Republic of the Philippines
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY

PURCHASE ORDER

PROCUREMENT OF MODULAR ENZYME IMMUNO ASSAY (EIA) FOR TRANSFUSION TRANSMISSIBLE INFECTIONS (TTIs) WITH MACHINE TIE-UP

NP No. 2020-036-A

Supplier:	**LIFELINE DIAGNOSTIC SUPPLIES, INC.**	PO No. :	**GOP-2020-12-123**
Address:	**1225 Quezon Ave., Brgy. Sta. Cruz, Quezon City**	Date:	FEB 11 2021
Telephone No.	**(02) 8376-5917 - (02) 8372-1675/98**	Mode of Procurement:	Negotiated Procurement
TIN	**214-150-811-000**		

Sir/Madam:
Please furnish this office of the following articles subject to the terms and conditions contained herein:

Place of Delivery:	**Reasearch Institute for Tropical Medicine Transfusion Transmissible Infection - National Reference Laboratory (RITM TTI-NRL)**	Delivery Term:	
Date of Delivery:	**Thirty (30) calendar days upon receipt of approved Notice to Proceed (NTP)**	Mode of Payment:	***Upon Delivery and Acceptance***

Item No.	Unit	Description	Quantity	Amount
1	Lot	**MODULAR ENZYME IMMUNO ASSAY (EIA) FOR TRANSFUSION TRANSMISSIBLE INFECTIONS (TTIs) WITH MACHINE TIE-UP** **Name of Manufacturer:** Bio-Rad Laboratories (Singapore) Pte. Ltd. , Trinity Biotech Manufacturing Limited **Brand:** Bio-Rad, Trinity Biotech **Country of Origin:** France, Ireland **Technical Specification** HIV screening test (15,840 tests) HBV screening test (26,880 tests) HBV Confirmation (425 tests) HCV screening test (7,680 tests) SYPHILLIS screening test (576 tests) **I. Application/Intended Use:** **a.** This assay is intended for screening of blood donations as indicated in the IFU (Instructions for Use). **b.** A qualitative Enzyme Immuno-Assay (EIA) for the detection of the following Transfusion Transmissible Infections in human serum or plasma. HIV- HIV p24 antigen and antibodies to HIV-1 (groups M, N, and O) and HIV-2 in human serum or plasma. This can be used for both HIV- Ag and HIV-Ab screening. (HIV Ag/Ab) HBV- identification of the Surface antigen of Hepatitis B Virus (HBsAg) in human serum or plasma. Preferably with availability of anti-HBc, IgM/IgG, anti- HBc IgM and anti-HBs markers (With valid Certificate of Product Registration). MUST have Confirmatory/Neutralization test for HBsAg with valid Certificate of Product Registration. HCV- identification of Hepatitis C Virus (HCV) based on the detection of anti-HCV antibodies and capsid antigen in serum or human plasma. (HCV Ag/Ab) **II. Specimen Requirements:** Undiluted serum or plasma (collected on EDTA, Heparin, Sodium Citrate, or ACD) **III. Sample Volume:** up to 100 ul **IV. Capacity:** 1. 96 tests per run including Negative and Positive controls. 2. Includes Microplate Washer Dry Incubator and Microplate 3. Reader with printer 4. LIS ready computer system with software sample data management 5. Prints out results automatically showing Optical Densities (ODs) of samples tested and Cut off Value (COV) with indication of final results (either Non- reactive, reactive, or invalid) **V. Reagent Requirements:** Provision of kit manufacturer Positive, Negative controls and/or calibrators (if applicable), and other consumables. **VI. Evaluation and performance characteristics:** 1. Evaluated using samples from random blood donors, patients and commercial seroconversion panels by the: a. Manufacturer, with 99.9% sensitivity and at least 99.5% specificity. b. DOH-SACCL with at least: Sensitivity- 99.5% or more, Specificity- 99.0% or more c. Capable of detecting early infection as seen in the Seroconversion panel results of SACCL. 2. Approved and regulated by the Food and Drug Authority (FDA) with valid and current Certification of Product Registration (CPR). **VII. Assay Reproducibility/Validation:** Results of TTI- NRL validation coincides with that of the manufacturer's claim or within the acceptable range of the NRL.	1	5,529,087.68

