

The Importance of Coronavirus Testing Explained

*Stephen Naylor Ph.D.**

*Address Correspondence to:
Dr. Stephen Naylor
Telephone: 812-272-0469
E-mail: lockett01@msn.com

1. Introduction

We are all struggling with the tidal waves of both misinformation and information concerning the coronavirus pandemic. Each one of us is trying to understand this complex and evolving situation in order to make decisions that benefit and protect our families and us as individuals. Also in this hyper-connected world we are aware that a pandemic requires us to think about the consequences of individual decisions. How do they affect the local community, state and ultimately the country? This situation is clearly overwhelming and most people succumb to the lowest common denominator, namely self-preservation, and “what is best for me and my family?” There is nothing wrong in setting priorities, but it is important to remember that the SARS-CoV-2 virus (the cause of Covid-19) originally infected just a single person. Now approximately six months later, over 8.2 million people (June 17th, 2020) worldwide have the disease! If your neighboring town or state capitulates to the those individuals clamoring for their “liberty back” before safety measures are in place, YOU can quickly become a statistic in the Covid-19 infection numbers. One stark example of this possibility can be found in the Pacific port city of Guayaquil, Ecuador. In mid-February 2020, a seventy-one-year-old woman traveled from Madrid, Spain back to her hometown. She celebrated her popular return by attending numerous parties. Alas, she was subsequently diagnosed as the first Ecuadorean with Covid-19. Now, Guayaquil is a heartbreaking hotspot. Hundreds of dead bodies remain in family homes! The local authority services are unable to respond to the overwhelming demands of body removal, all as the result of a single individual. (<https://www.theguardian.com/news/audio/2020/apr/27/covid-19-spread-southamerica>).

So how do we as individuals, families and populations avoid such situations and make thoughtful decisions about our situation and the future? It is remarkably straightforward, TESTING, TESTING, and TESTING. The paradigm

is simple in that testing generates data and information, which allows individual informed decision-making. At the population level, data from testing allows mathematical models to be constructed. This in turn facilitates predictive outcomes, which informs policy makers of priorities that need to be set. However it is important to understand that models are only as good as the quality and amount of data produced from testing. This is, in part, why the models you see each night on your television screens appear to change as a function of the number of tests done.

2. Testing

We are all familiar with the concept of medical or diagnostic testing. A visit to your physician often necessitates the taking of a blood sample. The blood is tested for the presence/absence of a specific cell type or molecule. These cell or molecular markers are then quantified and the numerical value is compared to the population “range” as to whether it is too low, too high or within normal range. Such measurements/tests determine if you have a disease, or in this case an infection.

a. Rigor and Jargon - The development of a test is not simple and is subject to numerous considerations. This is to ensure that the data and information from the test is accurate. Imagine the horror, trepidation and panic if an oncology test you had taken appeared to be positive, but in fact was an inaccurate or faulty test and you did not have cancer! In order to avoid such unacceptable errors a test is rigorously developed. The test must have defined and acceptable i) specificity (refers to the % of individuals with FALSE positive results); ii) sensitivity (% of individuals with FALSE negative results); accuracy (how close to the real value is the measured test result); iii) precision (a statistical measurement such that if you measured your blood sample 10 times how close together would be the 10 measured values); iv) limits of detection (LOD- what is the lowest level/amount that the test can measure); and v) time required for the test and analysis to be

undertaken. All these parameters, with jargon filled terms, define the quality of the test and whether it can be practically used in the determination/diagnosis of a disease.

b. Regulatory Framework - The approval of both a platform/machine to undertake tests and the tests themselves for use in humans is a complex patchwork of regulations and involve a number of US Government Agencies. In the current crisis, the US Health & Human Services (via the Food and Drug Administration) has approved a number of diagnostic tests involving the SARS-Cov-2 virus under what is known as the Emergency Use Authorization (EUA) provision of the Federal Food Drug and Cosmetic Act. For a list of such EUA approvals see <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>. It should be noted that under such provisions not all tests are created equal. A number of tests were “approved” but were not validated. This means that the platform and reagents used for the test, as well as the test itself were not compared to the “gold standard” method of making the diagnosis. This means that issues like accuracy, reliability, reproducibility and other metrics were not fully determined and therefore some data could be suspect.

