

LABORATORY ASPECTS OF COVID-19: CURRENT SCENARIO

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Writing editorial with the thematic concept related with Coronavirus Disease 2019 (COVID 19), it's quite important to highlight the present scenario of the disease. The reported case of first SARS-CoV-2 infection has already been more than 2 years, but still COVID-19 pandemic remains an acute global emergency. The more precipitation and acceleration of SARS CoV-2 transmission worldwide towards the end of 2021 was due to the emergence and rapid spread of Omicron Variant of Concern (VOC). In the first two months of 2022 alone, more than 143 million new cases were reported globally that accounts for one-third of the 433 million cases reported up to 28th February since the onset of the pandemic. The pandemic is not over and COVID-19 is now affecting countries and their population in very different ways. Almost six million deaths due to COVID-19 had been reported to WHO up to the end of February 2022: an unacceptably high number that is almost certainly an underestimate.¹

The components for the plan to end COVID-19 as depicted in figure below highlights the laboratory aspects in early screening, diagnosis and treatment of the disease proper.

Huge efforts have been instituted for the development of diagnostic tools and strategies 1) for the identification and isolation of SARS-CoV-2 infected population to control pandemic, 2) to limit the chain and risk of contamination, 3) to establish the differential diagnosis of COVID-19 and other viral respiratory infections, such as seasonal flu, and 4) to treat diagnosed patients efficiently with any respiratory signs and symptoms to avoid its complications and to distinguish severe and non-severe cases and outcome of disease process.² There are many biomedical companies and research laboratories working day and night to develop competent and approved methods with highest sensitivity and specificity for the rapid detection of SARS-CoV-2 ribonucleic acid (RNA), antigens and antibodies.³ The clinical diagnostic laboratories and diagnostics manufacturers play a key role for developing, validating, and running gold standard RT-PCR tests for detection of SARS-CoV-2. As commercial tests became available, laboratories had the issues regarding backorders and supply chain maintenance, not only for SARS-CoV-2 tests, but also for other routine tests and associated testing supplies, such as swabs, transport media, and extraction reagents. The staff shortages as more trained technologists were also the burning issue experienced by the laboratories. It becomes the lesson for the laboratory to constantly change and adapt to the evolving pandemic and the need for testing, the type of test needed, and the test demand.⁴

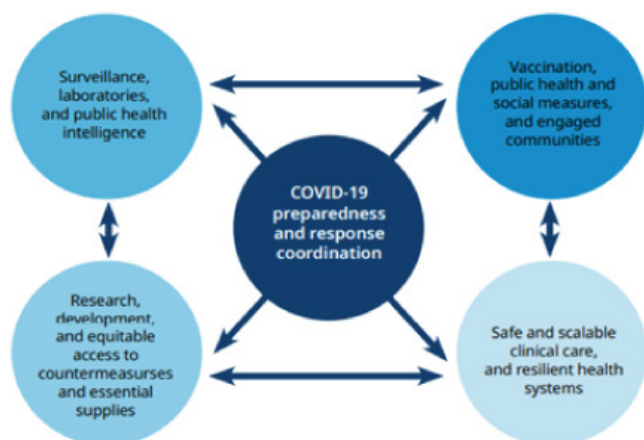


Figure 1: Five core components of COVID-19 preparedness, readiness and response¹

Optimal sample collection and testing of nasopharyngeal swab during the initial presentation of illness remains

the recommended testing standard. The multiple sites specimen testing may improve sensitivity and reduce false-negative test results, especially if clinical suspicion is high.⁵

The timing of testing strongly reflects the optimum efficacy of diagnostic laboratory value for detection of SARS-CoV-2 infection.² Molecular methods, such as RT-qPCR and isothermal amplification, are considered gold standard for SARS-CoV-2 diagnosis. A study by Vindeirinho et al. emphasizes on a comprehensive review of nucleic acid amplification tests (NAATs) and methods available for COVID-19 diagnosis in clinical laboratory and point of care (POC).^{4,6}

RT-PCR being gold standard for SARS-COV-2 diagnosis should be carried in different samples, with greater sensitivity in bronchoalveolar lavage and nasopharyngeal swab. The factors related to individuals, the collection procedure, and interference in the test technique affects the sensitivity of the tests. Thus, a negative test with a typical clinical picture should not rule out the possibility of COVID-19. The serological tests kits available are different and many factors influence their sensitivity and specificity. It's not necessary that all the patients who have SARS-CoV-2 infection will have detectable amounts of antibodies to be diagnosed by rapid diagnostic kits (RDTs). The absence of antibodies does not imply the absence of contact or protect against virus and in turn, presence of antibodies does not rule out the fact that patient is still infectious.⁷

Apart from the classical ongoing methods, additional diagnostic tools have also become available in this field. Virus culturing and next-generation sequencing (NGS) are the techniques that have been applied to identify the novel coronavirus and to characterize its molecular structure.³ Droplet digital PCR, clusters of regularly interspaced short palindromic repeats/Cas (CRISPR/Cas)-based methods, electron microscopy, biosensor, etc., can support the diagnosis of COVID-19 infection, which are under validation in routine laboratory and research settings.³

There are routine tests that is performed for the support in diagnosis, follow-up, and treatment of COVID-19

such as complete blood count, estimation of C-reactive protein (CRP), procalcitonin, renal and liver function test parameters, cardiac troponins, lactate dehydrogenase (LDH), interleukins, ferritin as well as coagulation profiles (including prothrombin time, D-dimer and fibrinogen) and arterial blood gas analysis.^{8,9}

Several biochemical tests have been identified as an independent parameter to assess disease severity and to predict the unfavorable outcome of COVID-19. Elevated LDH activity¹⁰, high soluble ACE2 activity¹¹ and increased D-dimer¹² suggest the greater severity of COVID-19. And the serological tests aid in the evaluation of the humoral response following the different types of vaccines injected.

The diagnosis of COVID-19 should rely on the clinical and epidemiological history, tests for etiological diagnosis, and the laboratory investigations to support the diagnosis of infections and/or to assess its complication and outcome of treatment. Newer diagnostic methods with higher sensitivity and specificity, as well as faster results, are necessary and are being developed. The review of the previously published scientific literatures and our experience in providing laboratory services in regard to COVID-19 management, it can very well be emphasized that there are no effective diagnostic procedures and therapeutic interventions without the thorough active role of clinical laboratories in early identification and thereafter the treatment of COVID-19 patients.

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