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		VIII. Features of Modular Machines: 1. Includes Microplate Washer, Microplate Dry Incubator, and Microplate reader with printer. 2. LIS ready computer system with software for sample data management 3. Prints out results automatically showing Optical Densities (ODs) of samples tested and Cut off value (COV) with indication of final results (either Non- reactive, reactive or invalid). 4. LIS ready computer system with software for sample data management. a. ELISA Reader i. full traceability and large memory storage of results ii. long life lamp with lamp saver features with external printer iii. wavelength range: 400-700 nm iv. supplied filters: 405nm, 450nm, 492nm, 620 or 630nm, with 4 free positions for optional filter v. Reading speed: less than 15 secs for single wavelength, less than 20 secs for dual wavelength. b. ELISA Washer i. Easy windows operation ii. washes flat, U and V bottom strips and plates iii. 12 way or 8 way manifold, automatic and manual positioning iv. large memory (up to 50 wash protocol) v. automatic monitoring for vacuum and pressure vi. automatic rinse cycle, washing pressure, priming and draining. vii. volume and time adjustable viii. liquid level detection and alert functions ix. no special airtight bottle required for wash bottle c. Incubator i. 2 or more plate incubator ii. Temperature range: 25-60 degree Celcius iii. Temperature accuracy: +/-0.5 degree Celcius d. Consumables: i. With printer toner or ink for entire contract duration. ii. With software and hardware upgrade if any iii. With installation of machine to include quarterly preventive maintenance and calibration. iv. In case of machine malfunction, availability of the service personnel within office hours. (8AM-5:30PM) v. Procuring entity shall not be liable to purchase the minimum amount in cases of force majeure, fire, flood or any event beyond its control. **IX. Standard requirement of the equipment:** 1. Power Supply: 230V, 60Hz 2. Functional Equipment 3. Includes installation, testing and commissioning 4. On-site calibration and validation with certification of conformity or equivalent 5. Actual demonstration and on-site training for 10 end- users with certificate 6. Semi-annually Preventive Maintenance Calibration or as the need arises upon request of the end-user with certificate and calibration sticker. 7. Prompt provision of technical support/assistance from Engineer and/or Product Specialist anytime when deemed necessary or during emergencies. 8. With provision of English operation and service manuals. 9. Provision of a back up modular machines to be returned upon consumption of reagents. **X. Additional End-User Requirements:** 1. Provision of at least two sets of modular machines during TTI Proficiency Workshop to be returned after every training. 2. Provision of fully automated machine in case of researches and when deemed necessary.		

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		B. Additional Requirements to be attached with this form arranged, numbered and tabbed as enumerated below: 1. Valid Certificate of Product Registration (CPR) issued by Philippine Food and Drug Administration (PFDA) or valid extension The CPR must be valid for the entire period of the award. If the CPR 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) as Medical Device Importer/ Wholesaler issued by PFDA. Provided that in case of expired LTO, the application for renewal was made timely as per PFDA Circular No. 2011-004. **In case of expired LTO, the following copies may be submitted:** a. Expired LTO; b. Application for renewal; and c. Official Receipt as proof of payment of renewal of LTO **3. The bidder shall submit any of the following whichever is applicable:** a. If the bidder is a manufacturer, certify that the bidder manufactures the products/items; or b. 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 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. Contract between the distributor/dealer and the bidder 4. Original brochure or downloaded from internet or product insert in English and any manufacturer's un-amended sales literature, unconditional statements of specification and compliances issued by the manufacturer, independent test data, etc., as appropriate for cross-referencing statement of compliance to the technical specification as indicated in the 2nd page of Section VII: Technical Specifications of this bidding documents; 5. Valid and current Certificate of Compliance with ISO 13485 of the Manufacturer of the offered product that was issued by an independent ISO Certifying Body; 6. Guarantee letter from Supplier to replace item with approved shorter shelf life when returned three (3) months before expiry date. 7. Certification or proof from the participating bidder of at least 1 local and 2 international installations; 8. Sworn Statement using the prescribed form.		
		C. Upon delivery the following shall be complied: **1. Shelf Life:** a) Must be fresh commercial stock with a total shelf life of at least 10 months from the date of delivery. b) Item maybe of shorter shelf life, replacement for fresh stocks shall be issued when returned three (3) months before expiry date. A guarantee letter from the Supplier is required as part of Post-qualification **2.** Lot number in the first tranche of delivery must be of the same batch valid for at least ten (10) months from the date of delivery while the lot number in the second tranche of delivery must of the same batch valid for at least ten (10) months from the date of delivery. **3. Packaging Instructions:** Standard packaging of the manufacturer		