3. Coronavirus Testing

The SARS-Cov-2 virus causes Covid-19 disease. How does it do that? Think of viral infection as a four-stage process. Stage I is infection. The virus is transmitted to you via droplets from a proximal infected individual or a contaminated surface. The virus ultimately enters your body through your nose or mouth or possibly eyes, and seeks out cells in your lungs (or other parts of the body) to invade and takes over the cellular machinery. Stage II is the propagation of the virus in your body. It replicates within your cells, infecting additional cells in the process, causing cellular, tissue and organ damage. Stage III is the immune

response of your body fighting back against the virus, but in this process additional damage to the host's body can occur. Stage IV is the final outcome, resulting in either recovery or death. As the infected host in Stages I-III you can "shed" virus and infect other people. In order to monitor all these complex inter-connected processes two different types of testing are now undertaken for the SARS-Cov-2 virus.

a. Are you infected now? - The test is simple for the patient, provided you have access to testing capabilities. A swab is inserted either up your nose or to the back of your throat to sample cells. If the virus is present then pieces of specific viral RNA will be detected. The swab is then analyzed using a process known as Reverse Transcriptase PCR. This analysis is designed to determine if the viral RNA is present and thus determine if you are infected or not.

b. Have you ever been infected? - This is a *different* test. Blood is drawn from the patient and the sample analyzed for specific antibodies. These antibodies are produced in Stage III (described above) when your adaptive immune system, involving B and T cells, fight against the viral infection. In the process, your body produces specific antibodies against SARS-Cov-2, which remain in your circulatory system. Detection of these antibodies informs you and the physician that you have been previously infected by the virus, but are no longer capable of transmitting the virus.

The information from these two tests is binary for the individual. Either you are currently or have been previously infected, or you are not infected nor previously been exposed to the virus. Based on these facts from the tests you and your family can then plan accordingly. However, besides this, all these data combined into population databases can be exceedingly powerful for policy makers to make public health and economic decisions. Understanding the number of people infected, how readily each individual infects another person, how many people have been infected and are now healthy, the rate of spread in a population, and the mortality rate are all derived from this process of testing!

4. Conclusions

There has been a crescendo of calls for more, improved, readily available testing in the USA. Public health officials and physicians have been at the forefront of this effort. As you now might understand this is not empty grandstanding. It is of vital necessity for the health and wellbeing of individuals, as well as states and nations, to understand what is happening as the virus sweeps through a country and the world.

The importance of early, efficient, easily accessible widespread testing is exemplified in comparing South Korea versus the USA. South Korea has been praised around the globe for its aggressive responsive testing regimen. In contrast the early efforts (January-March 2020) of the USA have been greeted with consternation and incredulity. The difference in opinions is open to discussion, however facts provide a sobering lesson. Only 12 weeks ago South Korea and the USA had officially reported the same number of deaths caused by Covid-19. Today (June 17th, 2020) South Korea has a total of only ~280 fatalities (with ~1-2 additional deaths per day). In stark contrast the USA fatality total is ~120,000 (with ~750 additional deaths per day). Even allowing for national population differences (USA - 328.2 Million versus South Korea - 51.6 million, an approximately 6:1 ratio) this is still a sobering and staggering difference in such a short period of time. In addition the differential effect of the virus on the two national populations continues to worsen for the American public. The South Korean Government implemented aggressive and expansive testing coupled with contact tracing, followed by quarantining infected patients. This model is belatedly being discussed in the USA as state by state as the country begins to open up. This is all predicated on adequate testing capability, which is still questionable here in the USA. Only time will tell if the USA Government (Federal and State) understands the foundational importance of testing. But hopefully now you do!

(Please note the opinions expressed in this article are solely those of the author and do not necessarily reflect the views of NEMSN. Readers should consult with their personal physicians as to how to manage the prevention, diagnosis and treatment of Covid-19 flu.)