Republic of the Philippines
DEPARTMENT OF HEALTH
Metro Manila Center for Health Development

BAGONG PILIPINAS

SUPPLEMENTAL/ BID BULLETIN NO. 1

IB#2024-127
Procurement of 31,250 pieces Hemoglobin Determination Cuvettes

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

1. Query during Pre-bidding Conference:

Technical Specifications	Query	Response of the End User Unit
No changes as stipulated in the technical specification		

Bidders are advised to use the **following attached forms and submit them together with all required documents for the submission of bids on the 7th day of August 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 31st day of July 2024 in MMCHD

Approved by:

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

TECHNICAL SPECIFICATIONS			
Item No. **1**	**HEMOGLOBIN DETERMINATION CUVETTES**	Qty./Unit	**31,250 Pieces**
Name of Manufacturer:			Country of Origin
Brand:			Model: (if applicable)
ABC: **1,000,000.00**			
PURCHASER'S SPECIFICATION			STATEMENT OF COMPLIANCE
Detailed Technical Specifications: 1. Cuvette, for determining hemoglobin level 2. Provision of eight (8) units Hemoglobin analyzer under Machine Tie-up **3. Terms and Condition for machine tie-up:** a) Hemoglobin analyzer with measuring range of 0 to 256 g/L and measuring time of less than 20 seconds b) Provision of blood based liquid control (quarterly) or built-in control materials c) Availability of service unit in case of machine breakdown or repair d) Provision of two (2) sets of batteries for each machine e) Quarterly preventive maintenance and calibration or as need arises with certificate and stickers f) Provision of technical support on 24 hours/ 7 days assistance from engineer and/or product specialist. g) Can be plugged at power supply of 220-240 VAC, 50-60 Hz and battery operated h) Provision of operation and service manuals in English i) Provision of actual demonstration and adequate training for the staff j) Provision of lancets for each cuvette and lancing device with depth setting for every 2,000 cuvettes **Type of Contract**: 1. Supply of Items			

2. Machine tie-up with lease of equipment supplied for use until consumables are all utilized.

Shelf Life:

Must be fresh commercial stock with life of not less than eighteen (18) months from the date of receipts of the ed-user

Packaging Instruction:

Standard Packaging by the manufacturer as approved by the Food and Drug Administration (FDA)

Labelling Instructions:

Each box 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 FRO SALE"

Date of Manufacture: _____

Date of Expiry: _____

Batch/Lot No.: _____. Of applicable

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. 2016-01.

2. In instances of product recalls due to failures of suppliers and manufacturer 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 stock and consumable wastages arising from machine malfunctions;

4. Replacement of fresh stock with approved shorter Life. If the item is approved with shorter shelf life, replacement for fresh stock shall be issued when the returned three (3) months before expiry dates and the

supplier will replace it with not less than twelve (12) months shelf life and the stocks within two (2) weeks

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 o 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, sample, independent test data etc., as appropriate for Cross-referencing statement of compliance 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. Valid and current Certificate of Compliance with ISO/IEC/PNS standard or its equivalent for quality of reagents, personnel and services;

E. The Bidder shall submit any of the following whichever is applicable;

   a. If the bidder is the manufacturer, a 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 he 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 distributor or dealer;

      ii. Certificate or Contract/Dealership Agreement between the distributor/dealer and the bidder.

F. Guarantee letter from the Supplier for item replacement as to shelf

life, consumable wastages arising from machine malfunction, and product quality. G. Certificate that the bidder will provide the following requirements: 1. Provision of Technical support for 24 hours / 7 days from Engineer and / or product Specialist. Immediate (within 8 hours upon notification) on-site repair o the equipment if resolution is not possible by remote trouble shooting. 2. Quarterly preventive maintenance and calibration or as need arises for the machine and all the machine and all the included equipment from the supplier with certificate and calibration sticker. 3. Actual demonstration and adequate for all technical staff. **Delivery Schedule**: **First Tranche**: 15,625 pieces; Thirty (30) calendar days upon receip of Approved Notice to Proceed **Second Tranche**: 15,625 pieces: Sixty (60) calendar days after the first delivery. **Delivery site**; Philippine Blood Center, Diliman, Quezon City **Allocation List**: For PBC use only	