Republic of the Philippines
NATIONAL POLICE COMMISSION
NATIONAL HEADQUARTERS, PHILIPPINE NATIONAL POLICE
OFFICE OF THE CHIEF, PNP
Camp BGen Rafael T Crame, Quezon City

MEMORANDUM CIRCULAR
NO.: 2021-065

20 MAY 2021

TEST PARAMETERS IN THE CONDUCT OF TEST AND EVALUATION FOR IMMUNOASSAY ANALYZER

1. **REFERENCES:**
   a. Republic Act (RA) No. 9184 entitled: "An Act Providing for the Modernization, Standardization and Regulation of the Procurement Activities of the Government and for Other Purposes and its Revised Implementing Rules and Regulation (IRR)";
   b. NAPOLCOM Resolution No. 2020-0061 entitled: "Prescribing the Minimum Standard for Immunoassay Analyzer" dated January 29, 2020;
   c. PNP Memorandum Circular (MC) No. 2020-089 entitled: "Approving the Minimum Specifications for Minimum Technical Specifications for Immunoassay Analyzer" dated December 14, 2020; and
   d. Uniform and Equipment Specification Board Resolution No. 2020-028 entitled: "Approving the Minimum Specifications for Minimum Technical Specifications for Immunoassay Analyzer" dated October 2020.

2. **RATIONALE:**

This Memorandum Circular (MC) covers all the components of Immunoassay Analyzer to be procured by the Philippine National Police (PNP).

3. **SITUATION:**

The Immunoassay Analyzer will be used by the PNP General Hospital to enhance its capability on testing patient samples for a variety of substances. It can perform a variety of test for infectious diseases, allergies, cardiac markers, endocrine hormone, protein and viral, or bacterial toxin determinations.

4. **PURPOSE:**

   a. To establish policy guidelines and test parameters for the conduct of functional test and evaluation for Immunoassay Analyzer purposely to enhance the capability of the PNP Health Service (HS) through acquisition of essential equipment; and
   b. The equipment will be used by the clinicians of the PNP HS to identify and quantify specific substances using an antibody as a reagent, to detect the substance of interest.

5. **DEFINITION OF TERMS:**
For purposes of this MC, the following terms shall mean:

a. Bacterial Endotoxins Test (BET) – refers to a test to detect or quantify endotoxins from Gram- negative bacteria using amoebocyte lysate from the horseshoe crab (Limulus polyphemusor).

b. Cardiac Markers – refer to biomarkers measured to evaluate heart function. They can be useful in the early prediction or diagnosis of disease.

c. Chemiluminescence – refers to the emission of light, as the result of a chemical reaction. There may also be limited emission of heat.

d. Enzyme-linked Immunosorbent Assay (ELISA) – refers to a commonly used analytical biochemistry assay, first described by Engvall and Perlmann in 1971. The assay uses a solid-phase type of enzyme immunoassay to detect the presence of a ligand in a liquid sample using antibodies directed against the protein to be measured.

e. Immunoassay – refers to a biochemical test that measures the presence or concentration of a macromolecule or a small molecule in a solution through the use of an antibody or an antigen.

f. Molecule – refers to an electrically neutral group of two or more atoms held together by chemical bonds.

g. Plasma – refers to an ionized gas consisting of positive ions and free electrons in proportions resulting in more or less no overall electric charge, typically at low pressures (as in the upper atmosphere and in fluorescent lamps) or at very high temperatures (as in stars and nuclear fusion reactors).

h. Retrovirus – refers to any of a group of viruses that belong to the family Retroviridae and that characteristically carry their genetic blueprint in the form of ribonucleic acid (RNA). Retroviruses cause tumor growth and certain cancers in animals and are associated with slow infections of animals.

i. Serum – refers to the fluid and solute component of blood which does not play a role in clotting. It may be defined as blood plasma without fibrinogens.

j. Windows-based program – refers to a software that is designed to work on a computer running the Microsoft Windows operating system.

6. **GUIDELINES:**

a. The Directorate for Research and Development shall function as independent testing facility of the PNP. As required, its personnel shall perform their duties and functions pursuant to the PNP MC 2015-015;

b. The post-qualification test and the conduct of inspection and acceptance test shall be based on the most recent standard issued by

NAPOLCOM and the specifications issued by the PNP for Immunoassay Analyzer;

c. Additional technical requirements imposed by the Bids and Awards Committee (BAC) may only be considered in the conduct of test if the same are accurately reflected in the bidding documents or in its supplemental bid bulletin (SBB). Likewise, in case there is a need to conduct additional tests, which are not included in the approved test parameters, the same may be allowed only if the additional test parameters are accurately reflected in the bidding documents or in its SBB;

d. Government Procurement Policy Board (GPPB) Circular No. 06-2016 with subject "Expenses Related to the Conduct of Post-Qualification" shall be observed during the conduct of post-qualification. Hence, the administrative and operational expenses shall be charged to the proceeds of the sale of the bidding documents as indirect cost of administrative cost pursuant to GPPB Resolution No. 04-2012;

e. On the other hand, administrative and operational expenses for the conduct of test and evaluation during inspection and acceptance shall only be imposed upon the supplier if the same were included in the computation of the Approved Budget for the Contract and integrated in the preparation of the Project Management Plan;