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4. Labeling Instructions:

Each small and bigger box/carton the following shall 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 FOR SALE"

Date of Manufacture:_____
Date of Expiry:_____
Batch/ Lot No.:_____

E. Recall & Disposal:

1. In instances of product recall due to failures of the suppliers and manufacturers to comply with the standards of safety and quality, the cost associated with the 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 FDA Circular No. 2016-012 or the latest policy for disposal).

2. In cases of expired items, the health facility shall bear the cost for disposal. The disposal of the expired goods shall be coordinated through a third-party accredited by the Department of Environment and Natural Resources (DENR), engaged by Administrative Service (AS) of the DOH health facility, subject to compliance to applicable laws.

3. The item is with approved shorter shelf life, replacement for fresh stocks shall be issued when returned three (3) months before expiry date.

Purpose: For the use of Reaserch Institute for Tropical Medicine Transfusion Transmissible Infections - National Reference Laboratory (RITM TTI-NRL)

Note: Subject to the conditions stated in the Request for Best and Final Offer

PS / COBAC
APPROVED PO / CONTRACT
Received by:
Date:

PS / COBAC
RELEASED: PO / CONTRACT
by:
Date: MAR 10 2021

Five Million Five Hundred Twenty-Nine Thousand Eighty-Seven Philippine Pesos and Sixty-Eight Centavos	**5,529,087.68**

Liquidated Damages (Section 68 of the Revised IRR of RA 9184: All contracts executed in accordance with the Act and this IRR shall contain a provision on liquidated damages which shall be payable by the contractor in case of breach thereof. For the procurement of Goods, Infrastructure Projects and Consulting Services, the amount of liquidated damages shall be at least equal to one-tenth of one percent (0.001) of the cost of the unperformed portion for every day of delay. Once the cumulative amount of liquidated damages reaches ten percent (10%) of the amount of the contract, the Procuring Entity may rescind or terminate the contract, without prejudice to other courses of action and remedies available under the circumstances.

Warranty (Section 62 of the Revised IRR of RA 9184): In order to assure that manufacturing defects shall be corrected by the supplier, a warranty security shall be required from the contract awardee for a minimum period of three (3) months, in the case of Expendable Supplies, or a minimum period of one (1) year, in the case of Non-expendable Supplies, after acceptance by the Procuring Entity of the delivered supplies. The obligation for warranty shall be covered by either retention money in an amount equivalent to at least one percent (1%) but not to exceed five percent (5%) of every progress payment, or a special bank guarantee equivalent to at least one percent (1%) but shall not exceed five percent (5%) of the total contract price. The said amounts shall only be released after the lapse of the warranty period, or, in the case of Expendable Supplies, after consumption thereof: Provided, however, that the supplies delivered are free from patent and latent defects and all the conditions imposed under the contract have been fully met.

By Authority of the Secretary of Health:

Conforme:

JOHN RIWENT S. GIANAN
Signature Over Printed Name of Supplier (Authorized Representative)
2-11-21
Date

NESTOR F. SANTIAGO, JR., MD, MPHC, MHSA, CESO II
Assistant Secretary of Health
Public Health Services Team

Fund Cluster: CAF 132

Funds Available: 022324
FILIPINA V. VELASQUEZ, CPA, MM
OIC-FMS ACCOUNTING DIVISION
Signature over Printed Name of Chief Accountant/Head of Accounting Division/Unit

ORS/BURS No.: 02-102|0|-2021-07-00310

Date of the ORS/BURS: 2/22

Amount: 5,529,087.68