

# COVID-19

## -An opportunity for strengthening laboratories and health systems in the region

**Diagnostics and Laboratory capacity are essential but often ignored pillars of both a responsive health system and effective global health security.**

**T**he Coronavirus pandemic has, more starkly than ever before, highlighted the critical importance of accurate, reliable and timely laboratory testing for diagnosis, patient care and management and understanding the scope of viral transmission, thereby protecting national, regional and global health security. For those of us that live in the Caribbean, as we watched the COVID-19 pandemic sweep through Asia, Europe and the United States, on its way to our shores, many lessons have been highlighted – the DOs and DON'Ts of how to manage this pandemic emerged and are emerging day by day!

### Key messages:

The critical importance of standardised, appropriate and accurate laboratory testing in control of the novel coronavirus SARS-CoV-2 that causes COVID-19.

What can governments do today to allow more widespread testing?

**P**erhaps the most striking message coming out of the Asian experience and now the expanding US epidemic is the urgent need for scaling up testing to identify those infected, in order to facilitate containment and mitigation efforts. Understanding who is infected today is a necessary first step to breaking the chains of transmission. In the US, a country with the world's most complex healthcare system, and where much biotechnology is initiated, it appears that the vast resources of the government, big pharma/biotech and the world's best biomedical research community have all been severely challenged by this issue. Public/private partnerships with large accredited, CLIA certified, private companies and laboratories are now being relied on to facilitate urgent but delayed expansion of testing.



**What are the lessons from this story for us in the Caribbean? What are the diagnostics and laboratory capacity needed to facilitate effective mitigation and containment?**

**W**e in the Caribbean, MUST ensure that quality-assured, reliable and scalable laboratory services are in place to ensure that these public health threats – emerging, current and future, can be addressed urgently when needed in an emergency and on an ongoing basis. Focus must be placed on the development of strong and well-resourced laboratory services, equipped with appropriate well maintained equipment, adequately staffed and led by competent personnel operating within a policy and legislative framework that demands and assures quality and trustworthy testing in **both** the public and private laboratory sectors.

**C**entralizing outbreak testing in a certified or accredited national laboratory allows for assurance of quality and confidence in the diagnosis. This is usually the first step in addressing any new

epidemic – whether HIV, SARS, H1N1 or SARS-CoV-2. As the Coronavirus pandemic emerged, the initial need was to identify the virus and its genome and to develop molecular tests that could quickly identify early infection with the virus. This was a major focus in China and South Korea at the start of the pandemic. The efforts of laboratory scientists in these countries led to the development of several nucleic acid tests using polymerase chain reaction (PCR) technology.

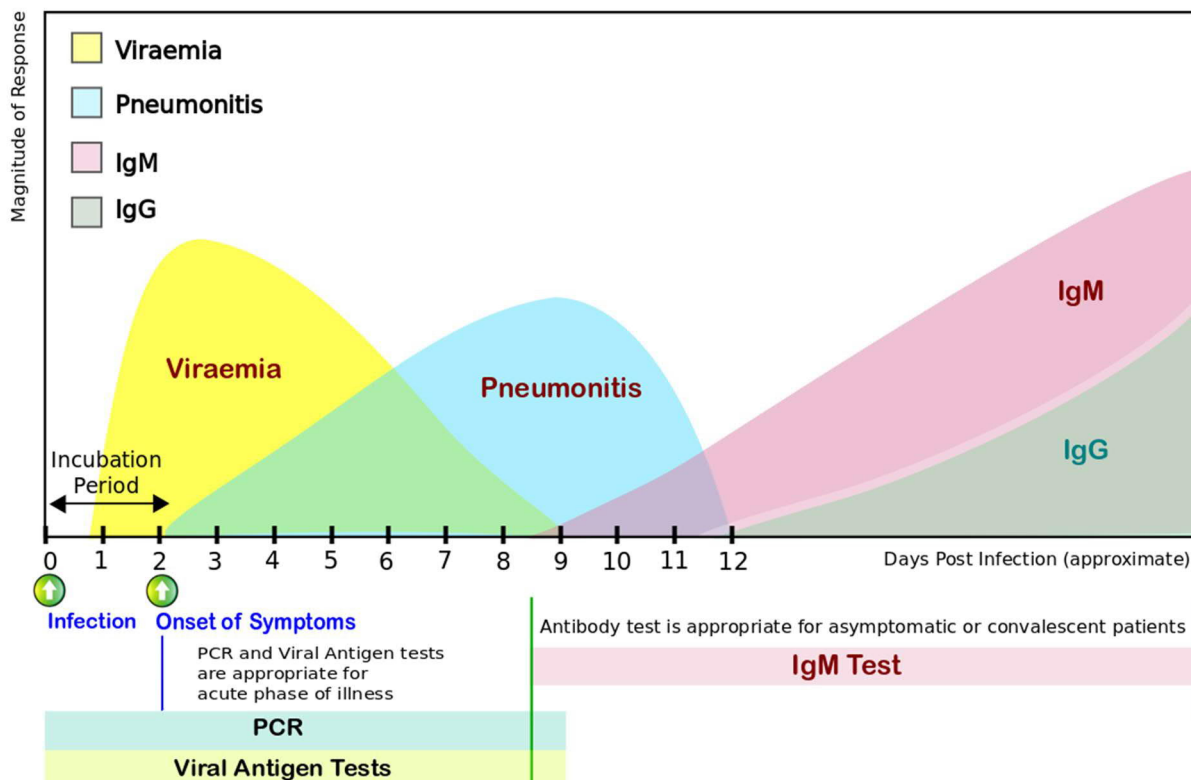
Multiple laboratory and sampling approaches are needed however, to define all the stages of an outbreak, from exposure to infection to clinical syndromes and recovery or death. As access to expanded testing becomes increasingly critical in the face of an exponentially increasing pandemic such as COVID-19, centralised testing becomes a rate limiter. In the COVID-19 global situation, this point was reached very swiftly. The ability to deliver accurate testing and diagnosis as close to the infected persons as possible is now of primary importance and multiple testing and sampling strategies are needed that allow for more decentralised testing.

