



PHILIPPINE SOCIETY OF PATHOLOGISTS, INC.

Diagnostic Testing Strategies to Manage COVID-19 Pandemic

Proposed by the Philippine Society of Pathologists, Inc.

The **Philippine Society of Pathologists, Inc. (PSP)** is an organization of physicians specializing in Pathology and Laboratory Medicine. It is one of the eight recognized specialty members of the **Philippine Medical Association**. It has a membership of over 1,000, whose specialization and sub-specializations are in various areas including Molecular Pathology and Immunopathology. It stands in solidarity with the rest of the nation in its fight against SARS-COV-2.

To date, the country has not gained inroads in producing significant number of SARS- COV-2 PCR testing. In over 3 months only 307,813 of cumulative tests, 283,147 tests of cumulative unique individuals have been deployed (*doh.gov.ph/covid19tracker, May 25, 2020*). This only represents less than 1% of over 110 million population who have been tested in the Philippines. A 7.6 % incidence has been established from a total of 21,643 positive cases identified, out the 283,147 unique samples tested. Country incidence rates and prevalence studies have not yet been established.

The RT-PCR which is the gold standard for SARS-COV-2 testing is a laborious procedure requiring high levels of sophisticated equipment, engineering and biosafety standards, controls, and personnel proficiency. The molecular testing technology is expensive and is not readily available in the country, although there is now a widely concerted effort to establish molecular pathology laboratories nationwide.

To flatten the COVID-19 curve, the PSP is proposing the formulation of an **expanded targeted testing strategy**. This will enlarge the population base of persons to be tested in the country in order to identify and survey the asymptomatic carriers who shed the SARS-COV-2 virus and unknowingly infect the community.

The proposed **expanded targeted testing strategy** will not test all of the 110 million Filipinos, but rather **escalate** the testing population base to the **Asymptomatic Population** who are at risk and those communities with high prevalence.

For this purpose, **expanded targeted testing** will be defined as an enhanced, wider based purposive testing, designed to test a greater number of **asymptomatic** populations at risk, based on robust scientific and epidemiologic data.

We propose an expanded targeted testing for screening **asymptomatic populations** to be conducted in the following situations:

- A. High prevalence communities for epidemiologic surveillance and aggressive contact tracing
- B. Health care workers with low risk exposure
- C. Workplace testing
- D. Border testing at airports and seaports for inbound foreign travelers and returning residents
- E. Overseas deployment of OFWs
- F. Returning OFWs
- G. Frontline government workers (police, military, quarantine, immigration officers to name a few)

Predictably, this will entail millions of PCR tests to be conducted. In a resource-poor environment, this is not practical. In addition, countries all over the world are suffering from the unavailability and shortage of diagnostic tests and supplies as cases continue to rise.

The disparity between the required number of reagent kits and the actual number needed to be tested has impeded efforts of DOH to identify and isolate infected individuals. In most cases, testing is restricted mainly towards symptomatic cases, with the vast number of asymptomatic cases going undetected.

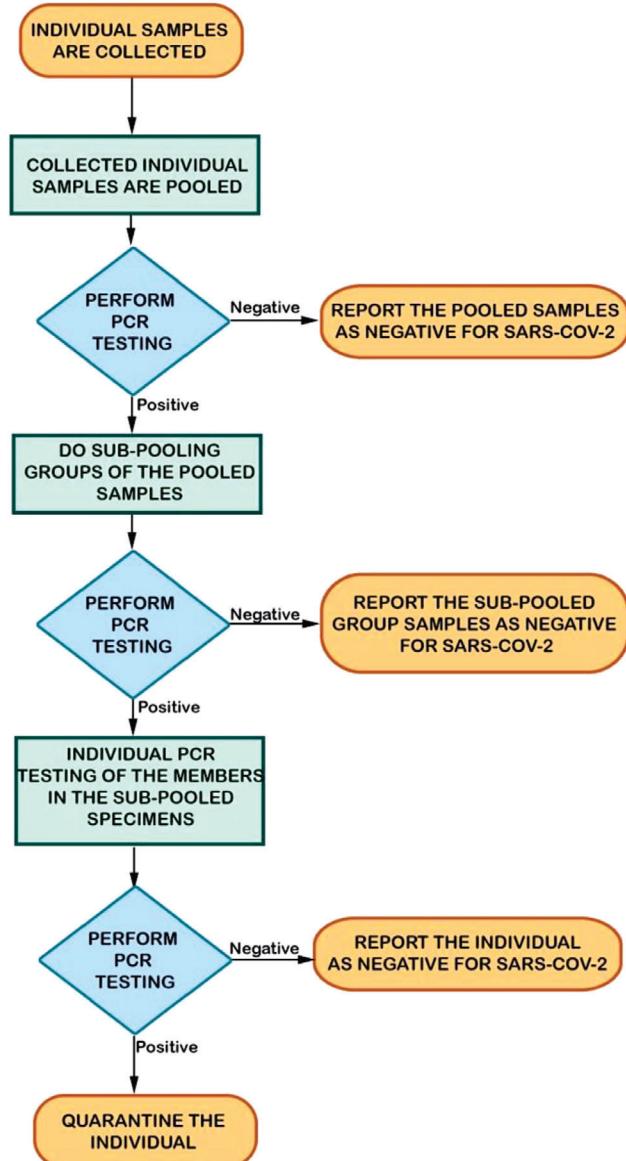
In order to achieve a significant and expanded number of target populations to be tested, there must be a comprehensive and cost-effective strategy in place. The Philippine Society of Pathologists, Inc. proposes the following:

