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

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB 2024 – 064 - PBC

PROCUREMENT OF 20,200 TEST HBV TEST KITS (ANTIGEN ASSAY)

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

Revision and clarification to provisions/specifications in the Bidding Documents:	
ORIGINAL TECHNICAL SPECIFICATIONS	**AMENDED**
Shelf Life Must be fresh commercial stock with a total shelf life of at least six (6) months from the date of receipt by the end-user.	Shelf Life Must be fresh commercial stock with a total shelf life of *would be four (4) to six (6) months* from the date of receipt by the end-user.

Bidders are advised to use the following attached forms and submit them together with all required documents for the submission of bids on the 25th day of March 2024, 9:00 AM:

This Supplemental/Bid Bulletin No. 1 shall form an integral part of the Bidding Documents. All other provisions indicated in the bidding documents that are not affected by this Supplemental/Bid Bulletin No. 1 shall remain in effect.

For guidance and information of all concerned.

Issued this 15th day of March 2024 in MMCHD

Approved by:

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

Section VII. Technical Specifications

Republic of the Philippines Department of Health Metro Manila Center for Health Development TECHNICAL SPECIFICATIONS			
Item No. **1**	**HBV TEST KIT (ANTIGEN ASSAY)**	Qty./Unit	**20,200 Test**
Name of Manufacturer:			Country of Origin
Brand:			Model: (if applicable)
ABC: **989,800.00**			
PURCHASER'S SPECIFICATION			STATEMENT OF COMPLIANCE
Detailed Technical Specification 1. Intended Use: a. Used as screening test for blood and blood components as indicated in the Instruction For Use of the reagent. b. Employs Chemiluminescent Immunoassay and/or Enzyme Immunoassay for the qualitative detection of Hepatitis B surface antigen in human serum or plasma. c. Able to detect HBsAg mutant and HBV genotypes A through F. d. With a 99.5% or higher Sensitivity and 99.0% or higher Specificity as tested and evaluated by DOH- SACCL as per Department Circular 2013-0132A. e. In vitro testing validated with blood donor population. Third party validation at least by the DOH SACCL or RITM-TTI NRL or its equivalent international quality assurance validation. 2. Specimen Requirements: Serum or Plasma a. Suitable to plasma collected in EDTA tubes and anticoagulant present in blood bag such as CPD, CPDA-1, and ACD. 3.With reagent specific controls in the manufacturer's kit until total			

consumption of HBV reagents: a. Positive and Negative controls b. Calibrators c. Other consumables (if applicable) 4. Terms and Condition for reagents with Machine tie- up: a. A fully automated analyzer with a throughput of not less than 100 tests/hour and capable of testing for HBsAg Assay, HIV Antigen & Antibody Assay, HCV Combo (Ag/Ab) or HCV Antibody Assay, and Syphilis Antibody Assay b. With on-board inventory management and alert features for incorrect position of reagents and samples c. With random access, batch, and STAT testing capabilities d. Capable of sample clot detection, liquid level detection, and low level notification e. Integral Levy-Jennings Chart f. Result print out with indication of final results. g. Accompanied with an Uninterrupted Power Supply (UPS) unit and AVR h. Can be plugged at a power supply of 220-240 VAC, 60 Hz i. One (1) machine and back up unit with the same specifications to be returned upon total consumption of reagents Type of Contract 1. Supply of Items 2. Machine tie-up with lease of equipment/ supplied for use until all consumables are all utilized Shelf Life Must be fresh commercial stock with a total shelf life of *would be four (4) to six (6) months* from the date of receipt by the end-user. Packaging Instructions Standard Packaging of the Manufacturer as approved by PFDA Labelling Instructions On each box and/ or carton, the following should be im printed 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.: _____ 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. Replacement of reagent and consumable wastages arising from machine malfunction; 4. Stocks with less than two (2) months remaining shelf life, the winning bidder will replace it with at least six (6) months shelf life and deliver such within two (2) weeks. The replacement of reagents is continuous until total consumption. Additional Requirements A. Valid and current Certificate of Product Registration (CPR) or Certificate of Medical Device Registration (CMDR) issued by Philippine Food and Drugs Administration (PFDA); B. Valid and Current License To Operate (LTO) as Medical Device Importer/Wholesaler issued by Philippine Food and Drugs Administration (PFDA) C. Hard copy of Product Insert/ Product Information of reagent and machine that can be 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	

D. 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/items; 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 Distributorship/Dealership Agreement by the Manufacturer with distributor or dealer; and ii. Certificate or Contract/Dealership Agreement between the distributor/dealer and the bidder. E. Performance Testing: 1. Track record certificate of Very Satisfactory performance for at least three (3) years since 2020 to 2022 from at least one (1) local installation; 2. With EQAS Certificate of Proficiency with Passed rating for at least one (1) year since 2021 to 2022 issued by RITM-TTI NRL. F. Valid and current SACCL evaluation report specifying the sensitivity and specificity of the Blood Screening (TTIs) reagents. In case of ongoing evaluation, the previous SACCL evaluation, application for renewal, and Official Receipt (OR) of current evaluation should be submitted. G. Valid and current Certificate of Compliance with ISO/IEC/PNS standards for quality of reagents, personnel, and services. H. Guarantee letter from supplier for item replacement as to shelf life, reagents wastages arising from machine malfunction, and product quality. I. Valid and current CE Certification or its equivalent such as Declaration of Conformity (DOC); J. Certification from the bidder that machine will be interfaced with Blood Bank Information System (BBIS) and NBBNets and shall be provided with middleware upon commissioning. K. Certificate that the bidder will provide the following requirements: a. Technical support for 24 hours /7 days from Engineer and/ or Product Specialist. Immediate (within 8 hours upon notification) on-site	

repair of the equipment if resolution is not possible by remote troubleshooting. b. Quarterly preventive maintenance and calibration or as need arises for the machine and all the included equipment from the supplier with certificate and calibration sticker c. Actual demonstration and adequate training for all technical staff. d. Reagent Refrigerator with UPS and AVR to be returned upon total consumption of reagents. e. Hard copy and soft copy of operation and service manuals in English. f. Independent temperature monitoring device including batteries for the Reagent Refrigerator. g. External printer with continuous ink supply system (black and colored) to be returned until total consumption of reagents. L. Sworn Statement using the prescribed form Delivery Schedule Sixty (60) Calendar Days upon receipt of approved Notice to Proceed. Delivery Site DOH-Philippine Blood Center, 6512 Quezon Ave. Diliman, Quezon City Allocation List For PBC use	

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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]