Testing approaches have now been expanded include many types of nucleic acid testing for viral antigens (finding evidence of the virus itself), as well as enzyme-immunosorbent assays (EIA) and rapid tests (RT) for antigen (Ag) and antibody (Ab) – Figure 1 below. An extensive list of tests currently being evaluated by WHO is available on the website of FIND at <https://www.finddx.org/covid-19/pipeline/>.

The recent FDA approval of the Cepheid point-of-care test for COVID19 is a game changer.

Each of the different types of tests, whether for virus, Ag and/or Ab, has its role within the natural history as illustrated in Figure 1.

**FIGURE 1:**  
**Illustrative graphic of disease progression and laboratory tests for COVID-19**





### ***What needs to be done to fully understand the scope of the epidemic within each country?***

Without expanding testing, as illustrated by the current US experience, we will have a deficit of information about the extent of spread and true scope of the coronavirus epidemic within our national populations. The lessons emanating from the global experiences are clear. They highlight the

fundamental importance of ensuring readiness of our public and private laboratory sectors to provide responsive, timely and accurate testing services that support early and effective disease diagnosis, management and control and epidemic mitigation, including isolation of cases and their contacts.

Accurate point of care testing is ideal in order to reduce wait times between clinical sampling and a result.

**P**olicy decisions are required to inform where, how, and by whom, lab testing should be conducted based on the current situation and relevant prevailing factors. Critical factors that influence policy include:

#### **1. Science**

- a. The specific SARS-CoV-2 tests
  - i. **Viral antigen and nucleic acid tests**– see Figure 1
    - 1. RT-PCR for viral detection (gold standard) – both standard and rapid methods (Cepheid)
    - 2. EIA antigen tests (rapid tests to help make decisions similar to RT-PCR but less reliable and negative predictive value (NPV) and positive predictive value (PPV) unknown).
  - ii. **IgM/IgG tests**
    - 1. Antibody tests may be useful in asymptomatic or late presenters or when contact tracing is delayed or in surveys to assess the extent of exposure in a population

#### **2. Resources**

- a. Planning and resourcing – governments must always lead in support to the defined national response to threats
- b. Supply chain reliability
- c. Public-private partnership<sup>1</sup>



### ***What are the main testing approaches and considerations for testing?***

- 1. **Aggressive mass screening, contact tracing and isolation (determining who is currently infected and who have they exposed)** – the South Korean response
  - a. Published data suggests that 79% of infections occurred in clinically undocumented, presumably asymptomatic or minimally symptomatic persons. This strategy is designed to identify this population and limit their spread of the virus
  - b. Requires appropriate planning, budget, human resources and reliable supply chain
- 2. **Targeted testing**
  - a. Health care workers

<sup>1</sup> Leveraging and partnering with the private sector as was done in several countries to expand testing e.g. for patients with mild disease, will require labs operating in accordance with standards and use of validated tests of different types depending on stage of infection.

