Republic of the Philippines
Department of Health
CENTRAL OFFICE BIDS AND AWARDS COMMITTEE

BID BULLETIN NO. 2
24 November 2023

PROCUREMENT OF SYPHILIS RAPID TEST KIT
IB NO. 2024-059

This Bid Bulletin is being issued to announce the new schedule of the Submission and Opening of Bids previously set on 06 November 2023, to respond to the queries during the Pre-Bidding Conference, to respond to the letter of the Prospective Bidder, and to amend or modify the bidding documents posted on the PhilGEPS and DOH websites for the Procurement of Syphilis Rapid Test Kit under IB No. 2024-059. This Bid Bulletin shall form an integral part of the bidding document. Listed below are the corresponding modifications/changes:

1. New Schedule of Activity: Submission and Opening of Bids

From	To	Venue
06 November 2023; 9:00 AM	**04 December 2023; 9:00 AM**	COBAC Conference Room, Ground Floor, Bldg. 6, Department of Health, Sta. Cruz, Manila, and/or through video conferencing or webcasting via Cisco Webex

2. Letter from the Prospective Bidder

PB	Requirement	Query	EUU's Response
Allied Hospital Supply International Corporation (AHSIC)	Section VI: Schedule of Requirements Delivered, Calendar Days **Ninety (90) calendar days** upon receipt of the approved Notice to Proceed (NTP).	To change the delivery period to Ninety (90) calendar days upon receipt of the approved NTP.	The requested delivery schedule is approved **"Ninety (90) calendar days** upon receipt of approved NTP." Refer to changes.
	Additional Requirements: 1. Valid and current Certificate Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by Philippine Food and Drug Administration (PFDA);	Request for revision of requirement from "Valid and Current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration) or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and Drug Administration (PFDA)" to "Valid and Current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration) or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and	The request to specify the item to which the requirement shall be applied was included in the revised PR. Valid and Current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration) or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and Drug Administration (PFDA) **for test kits,**

PB	Requirement	Query	EUU's Response
		Drug Administration (PFDA) **for test kits only**"	**lancets and alcohol swabs or pads** Refer to changes.
	Additional Requirements: 7. Guarantee letter from supplier to replace the item with approved shorter shelf-life when returned ***six (6)*** months before the expiry date.	Request to change the guarantee letter from six (6) months to three (3) months before the expiry date.	The change of guarantee letter from six (6) months to three (3) months before the expiry date is hereby granted. Refer to changes.
	Post-qualification Requirements: One (1) actual sample kit with complete set of the items for evaluation	Request to change the sample kit for evaluation requirement from "One (1) actual sample kit with complete set of the items for evaluation" to "One (1) actual sample kit with complete set of the items for evaluation **during post-qualification**"	Submission of sample was revised to "One (1) actual sample kit with complete set of the items for evaluation **during post-qualification**" Refer to changes.

3. Section VI: Schedule of Requirements

From	To
Delivered, Calendar Days • Sixty (60) calendar days upon receipt of the approved Notice to Proceed (NTP).	**Delivered, Calendar Days** • **Ninety (90)** calendar days upon receipt of the approved Notice to Proceed (NTP).

4. Section VII: Technical Specifications

From	To
Additional Requirements: 1. Valid and current Certificate Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by Philippine Food and Drug Administration (PFDA); xxx	**Additional Requirements:** 1. Valid and Current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration) or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and Drug Administration (PFDA) **for test kits, lancets and alcohol swabs or pads.** xxx
7. Guarantee letter from supplier to replace the item with approved shorter shelf-life when returned six (6) months before the expiry date.	a. Guarantee letter from supplier to replace the item with approved shorter shelf-life when returned **three (3*)*** months before the expiry date.

From	To
Post-qualification Requirements: One (1) actual sample kit with complete set of the items for evaluation	Post-qualification Requirements: One (1) actual sample kit with complete set of the items for evaluation **during post-qualification.**
Recall and Replacement: 3. If the item is with approved shorter shelf life, the replacement for fresh stocks shall be issued when returned six (6) months before the expiry date;	**Recall and Replacement:** 3. If the item is with approved shorter shelf life, the replacement for fresh stocks shall be issued when returned **three (3) months** before the expiry date;

2. **Section VIII: Checklist of Technical and Financial Documents**

From	To
Additional Requirements: 1. Valid and current Certificate Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by Philippine Food and Drug Administration (PFDA); xxx 7. Guarantee letter from supplier to replace the item with approved shorter shelf-life when returned six (6) months before the expiry date.	**Additional Requirements:** 1. Valid and Current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration) or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and Drug Administration (PFDA) **for test kits, lancets and alcohol swabs or pads.** xxx 7. Guarantee letter from supplier to replace the item with approved shorter shelf-life when returned **three (3)** months before the expiry date.

