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

BAGONG PILIPINAS

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB No. 2025-041
Procurement of Dengue NS1 Ag, IgG + IgM Kits
(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
3mL–5mL assay buffer	2 mL assay buffer - for clarification with end user	2 mL assay buffer - for clarification with end user NOT GRANTED
10 uL capillary pipette	5 uL capillary pipette- for clarification with end user	5uL to 10 ul capillary pipette
Sensitivity ≥ 94% and Specificity Dengue IgG/gM ≥ 96% Dengue IgG/IgM based on 3rd party evaluation or based on publication by national Reference Laboratory (NRL), Centers for Disease Control and Prevention (CDC) or World Health Organization (WHO	Sensitivity: ≥ 92% and Specificity ≥ 96% Dengue NS1 Ag based on 3rd party evaluation or based on publication by national Reference Laboratory (NRL), Centers for Disease Control and Prevention (CDC) or World Health Organization (WHO) – for clarification with end user	Sensitivity: ≥ 92% and Specificity ≥ 96% Dengue NS1 Ag based on 3rd party evaluation or based on publication by national Reference Laboratory (NRL), Centers for Disease Control and Prevention (CDC) or World Health Organization (WHO) – for clarification with end user NOT GRANTED
	~~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~~	~~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~~

	~~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)	~~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)~~ GRANTED

Bidders are advised to use the **following attached forms and submit them together with all required documents for the submission of bids on the 3rd day of December 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 25th 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	***Dengue NS1 AG, IgG+ IgM Kits***	Qty./Unit	900 kits
Name of Manufacturer:		Country of Origin (if applicable)	
Brand:		Model: (if applicable)	
ABC: P 3,600,000.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	

SPECIFICATIONS:

*RDT kit for the qualitative detection of dengue non-structural protein 1 (NS1) and dengue Ns1 IgG and IgM antibodies from all four (4) Dengue serotypes

*NS1 & IgG/IgM Combo in Immunochromatography in plastic cassette format

*3mL–5mL assay buffer

**5uL to 10 ul capillary pipette*

*1 disposable dropper

*1 lancet, ultra thin, 28 gauge, consistent depth penetration, universal design firs almost all lancing devices

*assay time 15-20 min

Sensitivity: ≥ 92% and Specificity ≥ 98% Dengue NS1 Ag based on 3rd party evaluation or based on publication by national Reference Laboratory (NRL), Centers for Disease Control and Prevention (CDC) or World Health Organization (WHO)

*Sensitivity ≥ 94% and Specificity Dengue IgG/gM ≥ 96% Dengue IgG/IgM based on 3rd party evaluation or based on publication by national Reference Laboratory (NRL), Centers for Disease Control and Prevention (CDC) or World Health Organization (WHO)

Additional Requirements: Certificate of Product Analysis (CPA) issued by the manufacturer

Delivery Period: 30 calendar days from receipt of approved NTP

Delivery Place: DOH MMCHD Pasig Warehouse	
B. Upon delivery, the following shall be complied with: **1. Shelf life**: Must be fresh commercial stock, with a minimum shelf life of eighteen (18) months remaining from the delivery date. **2. Packaging Instructions:** 1. Standard packaging of the manufacturers as approved by the Philippine Food Drug and Authority **2. Labeling instructions**: Standard labelling instruction as approved by FDA pursuant to Administrative Order No. 2016-0008 In addition to the labeling requirements of the PFDA: a. On each box, the following should be legibly imprinted or stickered with a non-removable or permanent sticker or label that is binding and will leave residue and rip if removed "Philippine Government Property-Department of Health" NOT FOR SALE Date of Manufacturer: Date of Expiry: Batch/Lot No.	
C. **Additional Requirements to be attached to Technical Specifications form arranged, numbered and tabbed as enumerated below**: 1. . 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; 2. 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 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)