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

BID BULLETIN NO. 2
24 November 2023

PROCUREMENT OF HIV RDT (RHIVDA TEST 1)
IB NO. 2024-060

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 clarification letter of the Prospective Bidder (PB), and to amend or modify the bidding documents posted in the PhilGEPS and DOH websites for the above-mentioned project. This Bid Bulletin shall form an integral part of the bidding document. Listed below are the corresponding modifications/changes:

1. New Schedule of the 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, San Lazaro Compound, Sta. Cruz, Manila, and/or through videoconferencing or webcasting via Cisco Webex

2. Queries during the Pre-bidding Conference

Particular	Query	Response
Delivered, Calendar Days 1st tranche – 2,000,000 tests Ninety (90) calendar days upon receipt of approved Notice to Proceed (NTP). 2nd tranche – 2,000,000 tests One Hundred Fifty (150) calendar days upon receipt of approved NTP	The PB requested to change the delivery period for the first (1st) tranche to "One Hundred Twenty (120) calendar days".	Granted, refer to changes.
Total ABC: PhP206,000,000.00	The PB said that the Total ABC is too low and requested for increase.	The unit cost and ABC will be retained. No changes.
Valid and current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and Drug Administration (PFDA) for Test, Lancet and Alcohol swab included in the kit.	The PB asked if the proof for renewal of the CPR/CMDR/CMDN will be acceptable.	Only **valid and current** CPR or CMDR or CMDN issued by the PFDA shall be accepted. No changes.
Guarantee Letter from supplier to replace the item with approved shorter shelf life when returned six (6) months before the expiry date.	The PB asked if the requirement can be changed to "three (3) months" as same with the	The change of guarantee letter requirement **from six (6) months to three (3) months before the expiry date** is hereby

Particular	Query	Response
	previous bidding.	**granted.** Refer to changes.

2. Response on the clarifications of the PB:

Bidder	Particular	Query	Response
Allied Hospital Supply International Inc. (AHSIC)	**Delivered, Calendar Days** 1st tranche – 2,000,000 tests Ninety (90) calendar days upon receipt of approved Notice to Proceed (NTP). xxx	Suggestion: 1st tranche – 2,000,000 tests One Hundred Twenty (120) calendar days upon receipt of approved Notice to Proceed (NTP).	Granted, refer to changes.
	Valid and current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and Drug Administration (PFDA) for Test, Lancet and Alcohol swab included in the kit.	Suggestion: **For Lancet and Alcohol Swab only:** To submit proof of renewal in lieu of Valid and Current Certificate of Product Registration (CPR) or Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and Drug Administration (PFDA) a. Application Form b. FDA Acknowledgement Receipt c. Proof of Payment	Only **valid and current** CPR or CMDR or CMDN issued by the PFDA shall be accepted. No changes.
	Guarantee Letter from supplier to replace the item with approved shorter shelf life when returned six (6) months before the expiry date.	Suggestion: Guarantee Letter from supplier to replace the item with approved shorter shelf life when returned **three (3) months** before the expiry date. As per Administrative Order No. 2019-0041-B dated August 17, 2022; states that under General Guidelines: Remaining shelf life of **MEDICINES** can be shorter that the claimed shelf life	The change of guarantee letter requirement **from six (6) months to three (3) months before the expiry date** is hereby **granted.** Refer to changes.

Bidder	Particular	Query	Response
		provided that the supplier will issue guarantee letter stating that the remaining stock shall be replaced six (6) months before the expiration date. Acceptance of the guarantee letter shall be subject to the approval of the end-user. Administrative Order No. 2019-0041-B refers only on the **Pharmaceuticals and/or Medicines** product only.	
	Recall and Replacement: The item is with approved shorter shelf life, replacement for fresh stocks shall be issued when returned six (6) months before the expiry date.	Suggestion: The item is with approved shorter shelf life, replacement for fresh stocks shall be issued when returned **three (3)** months before the expiry date.	Refer to changes.
	Total ABC: PhP206,000,000.00	The ABC is Two Hundred Thirty Two Million Philippine pesos (PHP232,000,000.00) The AHSIC is the exclusive distributor of Abbott Bioline HIV ½ Antibody Test kit. This test has been in use by the Department of Health for a significant period of the time for the rHIVda Test 1 or the Rapid HIV Diagnostic Algorithm. We are writing this letter to the DOH to inform that AHSIC will apply a price adjustment effective on the next procurement schedule for this particular product. For more than a decade, if you will notice, the price of this commodity has been fixed or steady. The AHSIC conscientiously absorbs the price adjustments if it remains affordable. In early year 2010, we would	The unit cost and ABC for the said procurement shall be **retained.** No changes.

Bidder	Particular	Query	Response
		recall that the Philippine peso exchange rate to a US Dollar was at around PhP40.00+ and gas prices was at PhP50.00+/ liter. This 2023, both have gone up to as closed as 30%. On that note, we are requesting for a price adjustment from PhP50.00 to PhP58.00 or a 16% increase or a measly PhP8.00 increase for the unit cost of Abbott Bioline HIV ½ Test kit. This will help cover the increased cost of acquisition, importation as well as operational expenses.	

