

Urgent Need for Polymerase Chain Reaction Protocols to be Adapted for Use in Small or Rural Hospitals to Expand Abilities to Test for Coronavirus COVID-19

Robert-A Ollar^{1,2*}

¹*Clinical Assistant Professor of Neurology, Department of Neurology, New York Medical College, Valhalla, New York, USA*

²*Director of Research, TBD Support Network Inc, Milford, Pennsylvania, USA*

***Corresponding Author:** Robert-A Ollar, Clinical Assistant Professor of Neurology, Department of Neurology, New York Medical College, Valhalla, New York, USA.

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“In the current global battle against Coronavirus COVID-19, all lab facilities are needed as it is crucial to have redundancies in our testing capacity in order to perform timely testing for the presence of this deadly viral pathogen”.

Coronavirus (COVID-19) “is an infectious disease caused by severe acute respiratory syndrome Coronavirus 2 (SARS Coronavirus 2, or SARS-CoV-2), a virus closely related to the SARS virus” [1]. This Coronavirus COVID-19 is a respiratory infection that is spread from person to person by respiratory droplets during periods of coughing or sneezing [1,2].

The COVID-19 strain was first identified in Wuhan China during the 2019 - 2020 outbreak [1,2]. The hallmarks of this infection can be fever, dry cough, fatigue, and shortness of breath [1,2]. The symptoms begin to appear at about 2 to 14 days from the time to exposure Time [1]. The majority of cases that are associated with this pathogen can be associated mild symptoms however, this infection can also develop into pneumonia, and can also progress into multi-organ failure [1].

There are more than 100,000 cases and 3,900 deaths worldwide circa 9 March 2020 [3]. At the present time there isn't any available vaccine against COVID-19 [2]. Diagnoses can made using antibody assays with a blood serum specimen type however, this assay can take a few days [1]. The infection can also be “diagnosed from a combination of symptoms, risk factors, and chest CT” that reveal features of pneumonia [1].

The most rapid method for the diagnosis of Coronavirus COVID-19 is achieved by the use of real time PCR Reverse Transcription Polymerase Chain Reaction also known as real-time RT-PCR using nasopharyngeal swabs or sputum specimens [1,4-6]. This procedure can provide results in a “few hours to two days” [1,4-6].

The RT-PCR assay was initially derived from the “genetic similarities between SARS-CoV-2 and its close relative SARS [6]. Later versions of this assay were improved upon using the SARS-CoV-2 genome or specifically the presence of SARS-CoV-2's E gene [6]. The World Health organization's RT-PCR screening system uses primers that test for the presence of the E gene of the Coronavirus [6]. These codes “for the envelope that surrounds the viral shell, and the gene for the enzyme RNA-dependent RNA Polymerase” [6].

The United States Centers for Disease Control (CDC) developed a different assay which “looks for three sequences in the N gene, which codes for the nucleocapsid phosphoprotein found in the virus's shell also known as the capsid [6]. In addition, the CDC's assay “also contains primers for the RNA-dependent RNA polymerase gene” [6].

In the United States lab testing for the Coronavirus COVID-19 was “exclusively performed by the CDC which resulted in a period of 24 - 72 hour turnaround time for the result to be received” [6].

In the United Kingdom testing for the COVID-19 is currently performed by a number of accredited labs located all over the country [6]. Two labs run by the CDC, and a few state labs were the only ones in the United States that could perform tests for COVID-19 [7]. The US testing program for the presence of Coronavirus COVID-19 was halted when it was discovered that one of the reagents in the testing kit was flawed, and the kits had to be recalled [6].

The US Food and Drug Administration on the 29th of February 2020 had to expand its Emergency Use Authorization (EUA) program in order to enable more labs to conduct testing for Coronavirus COVID-19 [7]. In USA, authorities are now working to make more test kits available.

It is necessary to expand the number of labs that are able to do COVID-19 testing, in order to accurately assess how widespread this virus actually is in the USA [7]. The lack of test kits has limited the ability to perform testing and has thus hampered the ability of public health officials to ascertain the actual number of cases of COVID-19 infected persons in the USA [7].

The ability of a hospital to perform its own testing for COVID-19 “in house” could speed up turnaround times, and generate results more rapidly [6].

A point that is often overlooked is that many small and rural hospitals located all over the developed and developing countries of the world could also perform “in house” or “point of care” testing for Coronavirus COVID-19. This testing could be achieved if the testing protocols were adapted for use with End Point or Conventional PCR systems.

There are many hospitals all over the world that do own End Point or Conventional PCR Thermocyclers and electrophoresis units. These pieces of available basic equipment could be utilized to provide accurate “point of care” Coronavirus COVID-19 testing with much faster turnaround times than could be achieved by sending testing to “off site” labs. Coronavirus COVID-19 testing capacity would be especially useful if multiple testing results were required to be performed in short order to confirm the infection status of a patient, or if a specimen processing error had occurred [6].

It should be remembered that before the availability of real-time PCR systems, End Point or Conventional Thermocyclers were used to perform RT-PCR procedures. The results obtained by this low cost basic technology were accurate and reproducible. There is a firm (BioinGentech) that manufactures a kit (HumPCR™-19 Detection Kit) that can utilize an End-Point PCR Thermocycling System for Coronavirus COVID-19 Testing.

In the current global battle against Coronavirus COVID-19, all lab facilities are needed as it is crucial to have redundancies in our testing capacity in order to perform timely testing for the presence of this deadly viral pathogen in both asymptomatic and symptomatic infected individuals, and hence control the spread of Coronavirus COVID-19 all over the globe [6].

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