I. THE USE OF MOLECULAR BASED PCR TESTING

A. "Smart Pooled Sample Testing"

This procedure will help meet the high demand of testing SARS-COV-2 in the early identification and isolation of **asymptomatic individuals**. The pooling of samples before nucleic acid testing is a safe and well-established procedure in blood banking. We recommend using this as well, in expanded and targeted screening for SARS-COV-2.

We propose two algorithms in the conduct of pooled testing of **asymptomatic individuals** during expanded targeted testing using:

**Algorithm A.** Algorithm for PCR pooled testing in asymptomatic individuals.

*Size of pools and subpools will depend on the prevalence of COVID-19 in the target population.

A1. Pooled nasopharyngeal / oropharyngeal samples for direct RT-PCR testing (Algorithm A)"

*Samples from several individuals are collected and uniquely identified from nasopharyngeal or oropharyngeal swabs. The samples are then pooled and tested together in a single tube using standard RT-PCR method. If a **POSITIVE** result is achieved from a pooled sample, this will be tested individually. If a negative pooled sample is achieved, all the samples are issued a **NEGATIVE** result.

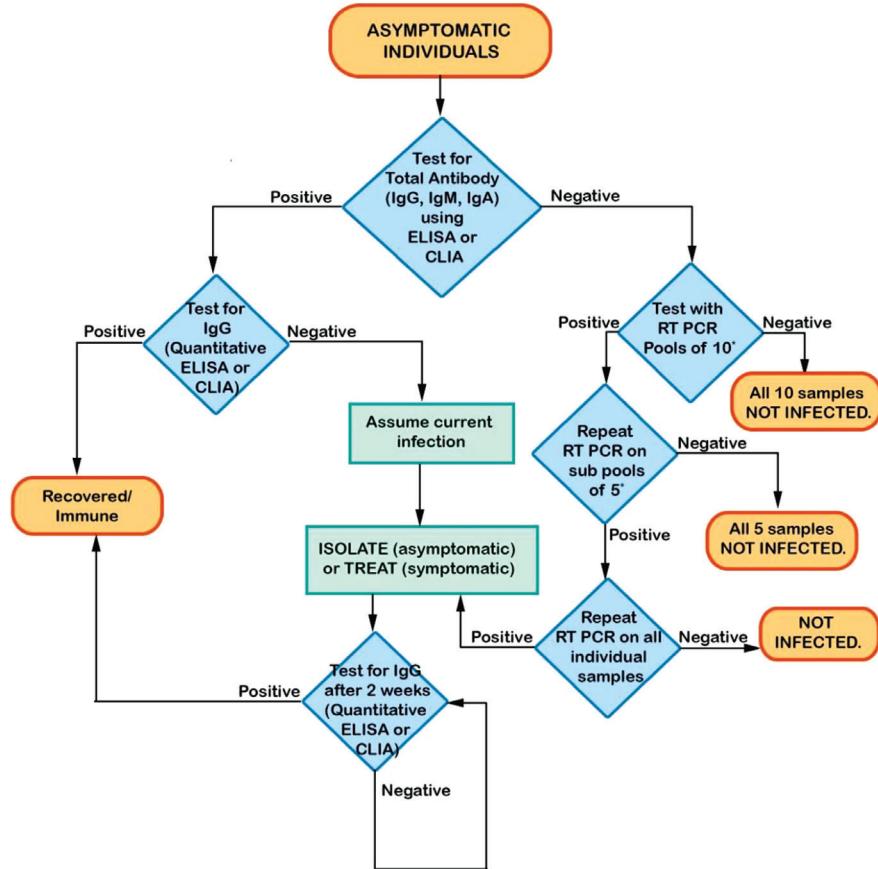
The number within the pooled sample would have to be guided and determined by robust statistical and epidemiologic data. When the infection rate in a given population is low and only a few people are infected, pool testing can significantly expand the testing capacity of the existing laboratory infrastructure.

In other countries (Pakistan, India, Israel, some EU countries), the pooled sample number ranged from 5-63

pooled samples. The higher the prevalence, the lower the recommended sample pool.

In our setting, we recommend a pooled sample range of 5-30 based on the risk, prevalence and suspected incidence. In case one of these 5-30 pooled samples turn out to be positive, same will be subjected to sub-pooling containing lower number of samples for PCR. The pooled sample that will turn out to be positive, will then be individually tested by PCR. This method would need to be scientifically validated by our COVID-19 PCR testing laboratories.