3. **Section VI. Schedule of Requirements**

From	To
Delivered, Calendar Days 1st tranche – 2,000,000 tests Ninety (90) calendar days upon receipt of approved Notice to Proceed (NTP). 2nd tranche – 2,000,000 tests One Hundred Fifty (150) calendar days upon receipt of approved NTP	**Delivered, Calendar Days** 1st tranche – 2,000,000 tests **One Hundred Twenty (120)** calendar days upon receipt of approved Notice to Proceed (NTP). 2nd tranche – 2,000,000 tests One Hundred Fifty (150) calendar days upon receipt of approved NTP

4. **Section VII. Technical Specifications**

From	To
B. **Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:** 7. Guarantee Letter from supplier to replace the item with approved shorter shelf life when returned six (6) months before the expiry date.	**B. Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:** 7. Guarantee Letter from supplier to replace the item with approved shorter shelf life when returned **three (3)** months before the expiry date.
C. **Additional requirement by the Single/Lowest Calculated Bid (S/LCB) as part of post-qualification:** • Submit one (1) whole kit sample.	**C. Additional requirement by the Single/Lowest Calculated Bid (S/LCB) as part of post-qualification:** • Submit one (1) whole kit sample **during post-qualification**.

From	To
E. Recall and Replacement: 1. The supplier must ensure the quality of product and if there will be problems in the quality, the supplier will recall and replace the products distributed in the regions hospitals/treatment and rehabilitation centers/RHU/HC/BHSs based on Guideline 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 six (6) months before the expiry date.	E. Recall and Replacement: 1. The supplier must ensure the quality of product and if there will be problems in the quality, the supplier will recall and replace the products distributed in the regions hospitals/treatment and rehabilitation centers/RHU/HC/BHSs based on Guideline 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 the expiry date.

5. Section VIII. Checklist of Technical and Financial Document

From	To
Guarantee Letter from supplier to replace the item with approved shorter shelf life when returned six (6) months before the expiry date.	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 Form, Technical Specifications Form 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 No.	Description	Quantity/ Unit	Total ABC (PhP)	Delivery Site	Delivered, Calendar Days
1	HIV RDT (rHIVda Test 1)	4,000,000 tests	206,000,000.00	Department of Health (DOH) warehouse(s) in Metro Manila	1st tranche – 2,000,000 tests **One Hundred Twenty (120)** calendar days upon receipt of approved Notice to Proceed (NTP). 2nd tranche – 2,000,000 tests One Hundred Fifty (150) calendar days upon receipt of approved 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	**HIV RDT (rHIVda Test 1)**	Quantity / Unit	**4,000,000 tests**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP206,000,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	
A. **Detailed Technical Specifications:** 1. Test Principle –Immunochromatographic Test (ICT) 2. Detects HIV ½ antibody 3. Individually foil pouched device 4. Cassette type 5. Approved for use per rapid HIV diagnostic algorithm (rHIVda) of the NRL-SACCL (Test 1) 6. A kit must include the ff: a. 25 or 30 tests per kit b. Assay diluent –1 pc. / kit c. Measuring or capillary pipettes or tubes –1 pc. / test d. Alcohol swabs or pads– 1 pc. / test e. Lancet – 1 pc. / test			

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

1. Valid and current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by the Philippine Food and Drug Administration (PFDA) for Test, Lancet and Alcohol swab included in the kit;

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

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

   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.

4. 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);

5. Product insert/information or downloaded from the internet and other manufacturer's un-amended sales literature, unconditional statements of specification and compliance issued by the

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**HIV RDT (rHIVda Test 1)**	Quantity / Unit	**4,000,000 tests**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP206,000,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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;

6. 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, 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.

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.

D. **Additional requirement by the Single/Lowest Calculated Bid (S/LCB) as part of post-qualification:**

- Submit one (1) whole kit sample **during post-qualification**.

E. **Upon delivery the following shall be complied with:**

1. **Shelf Life**: Must be fresh commercial stocks 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 – 25 or 30 tests per kit plus consumables
   b. Standard packaging of the manufacturer as approved by PFDA

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

3. **Labeling Instructions**:
   a. On each kit or box, the following shall be imprinted or stickered with non-removable

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**HIV RDT (rHIVda Test 1)**	Quantity / Unit	**4,000,000 tests**
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: **PhP206,000,000.00**			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

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.: _____

b. On each small and bigger box or 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 SALE"
Date of Manufacture: ____
Date of Expiry: _____

F. **Recall and Replacement:**

1. The supplier must ensure the quality of product and if there will be problems in the quality, the supplier will recall and replace the products distributed in the regions hospitals/treatment and rehabilitation centers/RHU/HC/BHSs based on Guideline 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 the 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 *equivalent to at least twenty-five percent (25%) of the ABC*, 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" Document

☐ (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 TECHINICAL SPECIFICATIONS FORM:

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

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

☐ (3) Marketing Authorization. Registration Approval or Free Sale Certificate of the product issued by the health authority in the country of origin;

Note: For imported Syringes: 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.

☐ (4) Valid and current Declaration of Conformity with appropriate ISO/IEC/PNS Standards issued to the manufacturer by an ISO certifying body or any appropriate agency or body or manufacturer's Conformity with Good Manufacturing Practice (GMP);

☐ (5) Product insert/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;

☐ (6) 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, 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.

☐ (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:

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) Authorization from the Main Distributor of the Manufacturer
   e) Secretary's Certificate;
   f) Special Power of Attorney;
   g) Statement of Ongoing Contracts; and
   h) 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