



Republic of the Philippines
 Department of Budget and Management
PROCUREMENT SERVICE
BIDS AND AWARDS COMMITTEE



Bid Bulletin No. 1
 19 November 2018

Public Bidding No. 18-288-3

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

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 **12 NOVEMBER 2018**, likewise, respond to bidders' written queries received within the prescriptive period for filing.

A. AMENDMENTS/INCLUSIONS

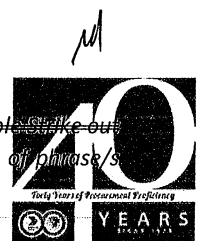
I. SECTION III. BID DATA SHEET

| <u>AMENDMENTS/INCLUSION</u> | BASES FOR AMENDMENT/INCLUSION |
|--|---|
| Page 39 Bid Data Sheet ITB Clause 5.4 xxx 5.4 For this purpose, similar contracts shall refer to any ➤ Contract for various laboratory or hospital or medical or radiological or <u>laboratory reagents or test kits.</u> xxx | To amend the similar contracts. |
| Page 44 Bid data Sheet ITB Clause 29.2 (9) xxx 9. Copy of <u>updated</u> World Health Organization (WHO) prequalification listing in the website. | To amend additional requirement for Post Qualification. |

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II. SECTION VII. TECHNICAL SPECIFICATIONS

| AMENDMENTS/INCLUSION | BASES FOR AMENDMENT/INCLUSION |
|---|--|
| <p>Technical Specifications Page 71 Lot 1: HIV Viral Load Reagents</p> <p>xxx Compatible with existing equipment of National Reference Laboratories (NRLs) <u>which is "COBAS TAQMAN 48"</u></p> <p>xxx Fully automated sample preparation or <u>sample extraction</u>, reagent preparation and detection system xxx</p> <p>Page 72</p> <p>xxx</p> <ul style="list-style-type: none"> ➤ <u>Certificate of Product Registration (CPR).</u> ➤ <u>Certificate of Exclusive/Authorized Distributor from the Manufacturer.</u> ➤ <u>Updated WHO Pre-Qualification listing in the website.</u> <p><u>The bidder shall submit any of the following whichever is applicable:</u></p> <ul style="list-style-type: none"> • <u>If the bidder is a manufacturer, certify that the bidder manufactures the products/items; or</u> • <u>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</u> • <u>If the bidder is an agent of the exclusive distributor or dealer, the following must be provided:</u> <ul style="list-style-type: none"> - <u>Certificate or Dealership Agreement by the Manufacturer with the distributor or dealer.</u> <p>xxx</p> | <p>To clarify that "COBAS TAQMAN 48" is the existing equipment used by the End-User.</p> <p>To clarify that sample preparation also refers to sample extraction.</p> <p>To include in the Technical Specification requirement.</p> <p>Please refer to revised Technical Specification Form labeled as Appendix "A"</p> |

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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 We would like to request to please consider aggregate of contracts for the requirement of SLCC to open more opportunities for the suppliers. xxx | Bid Data Sheet Lot 1 Page 39 5.4 SLCC | Original requirement for SLCC will remain. |
| ROCHE 9 (PHILIPPINES) | | | |
| 2 | Xxx We are asking for your consideration to accept the purchase order requests and invoices addressed to Roche Philippines Inc. in lieu of the SLCC requirement that is supposed to be provided by Metro Drug, Inc. xxx | Bid Data Sheet Lot 1 Page 39 5.4 SLCC | The bidder may only submit a contract wherein it is a party. |
| GETZ BROS. PHILS. INC. | | | |
| 3 | Perhaps we could also include instruments purchased which are used for viral loading extraction, preparation and detection aside from just reagents and consumables. | Bid Data Sheet Lot 1 Page 39 5.4 SLCC | Please see amendment part of this bid bulletin. |
| 4 | Technical Specifications: Fully automated sample preparation, reagent preparation (assay set up) and detection (analysis) "Clarification if "Sample Preparation" means Sample Extraction." | Technical Specifications Lot 1 Page 71 Agency Specifications | Please see amendment part of this bid bulletin. |