This strategy will considerably reduce the workload and conserve the much-needed PCR resources in the country (approximately 60-80% reduction); provide a more cost-effective method of testing and ramp up the number of populations to be screened for appropriate contact tracing and surveillance.



Algorithm B. Algorithm for identifying COVID-19 cases using combined serological and pooled polymerase chain reaction testing.

*The size of the initial pooled samples are best determined by the PCR laboratory based on available epidemiological data and the succeeding sub-pooling of individuals can be based on the size of the initial pooled sample. Sub-pooling may also be skipped if the initial pool size is small (e.g. 5 or less).

A2. Initial antibody testing using instrumented laboratory-based methods like ELISA and CLIA. (Algorithm B)

The rationale of the algorithm using instrumented antibody testing (**Algorithm B**) is that laboratory-based antibody tests are already available in the market. The instrumentation for such tests is already in place in many hospital laboratories, thus eliminating the need for capacity building, both in equipment and personnel. This is much faster and cheaper than molecular methods for screening purposes but will not replace it, rather they are meant to conserve and supplement molecular assays.

The laboratory based instrumented assays are **superior** to rapid antibody tests as they have undergone more scrutiny and validation, both internal and external before their introduction.

We recommend the pooling method for RT-PCR assays to reduce the volume of testing and facilitate clearance of low risk individuals. Negative serological tests will be subjected to pooled samples for PCR.

High risk individuals (symptomatic, frontline health care workers and those with history of exposure) should be tested individually. The pooling method will greatly reduce the limited resources, workload of the RT-PCR laboratories and reduce work-related injuries and illnesses due to fatigue.

We recommend the use of instrumented method of antibody testing for reasons of increased throughput that is required in expanded testing, coupled with higher analytical performance (better accuracy, sensitivity, specificity and lower limits of detection).

The use of Rapid Antibody Test kits is NOT recommended because of poor sensitivity and specificity, leading to higher false negatives and false positive which will ramp up for the need of PCR testing.

B. Ensuring efficient proactive supply chain management of PCR test kits/supplies and streamlining operations in COVID-19 testing

B1. Putting up a dedicated agency within DOH which will efficiently provide the following functions:

- Central management and tracking of inventories of reagents and supplies to ensure adequacy and availability;
- Repository of information on the source, origin, updated prices of reagent and supplies for end users. The PSP can assist DOH in the securing of this information.

C. Streamlining operations in COVID-19 testing.

- C1. Reduce the documentation requirements to be sent to various DOH agencies that do not add value to the testing process and increases the length of the turn-around-time, e.g. reporting for negative data, sub-national laboratories submission of daily work sheets to RITM.*
- C2. Review the reporting protocol for COVID-19 testing to reduce unnecessary documentation.*

D. Simplify licensing requirements for COVID -19 testing laboratories

- D1. To comply with the training requirements for COVID-19 testing, the PSP is willing to assist DOH/RITM by conducting recognized training modules in Molecular Pathology and Biosafety/Biosecurity procedures for pathologists, medical technologists and other relevant health care workers.*
- D2. Review and harmonize the licensing requirements of Rapid PCR testing that are not appropriate for the technology, like facility site, equipment, training and personnel.*

E. Use of Rapid PCR testing like GeneXpert technology

- E.1 Ensure that the donated GXP cartridges be deployed in hospital settings which require immediate results for management and decision making, e.g. critical care, pre-operative requirements and medical emergencies.*
- E.2. The donated cartridges should be deployed to the hospitals to allow immediate access and service delivery.*

II. THE EFFECTIVE, EFFICIENT UTILIZATION OF ANTIBODY TESTING

A. Antibody testing has a role in COVID-19 management. It is cost-effective strategy for the following situations:

- Workplace and conditions for return to work
- Epidemiologic surveillance for prevalence and population immunity
- Research

B. There are differences in analytical performance of different serologic methods. The prudent use of these should be based on performance characteristics of the different analytical methods in order to reduce incidence of false negatives and false positives.

C. We recommend the use of instrumented assays for Antibody testing using ELISA and ECLIA on the following basis:

- Higher throughput and turn-around-time, desirable in an expanded testing program
- Earlier detection of antibody levels in patients who are exposed
- Excellent analytical specificity and sensitivity
- Lower detection limit which allows to identify population with low antibody titers
- Less interferences and cross-reactivities
- Use of quantitative immunoassays and will allow for detection of neutralizing antibodies

D. Based on the Clinical laboratory Law (RA No. 4688, June 18, 1966) and AO 2007- 0027, laboratory tests must be performed and supervised by a Clinical Pathologist and results are issued by a licensed clinical laboratory. This is to ensure quality of test results and to assure the protection and safety of both personnel and environment.

In summary, we, the **Pathologists** stand ready to be in the forefront of diagnostic testing during this pandemic. We propose expanded targeted testing algorithms combining molecular virus detection and laboratory-based antibody assays in an effort to reduce transmission of SARS-CoV-2 in the Filipino population. We will win this battle and together we can heal as one.

For the Philippine Society of Pathologists, Inc:

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