

Covid-19 and race for rapid diagnosis

Abstract

COVID 19 is one of the greatest disasters that the humankind is facing. Since its outbreak in Wuhan in China, the whole world has come under its grip. Accordingly, the physicians as well as health workers are attempting all means so as to find out an effective approach for detection of it. The need of the hour is rapid diagnosis with high sensitivity. This manuscript briefly highlights the issues entailing the rapid diagnosis. Starting from the working principle, it appraises reader about the recent development, accompanied by future strategies to be deployed in combating this pandemic.

Keywords: Covid-19, POC, analysis, diagnosis, corona virus

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Introduction

The whole world is going through a tough phase since the first detection of corona virus in Wuhan, China. The virus COVID-19 is found to be a total nightmare as it has taken a large toll. Everyone is gearing up for getting a total control over it. Approximately, 150 million cases have been reported and nearing 0.4 million, deaths have been confirmed worldwide. The worst cases are seen in case of India, Brazil, USA, followed by UK.¹⁻⁶ The epicenter China had also witnessed lot of fatalities. Most importantly, the serious concern about this novel corona virus is the rapid transmissibility. Amid the changing symptoms as well as frightening invasion in vital parts of human beings, the world is fully relying on rapid detection of this Corona virus in the infected ones. Considering the worst-case scenario, the rapid diagnosis is one of the utmost concerns. The false negative as well as false positive cases have become nightmare for physicians. Once well diagnosed, only then the effective treatment procedures can be administered. Otherwise, the whole treatment will be like beating in the bushes in frantic hope of recovery. As such, it has become imperative for Pharma companies as well as Testing Labs to come up with innovative solutions for rapid testing. Many companies are gearing together to come up with it. This is going to be a total game-changer once these diagnostics kits get due approval. This report outlines some of the recent developments in the direction of rapid testing, accompanied by their operational analysis.

The 2019 Novel Coronavirus (2019-nCoV or SARS-CoV-2) bears similar sequence to the first SARS-CoV virus and bat coronaviruses. To be precise, belonging to the coronaviridae family, it is a positive-sense single-stranded RNA (+ssRNA). The main transmission of COVID-19 is ascribed to the respiratory droplets. Apart from this, there are recent evidence that this virus transmits through air with the capability of attacking with new variants. Few developments are being made in the labs to formulate a probe, which can detect the virus rapidly. In most of the cases, the testing is invasively conducted. Even after symptoms, the COVID 19 in some cases appear to be negative. Hence, the need of the hour is to get a probe with a faster sensitivity and reliability. The so far developed kits seems to be promising. Below is appended a list of developments in this direction.

COVID-19 rapid POC

A London based company named Assay Genie has so far developed a Getein COVID-19 Rapid POC (Point-of-Care) kit. As per the claim of the company, it takes 10 minutes in order to qualitatively detect

severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from patient samples. The schematic is shown in Figure 1. The specimen is mixed with a buffer solution, which will eventually confirm the presence of Covid-19.

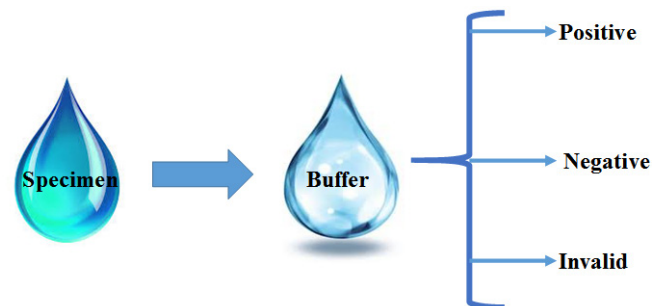


Figure 1 Schematic COVID-19 Rapid POC.

