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

BID BULLETIN NO. 2
24 November 2023

PROCUREMENT OF HIV VIRAL LOAD POINT OF CARE TEST (POC)
IB NO. 2024-061

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
Shelf life: Minimum shelf life of eighteen (18) months remaining from the time of delivery.	The PB requested to change the shelf life to "Ten (10) months remaining from the time of delivery".	Noting that the item has short shelf life. The shelf life requirement was **revised** to "Ten (10) months remaining from the time of delivery" Refer to changes.
Guarantee letter from the supplier to replace item with approved shorter life when returned six (6) months before expiry date.	The PB asked if they will only replace the item with approved shorter shelf life when delivered and asked if the Guarantee letter will be submitted during the Submission and Opening of Bids.	The Guarantee Letter shall be submitted by the supplier during the Submission and Opening of Bids. The approval of a guarantee letter with a short shelf life should be secured by the supplier have it approved by the contract signatory prior to the request for the schedule of delivery.

2. Response on the clarifications of the PB:

Bidder	Particular	Query	Response
Macare Medicals Inc. (MMI)	**Shelf life:** Minimum shelf life of eighteen (18) months remaining from the time of	**Shelf life:** Minimum shelf life of **Ten (10)** months remaining from the time of delivery. From date of manufacture, Xpert HIV-	Noting that the item has short shelf life. The shelf life requirement was **revised** to "Ten (10) months remaining from the time of delivery"

Bidder	Particular	Query	Response
	delivery.	1 Viral Load has **only** Twelve (12) months shelf life. We need no less than two (2) months to factor in the following: (QA of Lot/batch, quarantine of stocks, allocations to different countries, logistics challenges, customs clearance, schedule of delivery to DOH, etc.)	Refer to changes.

3. **Section VII. Technical Specifications**

From	To
Shelf life: Minimum shelf life of eighteen (18) months remaining from the time of delivery.	**Shelf life:** Minimum shelf life of **ten (10)** months remaining from the time of delivery.
B. <u>Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</u> 7. Guarantee letter from the supplier to replace item with approved shorter life when returned six (6) months before expiry date;	**B. <u>Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below:</u>** 7. Guarantee letter from the supplier to replace item with approved shorter life when returned **three (3)** months before expiry date;
C. <u>Additional Requirement(s) to be submitted by the Single/Lowest Calculated Bidder (S/LCB) during Post-Qualification:</u> 1) Submit one (1) whole kit sample.	**C. <u>Additional Requirement(s) to be submitted by the Single/Lowest Calculated Bidder (S/LCB) during Post-Qualification:</u>** 1) Submit one (1) whole kit sample **during post-qualification.**
E. <u>Recall & Replacement:</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	**E. <u>Recall & Replacement:</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

From	To
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 expiry date.	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.

The revised 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

Technical Specifications

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**HIV Viral Load Point of Care Test (POC)**	Quantity / Unit	44,000 cartridges
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: PhP77,574,640.00			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	
A. Detailed Technical Specifications: 1. Individually packed cartridges 2. Compatible with existing rapid RT-PCR machines allocated to DOH facilities 3. Principle: Quantitative Reverse Transcriptase PCR; 4. Sample: Plasma (1 mL-2mL) 5. Must include single-use disposable pipette 6. Brand and Model of the machine: GeneXpert machine by Cepheid			

B. <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 Philippine Food and Drugs Administration (PFDA);

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 Manufacturer's conformity with Good Manufacturing Practice (GMP);

5. 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;

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,

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**HIV Viral Load Point of Care Test (POC)**	Quantity / Unit	44,000 cartridges
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: PhP77,574,640.00			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	

Certificate or Contract from the manufacturer or importer 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 the supplier to replace item with approved shorter life when returned **three (3)** months before expiry date;

8. Sworn Statement using the prescribed form.

C. Additional Requirement(s) to be submitted by the Single/Lowest Calculated Bidder (S/LCB) during Post-Qualification:

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

D. Upon delivery the following shall be complied with:

1. **Shelf life:**

   Minimum shelf life of **ten (10)** months remaining from the time of delivery.

2. **Packaging instructions:**

   Standard packaging of the manufacturer as approved by PFDA.

3. **Labeling instructions:**

a) On each cartridge or box, 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: _____
Batch/Lot No.: _____

b) On each small and 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 SALE"
Date of Manufacture: ____
Date of Expiry: _____

Republic of the Philippines Department of Health TECHNICAL SPECIFICATIONS			
Item No. 1	**HIV Viral Load Point of Care Test (POC)**	Quantity / Unit	44,000 cartridges
Name of Manufacturer:		Country of Origin:	
Brand:			
Total ABC: PhP77,574,640.00			
PURCHASER'S SPECIFICATION		**STATEMENT OF COMPLIANCE**	
Batch/Lot No.: _____			

F. Recall & 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/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:

I. 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.

☐ (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:

☐ (a) Valid and current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) issued by Philippine Food and Drugs Administration (PFDA);

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

☐ (c) 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;

☐ (d) 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 Manufacturer's conformity with Good Manufacturing Practice (GMP);

☐ (e) Product Insert/Product Information or downloaded from the internet with specific URL indicated 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;

☐ (f) 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 or importer 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.

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

☐ (h) 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