Bid Bulletin No. 1
August 13, 2019

Public Bidding No. 19-091-3

SUPPLY AND DELIVERY OF HIV VIRAL LOAD REAGENTS FOR THE DEPARTMENT OF HEALTH (DOH)

Issued pursuant to Sec. 22.5 of the IRR of R.A. 9184 to clarify and/or amend certain provisions in the Bidding Documents issued for this project, considering the issues raised and clarifications made by prospective bidders during the Pre-Bid Conference held on **06 August 2019**, likewise respond to bidders' written queries received within the prescriptive period for filing:

A. AMENDMENTS/INCLUSIONS

<table>
<tr><th>REFERENCE</th><th>BASIS FOR AMENDMENT</th></tr>
<tr><td>
SECTION I INVITATION TO BID
Page 4

Xxx
2. The summary of the bidding activities is as follows:

<table>
<tr><td>Advertisement/Posting of Invitation to Bid</td><td>July 30, 2019</td></tr>
<tr><td>Issuance and Availability of Bid Documents</td><td>July 30, 2019</td></tr>
<tr><td>Pre-Bid Conference</td><td>August 06, 2019; 1:30 PM</td></tr>
<tr><td>Last day of Submission of Written Clarification</td><td><s>April 09, 2019</s> <u>August 09, 2019</u></td></tr>
<tr><td>Last day of Issuance of Bid Bulletin</td><td>August 13, 2019</td></tr>
<tr><td>Deadline for Submission of Bids</td><td>August 20, 2019; 1:30 PM</td></tr>
<tr><td>Opening of Bids</td><td>Immediately after the Deadline of Submission of Bids</td></tr>
</table>

Xxx
</td><td>To amend the timeline for the submission of written clarification.</td></tr>
</table>

For the purpose of this Bulletin and for better understanding of its contents, the following rules shall apply: (a) ~~Double Strike out~~ – denotes deletion; (b) <u>Underline</u> – denotes inclusion or new item/requirement; and "xxx" – denotes separation of phrase/s being amended from the rest of the main text.

SECTION VII TECHNICAL SPECIFICATION Page 71 & 72 Xxx Analytical sensitivity: <40 copies/ml ~~(33 IU/ml)~~ Xxx	Please refer to revised Technical Specification Form labeled as Appendix "A"

B. CLARIFICATIONS

The Department of Budget and Management–Procurement Service Bids and Awards Committee III (BAC III) hereby clarifies the bidder's concern/query:

ITEM	CONCERN	REFERENCE	CLARIFICATION/ RESOLUTION
METRO DRUG INC.			
1	xxx Compatible with existing **fully automated equipment** of Natioanal HIV Referene laboratory (NRL) – San Lazaro Hospital xxx	Technical Specification Page 71-72	Original requirement for Section VII Technical Specification will remain.
2	xxx Fully automated sample preparation, reagent preparation and HIV-1 RNA amplification, detection and quantification Xxx	Technical Specification Page 71-72	Original requirement for Section VII Technical Specification will remain.
3	xxx In vitro nucleic acid amplification test for the quantitation of Human Immunodeficiency Virus type 1 (HIV-1) RNA. xxx	Technical Specification Page 71-72	Original requirement for Section VII Technical Specification will remain.
4	xxx Limit of Detection of 20 copies/mL (33IU/mL). To correct the 40 copies/mL. xxx	Technical Specification Page 71-72	Original requirement for Section VII Technical Specification will remain.

MACARE MEDICALS, INC.			
1	xxx On a reagent-equipment tie-up basis, supplier to provide the needed equipment to run the reagent/test offered. If the supplier has already existing equipment installed at NRL-San Lazaro Hospital, there is no need for the supplier to change or bring-in another unit, provided however, that the model of equipment available is the required unit compatible to the reagent/test offered. Supplier to indicate the brand and model of equipment. If the equipment is already available at NRL-San Lazaro Hospital, supplier should also include the Brand, Model and Serial Number to prove that the unit is already installed and the one that will match the use of reagents/test offered. xxx	Technical Specification Page 71-72	Original requirement for Section VII Technical Specification will remain.
2	xxx Fully automated sample preparation, reagent preparation and/or detection system. Supplier to indicate Product Code/Catalogue Number of every Kit/Box. xxx	Technical Specification Page 71-72	Original requirement for Section VII Technical Specification will remain.
3	xxx Analytical Sensitivity: <40 copies/ml Note: 33 IU/ml is not included to remove confusion as WHO uses copy/ml only in its prequalification document. Xxx	Technical Specification Page 71-72	Please see amendment part of this bid bulletin.

