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

BAGONG PILIPINAS

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB No. 2025-030
Procurement of Hepatitis B Surface Antigen Rapid Diagnostic Test (100 tests/kit)
(EARLY PROCUREMENT ACTIVITY)

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

Query during Pre-bidding Conference:

Technical Specification	Query	Response of the End User Unit
	70,000 test	70,000 test
Test Principle: Immunochromatographic Test (ICT)	Test Principle: Immunochromatographic Test (ICT) / lateral flow test – for clarification with end user	Test Principle: Immunochromatographic Test (ICT) / lateral flow test – for clarification with end user
Specificity/Sensitivity – more than or equal to 99% Multi-device type	Specificity/Sensitivity – more than or equal to 99% Multi-device/ multi-strip type – for clarification with end user	Specificity/Sensitivity – more than or equal to 99% Multi-device/ multi-strip type – for clarification with end user
Specimen: Serum (less than or equal to 100uL), Plasma (less than or equal to 100uL), Whole Blood (less than or equal to 100uL), includes Assay diluent if needed, Capillary tube, Alcohol swabs and Lancets	Specimen: Serum (less than or equal to 100uL), Plasma (less than or equal to 100uL), Whole Blood (less than or equal to 100uL), includes Assay diluent or chase buffer if needed, Capillary tube, Alcohol swabs and Lancets – for clarification with end user	Specimen: Serum (less than or equal to 100uL), Plasma (less than or equal to 100uL), Whole Blood (less than or equal to 100uL), includes Assay diluent or chase buffer if needed, Capillary tube, Alcohol swabs and Lancets – for clarification with end user

Furthermore, this is to inform bidders that the bidding will be moved on the **29th of November, 2024** instead of November 27, 2024 due to lack of quorum

Bidders are advised to use the **following attached forms and submit them together with all required documents for the submission of bids on the 29th day of November 2024, 9:00 AM:**

This Supplemental/Bid Bulletin No. 1 shall be integral to the Bidding Documents. All other provisions indicated in the bidding documents not affected by this Supplemental/Bid Bulletin No. 1 shall remain in effect.

For guidance and information of all concerned.

Issued this 20th day of November 2024 in MMCHD

Approved by:

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

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

TECHNICAL SPECIFICATIONS

Item	***Hepatitis B Surface Antigen Rapid Diagnostic Test (100 tests/kit)***	Qty./Unit	*70,000 test*
Name of Manufacturer:		Country of Origin (if applicable)	
Brand:		Model: (if applicable)	
ABC: P 7,000,000.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	
SPECIFICATIONS: Test Principle: Immunochromatographic Test (ICT) Specificity/Sensitivity – more than or equal to 99% Multi-device type Result Time: less than or equal to 30 minutes Specimen: Serum (less than or equal to 100uL), Plasma (less than or equal to 100uL), Whole Blood (less than or equal to 100uL), includes Assay diluent if needed, Capillary tube, Alcohol swabs and Lancets Delivery Period: 30 calendar days from receipt of approved NTP Delivery Place: DOH MMCHD Pasig Warehouse		70,000 test Test Principle: Immunochromatographic Test (ICT) / lateral flow test – for clarification with end user Specificity/Sensitivity – more than or equal to 99% Multi-device/ multi-strip type – for clarification with end user Specimen: Serum (less than or equal to 100uL), Plasma (less than or equal to 100uL), Whole Blood (less than or equal to 100uL), includes Assay diluent or chase buffer if needed, Capillary tube, Alcohol swabs and Lancets – for clarification with end user	
B. Upon delivery, the following shall be complied with: **Shelf life:** Must be fresh commercial stock with a total shelf life of twenty (24) months from the date of manufacture but not less than eighteen (18) months from the date of delivery. **Packaging Instruction:** Standard packaging of the manufacturer as approved by PFDA Primary packaging: 100pcs per box **Labeling instruction:** Standard labelling instruction as approved by FDA pursuant to Administrative Order No. 2016-0008.			

In addition to the labeling requirement of FDA: A, on each blister pack/foil the following should be imprinted or stickered with a non removable or permanent sticker or label that is biding, and with residue and tearing, if removed: **Philippine Government Property Department of Health** **NOT FOR SALE** **B.** On each 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: _____ Batch/Lot No.: _____	
C. **Additional Requirements to be attached to the Technical Specifications form arranged, numbered and tabbed as enumerated below**: 1. Valid and current Certificate Product Registration (CPR) or Valid Extension issued by the Philippine Food and Drug Administration (PFDA); The CPR must be valid for the entire period of the award. If the CPR is about to expire, the supplier must have submitted a copy of an application of renewal to the FDA at least 3 months before the expiry date (a copy of the expiring CPR which is stamped with an "Extension of Validity" shall be submitted as proof); [AO 2019-0041] 2. Valid and current License to Operate (LTO) for drug suppliers, distributors and traders issued by Philippine Food and Drugs Administration (PFDA). Provided, that the application for renewal was made timely as per DOH AO No. 2016-003: In case of expired LTO, the following copies may be submitted: (i) expired LTO; (ii) application for renewal with FDA document tracking number; and, (iii) Official Receipt as proof of payment of renewal of LTO 3. Product Insert/Product Information or downloaded from the internet 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 Technical Specifications;	

4. Certification from the Manufacturer/Distributor/Importer/Wholesaler (as reflected in the Certificate of Product Registration of the product/s to be bid) that the Bidder is an authorized dealer or distributor of the product	

c. Additional requirement the Lowest/Single Calculated Bid (L/SCB) as part of post qualification:

1. You are requested to submit within (5) five days upon receipt of this notice three (3) copies of all documents needed for Post Qualification of the following documents:
   a. Eligibility Documents
      i. (Mayor's Permit (latest annual and quarterly)
      ii. SEC/DTI Registration,
      iii. Tax Clearance)
   b. Certificate of Registration from BIR
   c. Income Tax Returns – latest payment
   d. Bid Bulletin
   e. Product Sample /Brochure
   f. Authority from the Manufacturer to Distribute the Product
   g. License to Operate
   h. And other documents stated in BDS

2. One (1) original sample of the manufacturer's product to be submitted and returned after evaluation. The sample submitted and approved during the evaluation shall be the same item to be delivered upon contract award. The prototype of the labeling instruction must be part of the sample submitted; however, the technical specifications of the labeling instruction of the product must be complied with upon delivery.

E. Product Recall & Disposal:

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)

Section VI. Schedule of Requirements

The delivery schedule expressed as weeks/months 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, Weeks/Months
	Hepatitis B Surface Antigen Rapid Diagnostic Test (100 tests/kit)	***70,000 tests***	P 7,000,000.00	DOH-MMCHD Pasig Warehouse	Thirty (30) Calendar days After receipt of NTP.

Signature over Printed Name

[date of signing]

In the capacity of:

Duly authorized to sign bid for and on behalf of:

[title or other appropriate designation]

(Name of Company)

[Complete office address]

[Contact No.]

[Fax No.]

[Email Address]