



Republic of the Philippines  
Department of Health  
**METRO MANILA CENTER FOR HEALTH DEVELOPMENT**

**SUPPLEMENTAL/ BID BULLETIN NO. 1**

**IB#2024-067 PBC**

**PROCUREMENT OF 300 KIT PATHOGEN REDUCTION KIT (PLATELET)**

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

Revision and clarification to provisions/specifications in the Bidding Documents:	
<b>ORIGINAL TECHNICAL SPECIFICATIONS</b>	<b>AMENDED</b>
Shelf Life  Must be fresh commercial stock with a total shelf life of at least six (6) months from the date of receipt by the end-user.	Shelf Life  Must be fresh commercial stock with a total shelf life of <i>would be four (4) to six (6) months</i> from the date of receipt by the end-user.

Bidders are advised to use the following attached forms and submit them together with all required documents for the submission of bids on the 25<sup>th</sup> day of March 2024, 9:00 AM:

This Supplemental/Bid Bulletin No. 1 shall form an integral part of the Bidding Documents. All other provisions indicated in the bidding documents that are not affected by this Supplemental/Bid Bulletin No. 1 shall remain in effect.

For guidance and information of all concerned.

Issued this 15<sup>th</sup> day of March 2024 in MMCHD

Approved by:

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

**Section VII. Technical Specifications**

Republic of the Philippines  
Department of Health  
Metro Manila Center for Health Development

**TECHNICAL SPECIFICATIONS**

Item No. <b>1</b>	<b>PATHOGEN REDUCTION KIT (PLATELET)</b>	Qty./Unit	<b>300 Kit</b>
Name of Manufacturer:		Country of Origin	
Brand:		Model: (if applicable)	
ABC: <b>2,025,000.00</b>			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	
<p>Detailed Technical Specification</p> <ol style="list-style-type: none"> <li>1. Platelet Disposable Kit for Treatment in Plasma             <ol style="list-style-type: none"> <li>1.1 Sterile and non-pyrogenic</li> <li>1.2 Illumination/Storage Set                 <ol style="list-style-type: none"> <li>1.2.1 One Illumination/Storage bag for Platelets with attached tubing, frangible connectors, spike port, and sample bulb</li> <li>1.2.2 Made of Citrate Vinyl Bag</li> </ol> </li> <li>1.3. One opaque foil pouch with one bag of 35ml ± 5ml Riboflavin solution</li> </ol> </li> <li>2. Anticoagulant: ACDA for Apheresis. CPD and CPDA1 for Whole blood-derived Platelets</li> <li>3. Other requirements:             <ol style="list-style-type: none"> <li>3.1. Provision of Semi- annual Preventive Maintenance service of the equipment until total consumption of all kits</li> <li>3.2. Provision of back-up/service unit equivalent to the make and model of the equipment in the event of machine malfunction.</li> <li>3.3. Provision of one (1) unit colored continuous ink printer compatible with the existing machine for printing of Mirasol Manager report.</li> </ol> </li> </ol>			

3.4. Provision of actual demonstration and adequate

training of all technical staff with Certificate to be issued upon completion of training.

3.5 Provision of technical support on 24/7 assistance

from engineers and/or product specialist especially in cases of machine malfunction and/or breakdown until total consumption of all the kits.

Type of Contract

Supply of Items compatible with Existing Machine (MIRASOL)

Shelf Life

Must be fresh commercial stock with a total shelf life of *would be four (4) to six (6) months* from the date of receipt by the end-user

Packaging Instructions

Standard Packaging of the Manufacturer as approved by PFDA

Labelling Instructions

On each box, 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 SALE"

Date of Manufacture: \_\_\_\_\_

Date of Expiry: \_\_\_\_\_

Batch/Lot No.: \_\_\_\_\_, if applicable

Each small and bigger box/carton 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 SALE

Date of Manufacture: \_\_\_\_\_

Date of Expiry: \_\_\_\_\_ "

## Recall & Replacement

1. The Supplier must ensure the quality of products if there will be problems in the quality, the Supplier will recall and replace the products distributed in the regions/hospitals/treatment hubs/RHU/HC/HBSS based on the Guidelines on Product Recall, FDA Circular No. 2016-012
2. In instances of product recalls due to failures of suppliers and manufacturers to comply with standards of safety and quality, the cost 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 for fresh stocks of items with approved shorter shelf life and wastages arising from machine malfunction
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 and the supplier will replace it with not less than twelve (12) months shelf-life and deliver the stocks within two (2) weeks

## Additional Technical Documents

- A. Valid and Current Certificate of Medical Device Registration (CMDR) issued by Philippine Food and Drug Administration (PFDA).
- B. Valid and Current License To Operate (LTO) as Medical Device Importer/Wholesaler issued by Philippine Food and Drugs Administration (PFDA).
- C. Product Insert/ Product Information and downloaded 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 etc., 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.
- D. The Bidder shall submit any of the following whichever is applicable:
  - a. If the bidder is the manufacturer, certify that the bidder manufactures the products/items; or
  - b. If the bidder is an Exclusive/ Authorized Distributor or Dealer of the products/items, Certificate of Contract from the manufacturer must be provided as proof that the Bidder is an Exclusive/Authorized Distributor or Dealer of the products/items;
  - c. If the bidder is an agent of the exclusive distributor or dealer, the following must be provided:

<p>i. Certificate of Distributorship/Dealership Agreement by the Manufacturer with distributor/dealer; and</p> <p>ii. Contract between the distributor/dealer and the bidder.</p> <p>E. Guarantee letter from supplier for item replacement as to shelf life, machine malfunction and product quality</p> <p>F. Certificate indicating the Semi- Annual Preventive Maintenance service of the equipment until total consumption of all kits</p> <p>G. Sworn Statement using prescribed Form</p> <p>Delivery Schedule</p> <p>1st tranche: 150 pcs - Thirty (30) calendar days (CD) upon receipt of NTP</p> <p>2nd tranche: 150 pcs – Forty-Five (45) calendar days (CD) after the first delivery</p> <p>Delivery Site</p> <p>DOH-Philippine Blood Center, 6512 Quezon Ave. Diliman, Quezon City</p> <p>Allocation List</p> <p>For PBC use</p>	
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\_\_\_\_\_  
Signature over Printed Name

[date of signing]

In the capacity of:

[title or other appropriate designation]

Duly authorized to sign bid for and on behalf of:

(Name of Company)  
[Complete office address]  
[Contact No.]  
[Fax No.]  
[Email Address]