The revised Schedule of Requirements, Technical Specifications, and Checklist of Technical and Financial Documents are enclosed for the Prospective Bidder's reference and use.

All other provisions indicated in the bidding documents which are not affected shall remain in force and in effect.

For guidance and information of all concerned.

FRANCES ROSE E. MAMARIL, MPH
COBAC-E Vice-Chairperson

Section VI. Schedule of Requirements

The delivery schedule expressed as calendar days stipulates hereafter a delivery date which is the date of delivery to the project site.

Item Number	Description	Quantity	Total ABC (PhP)	Delivery Site	Delivered, Calendar Days
1	Syphilis Rapid Test Kit	160,000 tests	12,360,000.00	DOH Warehouse(s) in Metro Manila	**Ninety (90)** calendar days upon receipt of the approved Notice to Proceed (NTP).

_____
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]

Technical Specifications

Republic of the Philippines
Department of Health
TECHNICAL SPECIFICATIONS

Item No. 1	**Syphilis Rapid Test Kit**	Quantity / Unit	**160,000 tests**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP12,360,000.00**			

PURCHASER'S SPECIFICATION	**STATEMENT OF COMPLIANCE**
A. <u>Detailed Technical Specifications:</u> 1. Principle: Immunochromatographic Test 2. Detects isotypes IgG and IgM Treponema Pallidum 3. Sensitivity and Specificity: more than or equal to 99% 4. Specimen: serum, plasma, whole blood 5. Result Time: less than or equal to thirty (30) minutes 6. One Hundred (100) tests/kit that includes thefollowing: 6.1. One (1) piece/kit - Assay diluent or chase buffer for whole blood 6.2. One Hundred (100) pieces/kit -Measuring/Capillary pipettes or tubes 6.3. One Hundred (100) pieces/kit - Alcoholswabs or pads and 6.4. One Hundred (100) pieces/kit – Lancets 7. Can be stored at standard room temperature 8. Multi-device or multi-strip in a resealable foil pack	

B. <u>Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</u>

1. Valid and current Certificate Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by Philippine Food and Drug Administration (PFDA) ***for test kit, lancet and alcohol swab or pads***;

2. Valid and current License to Operate (LTO) for Medical Device Importer/Wholesaler issued byPFDA;

3. The bidder shall submit any of the following whichever is applicable:

   a. If the bidder is a manufacturer, certificate that the bidder manufactures the products/item; 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 Distributor/Dealership Agreement by the Manufacturer with the distributor

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Syphilis Rapid Test Kit**	Quantity / Unit	**160,000 tests**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP12,360,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

or dealer; and

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

4. Product Insert/Product Information or downloaded from the internet and other manufacturer's un-amended 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;

5. Valid and Current Declaration of Conformity with appropriate ISO/IEC/PNS Standard issued to the manufacturer byan ISO Certifying body or any appropriate agency or body or Manufacturer's Conformity with Good Manufacturing Practice (GMP);

6. Marketing Authorization, Registration Approval or Free Sale Certificate of the product issued by the Health Authority in the Country of Origin;

7. Guarantee letter from supplier to replace the item with approved shorter shelf-life when returned ***three (3)*** months before the expiry date.

8. Sworn Statement using the prescribed form.

Note: For imported items, Authentication or red ribbon certificate from the Philippine consulate/embassy or documents authenticated through an Apostille by the competent authority based on the Apostille Convention, if applicable.

C. <u>Additional Requirements to be submitted by the Lowest/Single Calculated Bidder (S/LCB):</u>

One (1) actual sample kit with complete set of the items for evaluation ***during post-qualification***.

D. <u>Upon delivery the following shall be complied with:</u>

1. **Shelf life:** Must be fresh commercial stock with a total shelf life of Twenty-Four (24) months from the date of manufacture but not less than Eighteen (18) months from the date of delivery.

2. **Packaging instructions:**
   a. Primary Packaging: One Hundred (100) tests per kit plus consumables
   b. Secondary packaging: Standard packaging of the manufacturer as approved by PFDA

Note: Consumables (measuring/capillarity pipettes or tubes, alcohol swabs or pads and lancet) may be packed in a separate box

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**Syphilis Rapid Test Kit**	Quantity / Unit	**160,000 tests**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP12,360,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

3. Labeling instructions:

i. On each kit, 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. _____

ii. On each small and bigger box/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 SALE"
Date of Manufacture: ____
Date of Expiry: _____
Batch/Lot No. _____

E. <u>Product Recall & Disposal:</u>

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

_____
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]

Checklist of Technical and Financial Documents Arranged numbered and tabbed as it appears below:

