



SUPPLEMENTAL/ BID BULLETIN NO. 1

IB#2024-131
Procurement of CD4 Cartridge (PIMA)

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 22nd 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 13th day of August 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	CD4 Cartridge, PIMA	Qty./Unit	40 boxes (100tests/box)
Name of Manufacturer:		Country of Origin (if applicable)	
Brand:		Model: (if applicable)	
ABC: P 7,200,000.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	
Specifications: Individually pouched, POCT (Point of Care Test) Single use cartridge, sealed cartridge with no manual sample handle or processing and with minimum testing time; 100 cartridges/box compatible with existing CD4 analyzer at recipient account (PIMA) Delivery Period : 60 calendar days from the receipt of approved NTP			
D. Upon delivery, the following shall be complied with: 1. Shelf Life: The product must have a minimum shelf life of eighteen (18) months remaining at the time of delivery. 1. Packaging Instructions: A. Standard Packaging of the manufacturers as approved by the PFDA. 3. Labeling instructions: 1. Standard Labeling instruction as approved by PFDA pursuant to Administrative Order No. 2016-0008 2. In addition to the labeling requirements of the PFDA: a. On each set, the following should be legibly imprinted or stickered: 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) , 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.