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

BAGONG PILIPINAS

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB#2025-005
Procurement of HIV Test Kits (30tests/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**
HIV Test Kits (30 tests/kit) 1,520 kits	HIV Test Kits (30 tests/kit) 1,520 kits to smallest unit = 45,600 test	HIV Test Kits -45,600 test
Immunochromatographic test (ICT); detects HIV ½ antibody, individually foil pouched device; cassette type ~~(30 tests per kit)~~ or Manufacturer Standard approved by FDA	Immunochromatographic test (ICT); detects HIV ½ antibody, individually foil pouched device; cassette type ~~(30 tests per kit)~~ or Manufacturer Standard approved by FDA	Immunochromatographic test (ICT); detects HIV ½ antibody, individually foil pouched device; cassette type or Manufacturer Standard approved by FDA
Delivery Period: Thirty (30) calendar days after receipt of the Notice to Proceed	Delivery Period: Thirty (30) to Forty Five (45) calendar days after receipt of the Notice to Proceed	Delivery Period: Thirty (30) to Forty Five (45) calendar days after receipt of the Notice to Proceed
Primary Packaging: end user's specification	30 test per kit	30 test per kit

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 No. 1	**HIV Test Kits (30 tests/kit)**	Qty./Unit	***45,600 tests***
Name of Manufacturer:		Country of Origin (if applicable)	
Brand:		Model: (if applicable)	
ABC: P 2,280,000.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	

SPECIFICATIONS:

Test Principle: Immunochromatographic test (ICT); detects HIV ½ antibody, individually foil pouched device; cassette type or Manufacturer Standard approved by FDA

100% sensitivity and 99.8% specificity

Result time: within 20 minutes

Specimen: 10 uL of serum/plasma or 20 uL of whole blood

Materials provided: assay diluent if needed capillary pipette, alcohol swabs and lancet

Delivery Period: Thirty (30) to Forty Five (45) calendar days after receipt of the Notice to Proceed

Delivery Place: DOH MMCHD Pasig Warehouse

Other Requirements:

1) Certificate of Product Registration (CPR) issued by FDA
2) WHO Prequalification Listing
3) Original brochure/package insert or download from the internet

B. Upon delivery, the following shall be complied with:

Packaging Instructions:

1. Primary Packaging:

2. Standard packaging of the manufacturers as approved by the Philippine Food Drug and Authority (PFDA)

2. Shelf life:

Products must have a minimum shelf life of eighteen (18) months remaining at the time of delivery

3. Labeling instructions:

Standard labelling instruction as approved by FDA pursuant to Administrative Order No. 2016-0008
The following should be imprinted or stickered, using a permanent non-removable sticker/label that is binding and will leave residue and ripping if removed:

a. On each pack the following should be legibly imprinted or stickered "Philippine Government Property-Department of Health" NOT FOR SALE Manufacturing Date: _____ Expiration Date: _____ Batch/Lot No.: _____	
C. Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below: 1.Valid and current Certificate 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); The CPR must be valid for the entire period of the award. If the CPR/CMDN/CMDR 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 Medical Device Exporter / Trader /Importer / Distributor / Wholesaler issued by Philippine Food and Drugs Administration (PFDA) 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 a cross-referencing statement of compliance to the technical specification in accordance to what is indicated in Technical Specifications; 4. 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 or	

dealer; and ii. Certificate/Contract between the distributor/dealer and the bidder.	

D. Additional requirement by 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
	HIV Test Kits (30tests/kit)	***45,600 tests***	P 2,280,000.00	DOH-MMCHD Pasig Warehouse	*Delivery Period: Thirty (30) to Forty Five (45) calendar days after receipt of the Notice to Proceed*

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]