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4	xxx To be delivered within Sixty (60) Calendar Days, the Supplier is given the OPTION to make only One Single Delivery of the whole 22,080 tests, provided however, that: 1. 12,000 tests must have EXPIRY Date no less than Eight (8) Months from date of Delivery. 2. 10,080 tests must have Expiry Date no less than Ten (10) Months from date of delivery. Otherwise, First and Second Batches deliveries indicated above shall be followed and the Supplier is required for the Second Batch to deliver tests/kits with batch/lot number/s which are different from the First Batch. This is to ensure that the Second Batch has longer Expiry Date by no less than Two (2) Months compared with the tests/kits delivered in the First Batch. xxx	Schedule of Requirements Page 69	Original requirement for Section VI Schedule of Requirements will remain.

The herein amendment forms an integral part of the bidding documents. Correspondingly, all other provisions in the bidding documents affected by this amendment is similarly amended or modified.

The clarification made explains in greater detail the purpose or intent of the requirement and does not amend that particular provision in the bidding documents.

For the Bids and Awards Committee III

SGD
ENGR. EDWARD R. SADDI
Chairperson

APPENDIX "A"

TECHNICAL SPECIFICATIONS

LOT NO. 1 : **Supply and Delivery of HIV Viral Load Reagents**

QUANTITY : **22,080 tests**

AGENCY SPECIFICATIONS	**BIDDER'S STATEMENT OF COMPLIANCE**	**REFERENCE**
HIV Viral Load Reagents	**Brand and Model**	
Compatible with existing equipment of National Reference Laboratories (NRLs) – San Lazaro Hospital		
Real time Polymerase Chain Reaction (PCR) Technology		
Fully automated sample preparation, reagent preparation and/or detection system		
Amplification preparation/ HIV-1 test		
analytical sensitivity: <40 copies/ml		
Shelf Life: Products must have a minimum shelf life of eight (8) months remaining at the time of delivery		
Labeling Instructions:• Standard labeling instruction as approved by PFDA pursuant Administrative Order No. 2016-0008 In addition to the labelling requirement of the FDA On each pack/box, the following should be legibly imprinted or stickered with non-removable or permanent sticker/label that is binding and with residue and tearing, if removed: "Philippine Government Property - DOH Not for Sale"		
Each corrugated carton should be legibly imprinted or stickered with non-removable or permanent sticker/label that is binding and with residue and tearing, if removed: "Philippine Government Property - DOH Not for Sale" Manufacturing Date: Expiration Date: Batch/Lot No:		

Packaging Instructions: Standard Manufacturer's/ Distributor's Packaging		
Current and valid Certificate of Product Registration (CPR) issued by the Philippine Food and Drug Administration (PFDA); Provided that in case of expired CPR the application for renewal was made timely as per PFDA Circulation No. 2011-004. The bidder shall submit any of the following whichever is applicable: • If the bidder is a manufacturer, certify that the bidder manufactures the products/items; or • If the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items, 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 • If the bidder is an agent of the exclusive distributor or dealer, the following must be provided: - Certificate or Dealership Agreement by the Manufacturer with the distributor or dealer. Valid and current License to Operate (LTO) issued by Philippine Food and Drugs Administration (PFDA) provided that in case of expired LTO, the application for renewal was made timely as per PFDA Circular No. 2011-004. Updated World Health Organization (WHO) prequalification listing in the website. Original brochure/ package insert or downloaded from the internet.		
Product Recall/Replacement: Pursuant to guidelines on product recall, FDA Circular No. 2016-012. In case of product recalls, damaged or expired medicines for replacements, the cost associated with the proper handling or pull out from health facilities where the medicines have already been distributed shall be borne by the Supplier.		

I hereby certify that the statement of compliance to the foregoing technical specifications are true and correct, otherwise, if found to be false either during bid evaluation or post-qualification, the same shall give rise to automatic disqualification of our bid.

Name of Company	Signature Over Printed Name of Authorized Representative	Date