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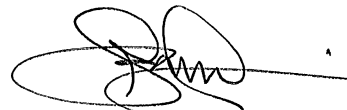
| | | | |
|-----------------------------|--|---|--|
| 5 | <p>Technical Specifications: Amplification Preparation / HIV Test version 2.0 kit of 48 test "It is quite specific to one brand. Since different brands would have different formats/ packaging, can we based it on the required number of test which is 22,080 tests in relation to the ABC."</p> | | The requirement stated in Section VII Technical Specification is retained. |
| 6 | <p>Technical Specifications: Sample input tubes, 288 pieces per rack-85, K-tips 12x36 piece per rack, K-tubes 10x96 tubes per 20 boxes "is a bit specific to one brand, can we include other ancillary consumables in the financial documents in relation to the number of test required."</p> | | The requirement of all reagents and consumables needed to run the tests stated in Section VII Technical Specification is retained. |
| 7 | <p>Technical Specifications: Analytical Sensitivity 20 copies/ml (30IU/ml) "Can we adjust/ revise this based on the WHO Guidelines of 1000 copies per ml as basis for therapeutic approach, whether to use first line or second line therapy. Which is the objective of the whole viral load monitoring program."</p> | | The requirement stated in Section VII Technical Specification is retained. |
| MACARE MEDICAL, INC. | | | |
| 8 | <p>Similar contracts: Contracts of Various laboratory reagents or test kits ... by narrowing the similar contracts to laboratory reagents or test kits, the bidders capacity to fulfil the requirements of the bidding is ensured." - "May we suggest to include the following documents under Technical Specification Required Documents: ➤ Certificate of Product Registration (CPR) ➤ Certificate of Exclusive/Authorized Distributor from the Manufacturer</p> | <p>Technical Specifications Lot 1 Page 71 Agency Specifications</p> | Please see amendment part of this bid bulletin. |

| | | | |
|----|---|--|--|
| | ➤ WHO Pre-Qualification listing in the website | | |
| 9 | Replace with Compatible with the existing equipment of NRLs or other equivalent brand of machine using NAAT or PCR Technology, with the bidder to provide the NRL-SACCL free use of one (1) unit of compatible equipment. | | Please see amendment part of this bid bulletin. |
| 10 | Quantity: 22,080 tests / cartridges | | The requirement stated in Section VII Technical Specification is retained. |
| 11 | From Fully automated sample preparation, reagents preparation and detection system to Single machine with fully-automated DNA extraction, amplification and detection." | | Please see amendment part of this bid bulletin. |
| 12 | From Analytical Sensitivity: 20 copies/ml (30IU/ml) to Analytical sensitivity or limit of detection: less than or equal to 20copies/ml (20IU/ml). | | The requirement stated in Section VII Technical Specification is retained. |

All provisions of the bidding document that are affected by newly issued bidding documents template s are deemed modified / amended / revised.

By Rules, all other related provisions in the Bidding Documents correspondingly affected by these amendments are likewise deemed amended to conform to this Bid Bulletin.

Amendments made herein shall be considered an integral part of the Bidding Documents.



ENGR. EDWARD R. SADDI
Chairperson, Bids and Awards Committee III

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APPENDIX "A"

TECHNICAL SPECIFICATIONS

LOT NO. 1 : **HIV Viral Load Reagents**

QUANTITY : **22,080 tests**

| AGENCY SPECIFICATIONS | QUANTITY | BIDDER'S STATEMENT OF COMPLIANCE |
|--|---------------------|----------------------------------|
| HIV Viral Load Reagents | 22,080 Tests | Brand |
| Compatible with existing equipment of National Reference Laboratories (NRLs) which is "COBAS TAQMAN 48". | | |
| Real time Polymerase Chain Reaction (PCR) Technology | | |
| Fully automated sample preparation or sample extraction, reagent preparation and detection system | | |
| To include all reagents and consumables needed to run tests. | | |
| - amplification preparation/ HIV-1 test, version 2.0, kit of 48 tests | | |
| - Wash reagent, bottle of 5.1 Liters – 65 Bottles | | |
| - Sample processing units, 288 pieces per pack – 85 Packs | | |
| - Sample input tubes, 288 pieces per pack – 85 Packs | | |
| - K-tips, 12x36 pieces per pack – 70 Packs | | |
| - K-tube, 10x96 tubes per box – 20 Boxes | | |
| analytical sensitivity: 20 copies/ml (30IU/ml) | | |
| Shelf Life: Products must have a minimum shelf life of eight (8) months remaining at the time of delivery | | |
| <p>Labeling Instructions:• Standard labeling instruction as approved by PFDA pursuant Administrative Order No. 2016-0008</p> <p>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:</p> <p>“Philippine Government Property - DOH Not for Sale”</p> | | |

| | | |
|---|--|--|
| <p>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:</p> <p>“Philippine Government Property - DOH Not for Sale” Manufacturing Date: Expiration Date: Batch/Lot No:</p> | | |
| <p>Packaging Instructions: Standard Manufacturer's/ Distributor's Packaging</p> | | |
| <p>Current and valid Certificate of Product Registration (CPR) issued by the Philippine Food and Drug Administration (PFDA); Provided that the application for renewal was made timely as per PFDA Circulation No. 2011-004.</p> <p>The bidder shall submit any of the following whichever is applicable:</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> - Certificate or Dealership Agreement by the Manufacturer with the distributor or dealer. <p>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.</p> <p>Updated World Health Organization (WHO) prequalification listing in the website.</p> | | |

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 |
|-----------------|---|------|



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