f. Consistent with the "pass or fail criteria," non-compliance with the NAPOLCOM-Approved Standard and PNP Specifications during post-qualification test is a ground for post-disqualification;

g. If during the inspection and acceptance test, the items delivered by the supplier failed to pass any test and/or inspection or do not conform with the specifications, the same shall be subject to the provision of clause 16.4 of the General Conditions of the Contract of the Philippine Bidding Documents;

h. Samples submitted for post-qualification and acceptance test and evaluation shall not be considered part of the delivered items, unless otherwise specifically provided in the bidding documents. Except in cases where samples are considered part of the delivered items or when a Motion for Reconsideration is filed by the suppliers with the BAC or Committee on Inspection and Acceptance, all samples submitted shall be returned to the suppliers immediately after the termination of the post-qualification and acceptance test and evaluation; and

i. All the members of the Technical Working Group (TWG) shall sign the result of the post-qualification and acceptance test and evaluation. In case there are disagreements on the findings of the TWG, the member who did not conform with the findings/results is allowed not to sign the report, provided that he will submit his written explanation, which shall be attached to the report of the TWG.

CERTIFIED PHOTO COPY FROM THE ORIGINAL

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7. **PROCEDURES:**

a. Preparation of Reagents and Samples: The proponent must provide the required reagents and samples for testing.

b. Visual/Dimensional and Technical Specifications Evaluation

1) Purpose: To ascertain if the Immunoassay Analyzer conforms with the NAPOLCOM-Approved Standard and PNP Specifications through the conduct of visual, dimensional, and technical specification evaluation.

2) Procedures: To validate the visual, dimensional and technical specifications of the equipment based on the brochure submitted, and/or actual inspection/evaluation of the equipment for its conformity as indicated in NAPOLCOM-Approved Standard, PNP-Approved Specifications and other requirement.

3) Standard: The Immunoassay Analyzer must conform with the NAPOLCOM-Approved Standard, PNP-Approved Specifications, and other requirements. Any defect noted during the test shall be classified as major defect and a basis for disqualification or non-acceptance of the items.

	Standard	Class of Defects
a)	The item should be tidy and must not have any disfigurements, such as deflection and hollowness.	Major
b)	All components must be complete and compatible	Major
c)	Must be provided with brochure with certification/warranty.	Major

c. Functional Test

Note: A technician or authorized trained representative of the proponent must be present to operate or guide the actual operation of the equipment.

1) Purpose: To ensure that the Immunoassay Analyzer is in good working condition.

2) Preparation/Installation of the Instrument: Prior to functional test, necessary installation of all complimentary equipment and accessories, and verification of the operational condition of the Immunoassay Analyzer must first be established. Any abnormal performance or condition that was detected must be referred to the supplier.

3) Actual Test: A functional test must be performed based on the operational manual of the Immunoassay Analyzer.

4) Standard: The submitted/delivered Immunoassay Analyzer must be able to deliver its purpose and perform all the required tests. Any

defect noted during the test shall be classified as major defect and its basis for post-disqualification or non-acceptance of the item.

Particulars		Standard/ Secifications	Test Procedure	Class of defects
a)	System	Must have auto-sampler, reagents dispenser, washer and detector	Demonstration	Major
b)	Sensor	Must have clot and sample level detection	Demonstration	Major
c)	Type	Must be floor or bench-top	Visual Inspection/ Review	Major
d)	Contamination	Must avoid sample carryover (disposable pipette tips)	Demonstration	Major
e)	Sample Position	Must have at least 84 sample tubes	Visual Inspection	Major
f)	Power Supply	Must have 100 to 240 volts	Visual Inspection and Testing using volt meter	Major
g)	Parameters	Must be at least capable to run hepatitis, HIV profile, Retroviruses, and other infectious disease markers to include TORCH or - Toxoplasmosis - Other diseases including HIV, syphilis and Hepatitis B - Rubella or German Measles - Cytomegalovirus - Herpes Simplex	Visual Inspection and Testing Certificate of Product Registration from FDA	Major
h)	Sample Type	Must be Serum, Plasma and Urine	Validation through Test Demonstration	Major
i)	Result	Can be available, viewed, editable and analyzed	Actual Demonstration	Major
j)	Techniques/ Principles	Must have an ELISA or Chemiluminescence	Brochure Validation through Actual Demonstration	Major

k)	Integrity Control	Can validly read test order	Actual Demonstration	Major
l)	Display	Must be colored or have LCD screen	Demonstration and Inspection	Major
m)	Software	Must have Windows-based software or better	Brochure validation through actual inspection	Major
n)	Memory Storage	Must have an internal memory for patient and event results	Brochure comparison through Inspection	Major

d. Parallel Testing

Process	Expected Output	Class of Defect
Run the sample in the new Immunoassay machine and send same sample to the appropriate national reference laboratory.	The result must conform with the standard of the national reference laboratory.	Major

8. **REPEALING CLAUSE:**

All previous MCs inconsistent with the foregoing are hereby modified, amended, or repealed accordingly.

9. **EFFECTIVITY:**

This MC shall take effect after 15 days from filing a copy thereof at the University of the Philippines Law Center in consonance with Sections 3 and 4, Chapter 2, Book VII, E.O. No. 292, otherwise known as the "Revised Administrative Code of 1987," as amended.

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