- i. Testing to keep workers in service rather than to quarantine or isolate and to ensure that the most critical workforce needed to support the response is maintained.
- b. Hospitalized patients, particularly those over 60 with pneumonia or respiratory distress
  - i. Testing to confirm diagnosis
  - ii. Testing to ensure proper/safe cohorting of patients
- c. All symptomatic cases (high fever, dry cough etc)
  - i. Triage to make isolation and treatment decisions
  - ii. Keep in isolation to decide if patient is not shedding virus and can be released
- d. Persons in quarantine, including contacts of established cases
  - i. Testing to decide if there is virus present (RT-PCR, Antigen) or viral exposure (IgM/IgG) and to decide on cohorting

**T**o date, both CARPHA, the regional public health organization, and national laboratories in several Caribbean countries have stepped up to the plate and have either introduced or are in the process of introducing PCR testing capacity for SARS-COV-2 to support expansion of testing. The region looks forward to the validation and release of additional rapid and other simpler tests for SARS-COV-2.



### ***What other lab tests are needed for COVID-19?***

**L**aboratories may also need to scale up other types of non-disease specific tests for monitoring patients infected or suspected of being infected with SARS-CoV-2. These laboratory tests are used in sick, especially hospitalised patients to: 1) **determine when to ventilate**, for example, measurement of arterial blood gas (ABG) and partial pressure of oxygen (PaO<sub>2</sub>). 2) **to predict adverse clinical outcomes and indicate additional, supportive measures such as renal dialysis**, for example, tests such as D-dimer, coagulation, marked lymphopenia, flow cytometry for T-cell abnormalities, renal function and liver function (lactate dehydrogenase (LDH) and 3) **to identify bacterial infection and sepsis** through blood cultures, procalcitonin and hs-CRP. Smooth running of quality assured clinical chemistry and hematology laboratories are essential when demand increases in epidemic situations.



### ***Where to from here?***

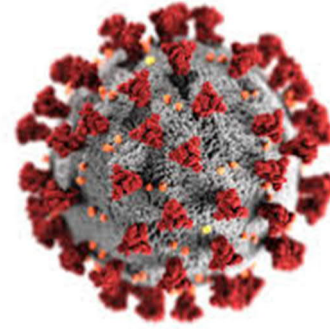
**O**ur response to SARS-CoV-2 creates the opportunity to focus appropriate attention on, and to build and strengthen laboratory and public health capacity in readiness not only to effectively manage our COVID-19 response but to respond to future disease outbreaks quickly, reliably and responsibly.

COVID-19 has emphatically reinforced the economic and human value of laboratory and public health services. The global pandemic experience has brought to the forefront the critical importance of **effective policy, legislation and regulation** to sustaining laboratory quality, relevance, reliability and best practice. The COVID-19 experience has also reinforced the importance of establishing strong **public/private laboratory partnerships** as a strategy for enabling countries to rapidly expand the diagnostic and testing response capacity needed in times of public health crisis.



## ***Is the time to Act on Laboratory Policy and Legislation upon us?***

**D**iagnostics and laboratory capacity are critical to a strong economy and to withstanding current and future public health threats. The message that CMLF has tenaciously pursued and committed to promoting throughout the Caribbean for over 10 years through varied laboratory strengthening interventions was intended, inter alia, to prepare laboratories for public health challenges such as COVID-19. Standardising testing systems that facilitate rapid and quality-assured laboratory services is dependent on national laboratory policies and legislation that are the basis for regulation of both public and private laboratories.



**O**ver the past five years CMLF has promoted, continuously advocated for and supported regional Government efforts to develop and introduce laboratory policy, legislation and regulation. Towards achieving this, Ministers of Health have endorsed this national laboratory policy initiative since 2014 at their Council for Human and Social Development (COHSOD). In 2019 the COHSOD again endorsed the need for adoption and implementation of laboratory policies as critical to achieving quality-assured and adequately resourced laboratories in support of patient management and public health. COVID-19 has reminded us all that the time to implement policy and legislation and to improve resourcing of public laboratories to ensure readiness of regional laboratories to address public health threats is now!

*Farley Cleghorn<sup>1</sup>, Stephen King<sup>2</sup>, Wendy Kitson-Piggott<sup>3</sup>, Wayne Labastide<sup>3</sup>, Valerie Wilson<sup>3</sup>*

<sup>1</sup> Palladium, Board Member - CMLF

<sup>2</sup> St. Lucia Laboratory Services, Chairman - CMLF

<sup>3</sup> Caribbean Med Labs Foundation (CMLF)