TECHNICAL COMPONENT ENVELOPE

Class "A" Documents

Legal Documents

☐ (a) Valid PhilGEPS Registration Certificate (Platinum Membership) (all pages) in accordance with Section 8.5.2 of the 2016 Revised IRR of RA No. 9184;

Technical Documents

☐ (b) Statement of the prospective bidder of all its ongoing government and private contracts, including contracts awarded but not yet started, if any, whether similar or not similar in nature and complexity to the contract to be bid; **and**

☐ (c) Statement of the bidder's Single Largest Completed Contract (SLCC) similar to the contract to be bid, except under conditions provided for in Sections 23.4.1.3 and 23.4.2.4 of the 2016 revised IRR of RA No. 9184, within the relevant period as provided in the Bidding Documents; **and**

☐ (d) Original copy of Bid Security. If in the form of a Surety Bond, submit also a certification issued by the Insurance Commission;

or

Original copy of Notarized Bid Securing Declaration; **and**

☐ (e) Conformity with the Schedule of Requirements and Technical Specifications, which may include production/delivery schedule, manpower requirements, and/or after-sales/parts, if applicable; **and**

☐ (f) Original duly signed Omnibus Sworn Statement (OSS);

and if applicable, Original Notarized Secretary's Certificate in case of a corporation, partnership, or cooperative; or Original Special Power of Attorney of all members of the joint venture giving full power and authority to its officer to sign the OSS and do acts to represent the Bidder.

Financial Documents

☐ (g) The prospective bidder's computation of Net Financial Contracting Capacity (NFCC);

or

A committed Line of Credit from a Universal or Commercial Bank in lieu of its NFCC computation.

Class "B" Documents

☐ (h) If applicable, a duly signed joint venture agreement (JVA) in case the joint venture is already in existence;

or

duly notarized statements from all the potential joint venture partners stating that they will enter into and abide by the provisions of the JVA in the instance that the bid is successful.

Other documentary requirements under RA No. 9184 (as applicable)

☐ (i) *[For foreign bidders claiming by reason of their country's extension of reciprocal rights to Filipinos]* Certification from the relevant government office of their country stating that Filipinos are allowed to participate in government procurement activities for the same item or product.

☐ (j) Certification from the DTI if the Bidder claims preference as a Domestic Bidder or Domestic Entity.

II. FINANCIAL COMPONENT ENVELOPE

☐ (a) Original of duly signed and accomplished Financial Bid Form; **and**
☐ (b) Original of duly signed and accomplished Price Schedule(s).

III. ADDITIONAL DOCUMENTARY REQUIREMENTS TO BE ATTACHED IN THE TECHNICAL SPECIFICATIONS FORM:

☐ (1) Valid and current Certificate Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by Philippine Food and Drug Administration (PFDA) ***for test kit, lancet and alcohol swab or pads***;

☐ (2) Valid and current License to Operate (LTO) for Medical Device Importer/ Wholesaler issued by PFDA;

☐ (3) The bidder shall submit any of the following whichever is applicable:

a) If the bidder is a manufacturer, a certificate that the bidder manufactures the products/item; 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 Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and
   ii. Certificate or Contract/Dealership Agreement between the distributor/dealer and the bidder.

☐ (4) Product Insert/Product Information or downloaded from the internet and other manufacturer's un-amended 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

☐ (5) Valid and Current Declaration of Conformity with appropriate ISO/IEC/PNS Standard issued to the manufacturer by an ISO Certifying body or any appropriate agency or body or Manufacturer's Conformity with Good Manufacturing Practice (GMP);

☐ (6) Marketing Authorization, Registration Approval or Free Sale Certificate of the product issued bythe Health Authority in the Country of Origin;

☐ (7) Guarantee letter from supplier to replace the item with approved shorter shelf-life when returned ***three (3)*** months before the expiry date;

☐ (8) Sworn Statement using the prescribed form.

Note: For imported items, Authentication or red ribbon certificate from the Philippine consulate/embassy or documents authenticated through an Apostille by the competent authority based on the Apostille Convention, if applicable.

Note:

1) Please refer to **https://doh.gov.ph/sites/default/files/basic-page/COBAC-Sample-Forms.pdf** for the following requirements:

   a) Sworn Statement;
   b) Computation of NFCC;
   c) Manufacturer's Authorization;
   d) Secretary's Certificate;
   e) Special Power of Attorney;
   f) Statement of Ongoing Contracts; and
   g) Statement of SLCC.

2) For the following requirements, please refer to **GPPB Resolution No. 16-2020:**
   a) Bid Form;
   b) Price Schedule;
   c) Bid Securing Declaration; and
   d) Omnibus Sworn Statement