It is basically a qualitative membrane-based immunoassay, which facilitates sensing of IgG and IgM patient-generated antibodies to the SARS-CoV-2 virus through usage of whole blood, serum, or plasma specimens. Comprising of two parts viz, an IgG component and an IgM component, the sample reacts with SARS-CoV-2 antigen-coated particles in the test cassette, resulting in colored lines in IgG and IgM, respectively. The throughput occurs chromatographically driven by capillary action. Based on the color as produced by the reaction of the specimen with those antigens, the results are categorized as positive else, it is negative. However, in the disclaimer as issued, the company rules out 100% assurance of negative results; thereby advising to follow norms of self-hygiene, isolation, and quarantine.

- In another development, two companies in Northern Ireland are reported to have distributed testing kits around the world. However, Department of health is yet to give nod. The companies named Randox Laboratories and Biopanda Reagents in Belfast designed rapid and inexpensive testing kits for the virus. However, mass testing has not been accomplished as of now. Biopanda Reagents has come up with its "Covid-19 Rapid Test". This can detect the virus based on the identification of antibodies. The results can be obtained in a record ten minutes. Being encased in a plastic cassette, blood is injected which is then allowed to cause a reaction owing to the existence of the virus. In a similar way, Randox Laboratories designed a "multiplex viral respiratory infection array" that detects Covid-19 and nine other infections simultaneously. Quite interestingly, the test

can process 324 patient samples thus yielding 3240 reportable results, in just eight hours. The uniqueness of the kit, as claimed by the company, is the differentiation of patients infected with the coronavirus as well as nine other similar infections. However, the clearance from Department of Health is still awaited.²

- II. The Centers for Disease Control and Prevention, USA came up with development of a laboratory coronavirus test kit. The sensing kit is rooted on full viral sequence of COVID-19. Although, the test was restricted in CDC laboratories; however, there was then expansion to CDC certified labs for use of this diagnostic kit throughout in USA from February 2020. The test includes a standard viral testing protocol that initiates with nucleic acid purification. As compared to other tests, it comes with a provided primer and probe. Subject to addition of sample and other components, the analysis is executed by amplification through Real Time reverse transcriptase polymerase chain reaction (Real Time RT-PCR) monitored through a designated instrument and software³
- III. In another development, there arises another molecular diagnostic test from Hologic, Inc. becomes the first COVID-19 product selected for development through ASPR's Biomedical Advanced Research and Development Authority streamlined selection process, called an easy broad agency announcement (EZ-BAA).
- IV. A Derby based SureScreen Diagnostics; known for working in infectious diseases has also come up with a novel kit, which can yield results in ten minutes. It has been immensely popular in Europe, the Middle East and Australia, costing five pounds. Basically, it seeks two specific markers that escalates in people with this one. However, it is not yet cleared by British Govt.
- V. In similitude to COVID-19 POC, Nantong Egens Biotechnology Company Ltd. in China did design a rapid test for the virus. It delivers the result in fifteen minutes. Widely adopted in China and Europe, it is yet to get clearance from other countries.

Although there are certain developments in designing testing kit, which is rapid as well as inexpensive, there are certain points, which require mention. All these test kits, as a matter of fact, need certification as well as clearance from competent authorities. Before direct implementation with sample, they have to go through in-vitro

diagnostics regulatory scheme. Again, another point of caution is that majority of the kits look for antibodies associated with the virus rather than the virus itself. Thus, there is a higher possibility of false-negatives when dealt in a wrong way. At the same time, there is no established vaccines or treatments for COVID-19 infections although trials are in plenty. Hence, there is a need for stringent testing before letting it go for commercial development and implementation in diagnostics. Apart from this, most of the probes come with invasive testing, rather than non-invasive ones. Equally important is that the inclusion of surface enhanced Raman Spectroscopy, Tip enhanced Raman Spectroscopy as well as bio-labelled LSPR diagnostics can be some viable options, which may find use in detecting COVID-19. However, time will say. As prevention is better than cure, hence wearing of mask, social distancing can be better boon if diagnosed with COVID 19; thereby limiting its fast spread. Above all, contaminant, vaccination as well as Covid appropriate behavior have been earmarked as the best remediative measures to curb this pandemic. This, however, can be feasible only when we have a effective rapid testing kit with optimal sensitivity as well as least false rates.

Acknowledgments

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Declaration of competing interest

Author declares no competing interest.

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