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

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB2024 – 061-PBC

PROCUREMENT OF 59,344 TEST MALARIA TEST KITS (ANTIGEN ASSAY) WITH MACHINE TIE-UP

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:	
ORIGINAL TECHNICAL SPECIFICATIONS	**AMENDED**
Delivery Schedule First Tranche: 30,000 tests – within thirty (30) calendar days upon receipt of approved Notice to Proceed. Second Tranche: 28,080 tests - Sixty (60) calendar days after the first delivery.	*Second Tranche: 29,344 tests - 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 25th 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 15th day of March 2024 in MMCHD

Approved by:

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

Section VII. Technical Specifications

<table>
<tr><td colspan="4">Republic of the Philippines
Department of Health
Metro Manila Center for Health Development

TECHNICAL SPECIFICATIONS</td></tr>
<tr><td>Item No. 1</td><td>MALARIA TEST KIT (ANTIGEN ASSAY) WITH MACHINE TIE-UP</td><td>Qty./Unit</td><td>59,344 Test</td></tr>
<tr><td colspan="3">Name of Manufacturer:</td><td>Country of Origin</td></tr>
<tr><td colspan="3">Brand:</td><td>Model: (if applicable)</td></tr>
<tr><td colspan="3">ABC: 5,637,680.00</td><td></td></tr>
<tr><td colspan="3">PURCHASER’S SPECIFICATION</td><td>STATEMENT OF COMPLIANCE</td></tr>
<tr><td colspan="3">Detailed Technical Specification

1. Principle:

Employs Enzyme-Linked Immunosorbent Assay (ELISA) or Enzyme Immunoassay

(EIA) for the detection of Plasmodium falciparum, P. vivax, P. malariae, and P. ovale antigen.

2. Specimen Requirements: Whole blood collected in EDTA tubes.

3. With reagent-specific positive and negative controls in the manufacturer’s kit.

4. Terms and Condition for Reagent with machine tie- up:

a. A fully automated analyzer

b. Can be plugged into a power supply of 220-240 VAC, 60 Hz with provision of an Uninterrupted Power Supply (UPS) unit and AVR.

c. One (1) machine and back-up unit with the same specifications to be returned upon total consumption of reagents.

d. Provision of external printer with continuous ink supply system (black and colored) to be returned until total consumption of reagents.

e. Provision of at least three (3) pipettors with pipette rack; one (10</td><td></td></tr>
</table>

to 100uL), one (100 to 1000uL) and one multi dispense 8-channels pipettor (10 to 100uL). f. Provision of pipette tips compatible with the pipettor as needed. Type of Contract 1. Supply of items 2. Machine tie-up with lease of equipment/supplied for use until consumables are all utilized Shelf Life Must be fresh commercial stock with a shelf life of not less than one (1) year from the date of receipt by the end-user. Packaging Instructions Standard Packaging of the manufacturer as approved by PFDA Labelling Instructions Each primary packaging should be imprinted or sticker ed with non-removable or permanent sticker or label th at 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.: _____ 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/BHSs based on 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 of reagent and consumable wastages arising from machine malfunction. 4. Stocks with less than two (2) months remaining shelf life, the winning bidder will replace it with at least six (6) months shelf life and deliver such within two (2) weeks. The replacement of reagents is continuous until total consumption. Additional Requirements A. Valid and Current License To Operate (LTO) as Medical Device Importer/Wholesaler issued by Philippine Food and Drugs Administration (PFDA). B. Hard copy of Product Insert/ Product Information of reagent and machine that can be 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. C. The Bidder shall submit any of the following whichever is applicable: a. If the bidder is the manufacturer, certificate that the bidder manufacturers the products/items; or b. If the bidder is an Exclusive/ Authorized Distributor or Dealer of the products/items, a 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 distributor or dealer; and ii. Certificate or Contract/ Dealership Agreement between the distributor/dealer and the bidder. D. Valid and current Certificate of Compliance with ISO/IEC/PNS standards for quality of reagents, personnel and services.	

E. Guarantee letter from the Supplier for item replacement as to shelf life, reagents wastages arising from machine malfunction, and product quality. F. Certificate that the bidder will provide the following requirements: 1. Provision of Technical support for 24 hours /7 days from Engineer and/ or Product Specialist. Immediate (within 8 hours upon notification) on-site repair of the equipment if resolution is not possible by remote troubleshooting. 2. Quarterly preventive maintenance and calibration or as need arises for the machine and all the included equipment from the supplier with certificate and calibration sticker. 3. Actual demonstration and adequate training for all technical staff. 4. Reagent Refrigerator with UPS and AVR to be returned upon total consumption of reagents. 5. One (1) hard copy and a soft copy of updated operation and service manuals in English. 6. Independent temperature monitoring device including batteries for the Reagent Refrigerator. 7. Uninterrupted Power Supply (UPS) unit and AVR for the tie-up machine. 8. One (1) machine and back-up unit with the same specifications to be returned upon total consumption of reagents 9. Provision of external printer with continuous ink supply system (black and colored) to be returned until total consumption of reagents. 10. Provision of at least three (3) pipettors with pipette rack; one (10 to 100uL), one (100 to 1000uL), and one multi dispense 8-channels pipettor (10 to 100uL).	

11. Provision of pipette tips compatible with the pipettor as needed. 12. Provision of consumables and water requirement until total consumption of all the reagents. 13. Certification from the bidder that machine will be interfaced with Blood Bank Information System (BBIS) and NBBNets and shall be provided with middleware upon commissioning. G. Sworn Statement using the prescribed form Delivery Schedule First Tranche: 30,000 tests – within thirty (30) calendar days upon receipt of approved Notice to Proceed. *Second Tranche: 29,344 tests - Sixty (60) calendar days after the first delivery.* Delivery Site DOH-Philippine Blood Center, 6512 Quezon Ave. Diliman, Quezon City Allocation List For PBC use	

_____

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]