized Distributor or Dealer of the products/items, Certificate or Contract from the manufacturer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items; or c) If the bidder is an agent of the exclusive distributor or dealer the following must be provided: i. Certificate or Distributorship/Dealership Agreement by the Manufacturer with the distributor or dealer; and ii. Certificate or Contract between the distributor/dealer and the bidder. D. Valid and current Certificate of Compliance of the Manufacturer with ISO standards or its equivalent for quality of medical device, personnel, and services. E. Valid and current CE Certificate of blood bag. F. Product insert/ Product Information and download from the internet with specific URL indicated and other manufacturer's unamended sales literature, unconditional statements of specification and compliance issued by the manufacturer. Samples, independent test data et., as appropriate for cross-referencing statement of compliance to the technical specification in accordance to what is indicated in 2nd page of Section VII. Technical Specifications of the Bidding Documents.	

distributed in the regions, hospital/treatment/ hubs/RHU/HC/BHSs, FDA Circular No. 2016-012

2. In instance of he product recalls due to failures of suppliers and manufacturers to comply with standard of safety and quality the cost of associated with proper disposal/destruction, handling or pull out from health facilities where these products have already been distributed shall be borne by the supplier (subject to the latest policy for disposal) DOH Administrative Order (AO) No. 2019-0041).

3. Replacement of stocks with approved shorter shelf life.

4. If the item approved is with shorter shelf life, replacement for fresh stocks shall be issued when returned three (3) months before expiry date.

Replacement Instructions

Replacement for fresh stocks shall be issued when returned three (3) months before expiry date

Additional Technical Documents

A. With valid and current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration issued by the Philippine Food and Drug Administration (PFDA)
B. Valid and current License to operate (LTO) as Medical Device Importer/Wholesaler issued by the Philippine Food and Drug Administration (PFDA)
C. The bidder shall submit any of the following whichever is applicable;
   a) If the bidder is the manufacturer, certify that the bidder manufactures the bidder manufactures the products/items or
   b) If the bidder is an exclusive/Authorized Distributor or Dealer of the products/items, Certificate or Contract from the manufacturer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items; or
   c) If the bidder is an agent of the exclusive distributor or dealer the following must be provided:
      i. Certificate or Distributorship/Dealership Agreement by the Manufacturer with the distributor or dealer; and

      ii. Certificate or Contract between the distributor/dealer and the bidder.

D. Valid and current Certificate of Compliance of the Manufacturer with ISO standards or its equivalent for quality of medical device, personnel, and services.
E. Valid and current CE Certificate of blood bag.
F. Product insert/ Product Information and download from the internet with specific URL indicated and other manufacturer's unamended sales literature, unconditional statements of specification and compliance issued by the manufacturer. Samples, independent test data et., as appropriate for cross-referencing statement of compliance to the technical specification in accordance to what is indicated in 2nd page of Section VII. Technical Specifications of the Bidding Documents.

If specification /feature cannot be support by product brochure /product information the following must be submitted.

i. Product drawing or photo showing actual dimension.

G. Guarantee Letter from the winning bidder to replace the item with an approved shorter shelf life when returned three (3) months before the expiry date.
H. Sworn Statement using the prescribed form

Additional Requirement to be submitted by the Lowest Calculated Bidder

1. Provision of one (1) unopened pouch of sample blood bags to verify the technical specifications.

Delivery Schedule

1st tranche: 15,000 pieces - Sixty (60) calendar days upon receipt of approved Notice to Proceed (NTP)

2nd tranche: 9,545 pieces – Sixty (60) calendar days after the first delivery

Delivery Site

Philippine Blood Center,

Quezon Avenue, Diliman, Quezon City

Allocation List

For PBC use

NOTHING FOLLOWS