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

MAY 20 2021

MEMORANDUM CIRCULAR
NO.: 2021 - 062

TEST PARAMETERS IN THE CONDUCT OF TEST AND EVALUATION FOR REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION SYSTEM

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. 2020-0761, entitled: "Prescribing the Minimum Standard for Reverse Transcription Polymerase Chain Reaction System" dated September 11, 2020;

   c. PNP Memorandum Circular (MC) No. 2020-084 entitled: "Approving the Minimum Specifications for Reverse Transcription Polymerase Chain Reaction System" dated December 3, 2020; and

   d. PNP Uniform and Equipment Specification Board Resolution No.2020-027 entitled: "Prescribing the Minimum Specifications for Reverse Transcription Polymerase Chain Reaction System" dated October 22, 2020.

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POLICE LIEUTENANT COLONEL
Chief Administrative Section

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2. **RATIONALE:**

This Memorandum Circular (MC) covers all the components of Reverse Transcription Polymerase Chain Reaction (RT-PCR) System to be procured by the Philippine National Police (PNP).

3. **SITUATION:**

The RT-PCR System will be procured by the PNP to strengthen its fight against COVID -19. It has a temperature control technology and its thermal cycling exposes reactants in repeated cycles of maximum heating and cooling to permit different temperature-dependent reactions.

4. **PURPOSE:**

   a. To establish policy guidelines and test parameters for the conduct of functional test and evaluation for RT-PCR System to be used by the PNP in its procurement; and

b. The RT-PCR System will be used by the PNP in medical laboratory and clinical research for a broad variety of applications including biomedical research and criminal forensics.

5. **DEFINITION OF TERMS:**

For purposes of this MC, the following terms shall mean:

a. **Amplify** - refers to the increase of the volume, especially using an amplifier.

b. **Charge-Coupled Device (CCD) Camera** - refers to a video camera that contains a CCD, which is a transistorized light sensor on an integrated circuit. In plain English, CCD devices convert or manipulate an electrical signal into some kind of output, including digital values.

c. **Dynamic Range** – refers to the ratio between the largest and smallest values that a certain quantity can assume. It is often used in the context of signals, like sound and light. It is measured either as a ratio or as a base-10 or base-2 logarithmic value of the difference between the smallest and largest signal values.

d. **Deoxyribonucleic Acid (DNA) Sequencing** - refers to the process of determining the sequence of nucleotides within a DNA molecule.

e. **Excitation** – refers to the state of enhanced activity or potential activity of a cell, organism, or tissue that results from its stimulation.

f. **Fluorescent Amidite (FAM)** – refers to the most commonly used fluorescent dye attachment for oligonucleotides and is compatible with most fluorescence detection equipment.

g. **Linear** - relating to, resembling, or having a graph that is a line and especially a straight line.

h. **Multiplex PCR** – refers to a widespread molecular biology technique for amplification of multiple targets in a single PCR experiment. In a multiplexing assay, more than one target sequence can be amplified by using multiple primer pairs in a reaction mixture.

i. **Nucleic Acid** – refers to a complex organic substance present in living cells, especially DNA or Ribonucleic Acid (RNA), whose molecules consist of many nucleotides linked in a long chain.

j. **Oligonucleotides** – refer to short DNA or RNA molecules, oligomers, that have a wide range of applications in genetic testing, research, and forensics.

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k. **Pathogen** – refers to any organism such as a virus, fungus, or a bacterium that causes a disease in another organism. Diseases caused by organisms can range from the common cold to food poisoning to meningitis. They can be spread in many ways, such as by coming in contact with bodily fluids, ingesting undercooked food, or swimming in contaminated water.

l. **Peltier** - refers to the cooling of one junction and the heating of the other when electric current is maintained in a circuit of material consisting of two dissimilar conductors; the effect is even stronger in circuits containing dissimilar semiconductors.

m. **Peltier Effect** – refers to a created heat flux at the junction of two different types of materials.

n. **Photomultiplier Tubes (PMT)** - refer to members of the class of vacuum tubes, and more specifically vacuum phototubes, extremely sensitive detectors of light in the ultraviolet, visible, and near-infrared ranges of the electromagnetic spectrum. These detectors multiply the current produced by incident light by as much as 100 million times or 108, in multiple dynode stages, enabling individual photons to be detected when the incident flux of light is low. Dynodes inside a photomultiplier tube.

o. **Photodiode** – refers to a semiconductor device that converts light into an electrical current. The current is generated when photons are absorbed in the photodiode. Photodiodes may contain optical filters, built-in lenses, and may have large or small surface areas. Photodiodes usually have a slower response time as their surface area increases.

p. **Primer** – refers to a single stranded nucleic acid utilized by all living organisms in initiation of DNA synthesis.

q. **Sensitivity** - refers to the quality or state of being sensitive: such as. the capacity of an organism or sense organ to respond to stimulation.

r. **YBR Green** - refers to an asymmetrical cyanine dye used as a nucleic acid stain in molecular biology. The SYBR family of dyes is produced by Molecular Probes Inc., now owned by Thermo Fisher Scientific. SYBR Green binds to the DNA.

6. **GUIDELINES:**

a. The Directorate for Research and Development shall function as independent testing facility of the Philippine National Police (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 RT-PCR System;

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. During the inspection and acceptance, the procuring entity may reject any goods or any part thereof that fail to pass any test and/or inspection or do not conform to the specifications;

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.

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7. PROCEDURES

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

b. Visual/Dimensional and Technical Specifications Evaluation.

1) Purpose: To ascertain if the RT-PCR System 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 requirements.

3) Standard: The RT-PCR System must conform with the NAPOLCOM-Approved Standard and must comply with 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)	Manual, brochures, and copy of the certification of the equipment must be provided.	Major
c)	All components must be complete, compatible, and functional.	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 RT-PCR System 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 RT-PCR System must be first 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 RT-PCR System. 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	Test Procedure	Class of Defect
a)	Hardware	Must have a minimum of 96 wells	Validation through Visual Inspection and Brochure	Major
b)	Software	Must have a multiple PCR in simultaneous detection of five targets	Brochure validation through demonstration	Major
c)	Dynamic Range	Must have at least nine orders of magnitude or logs of Linear	Procedural demonstration	Major
d)	Temperature Control Technology	Must be Peltier	Procedural demonstration	Major
e)	Heating and Cooling	Must be 6.0°C/s maximum	Procedural demonstration	Major
f)	Temperature Accuracy	Must have a ± 0.25°C maximum	Procedural demonstration	Major
g)	Temperature Uniformity	Must have a ± 0.50°C 30 seconds after clock start	Procedural demonstration and visual inspection	Major
h)	Compatible/ Supported Dyes	Must have at least FAM/SYBR Green	Procedural demonstration	Major
i)	Temperature Range	Must have at least 4 to 100°C	Demonstration	Major
j)	Reaction Volume Range	Must have at least 1 to 50 µl	Visual inspection	Major
k)	Sensitivity	Must have at least a single copy	Process Demonstration	Major
l)	Excitation	Must have at least halogen lamp	Process Demonstration	Major
m)	Detection Device	Must be CCD camera or PMT	Brochure validation through inspection	Major

n)	Channels	Must have at least five channels	Brochure validation though demonstration	Major

d. Certificate of Product Registration from the Food Drug Administration (FDA).

Process	Test Procedure	Class of Defect
Must have an approved product registration from the Food and Drug Administration	Check	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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