

Dr. Delgado COVID-19 Update 4-13-20

SEROLOGIC TESTS 4.0

If someone has been infected with Covid-19, their blood, presumably, will produce antibodies that will protect against subsequent infection by the virus. Get a serologic test and, in theory if positive, that person is now immune and free to resume normal activity. Simple.

Except it's not. There remain some serious shortfalls in trying to use these tests to determine one's immunity status. It still remains unknown what immunity to this specific virus looks like.

Are you still infectious to others after an antibody response? If immune, how long does it last and will that response even prevent reinfection. Lastly, immune responses can vary greatly between patients and its not clear as to why.

Sars or Cov-1, which shares up to 76% of its viral genome with the current strain circulating, elicits immunity that last up to three years in some reports. Other coronaviruses, such as the common cold, elicit an immunity that is far shorter in duration. As to where this current strain will fall, it remains too early to tell.

Because these serologic tests aren't 100% accurate, a diagnostic conundrum exists. If these tests are overly sensitive (rate of sensitivity), this may lead a test to react with any antibodies strains that are similar. This could lead to many false positive results as to immunity status. If a test is particularly specific for the antibody (rate of specificity), it will not target the wrong antibody, but may potentially miss the subtle differences at the

molecular level of antibodies which normally occur. This could contribute to increased rates of false negatives.

Why is this important? Because we don't know what the true infection rate is in our population-1%, 2%, 5%, etc. Without knowing this rate, we cannot truly predict what proportion of these immunity test would be incorrect-either the false positives or false negatives. That is because the lower the overall infection rate in a target population, the more likely a test, statistically, would tend to be inaccurate.

Lastly, some patients who survive the infection may not even generate antibodies and if so only generate them at levels that don't confer lasting immunity.

SO HOW TO PROCEED?

These issues imply that any modification of current restrictions, assurance of immunity and hence clearance to resume normal activity would necessitate a population being tested repeatedly over a period of weeks to months. This volume would help to establish the level of infection in a specific community and as such grant more confidence as to the test's validity. Even if that scenario was to take place, it would only reduce, not completely eliminate, the risk further.

This easing of restrictions with testing would need to be in conjunction with the continued strategies employed-use of masks, social distancing and limiting gatherings of any significant density.

Voluminous testing of a population could be deployed. It would be most impactful in areas where the virus has circulated as a means to confirm that those infected have developed an immune response for validity testing. In addition, this would help to elucidate the many (up to 30%) of those

infected who were false negatives in the initial round of testing for the acute illness.

Lastly, the testing would likely reveal those who had asymptomatic infections or potentially developed an immune response due to exposure.

All of these cohorts could then be followed as to the risk of reacquiring the infection (true immunity), their ability to transmit it to others and to gain a better estimate as to the actual asymptomatic rate of infection.

POINT OF CARE TESTING (POCT)

Once delivered to our office, we will proceed with testing. These results will not determine the finality of your immunity status. Please keep this fact in mind. As noted above, assurance of immunity will likely require a sequence of tests which show a consistency of results in combination with your clinical history as to infection and/or exposure. This is only a beginning toward that end.

The test will be a finger stick and much like a diabetic sugar test. Results will generally take 15 minutes or so. Some data has emerged that separating the serum from a blood sample, via phlebotomy, might offer more accuracy. I may suggest repeat testing with a blood draw to provide additional information or ensure accuracy.

By testing those in the practice who previously tested positive for Covid-19, it will offer validity testing of this specific test. That is, it will help in ascertaining if those patients have mounted an immune response and it is detectable and reproducible.

The test I have chosen is not FDA approved, but has been granted Emergency Use Authorization by the FDA due to the nature of this situation. Its relevant data suggests excellent sensitivity & specificity, but it still requires appropriate confirmatory volume and subsequent peer review.

Secondarily, it will provide credence to my clinical intuition as to those with the classic symptoms whom tested negative, but who likely were the product of the high false negative rate of the initial swab tests mentioned previously.

Lastly, if anyone one of you is able to get serologically tested elsewhere, I would reiterate that you do so, in addition to proceeding with our intra-office testing, to begin that confirmatory sequencing of results. Any ancillary testing or results would be beneficial if shared with us. I urge all of you to try to resister for additional testing locally at covid19responsegroup.com.

OUR OFFICE WILL CALL FOR TESTING AND PROCEED IN A SYSTEMATIC FASHION ONCE WE HAVE THE TESTS.

PLEASE DO NOT CALL OUR OFFICE AS TO WHEN IT WILL ARRIVE OR TO MAKE AN APPOINTMENT FOR THE TEST. WE WILL CONTACT YOU DIRECTLY.

OFFICE UPDATE

As mentioned, we will begin a “soft opening” of the office today. I will try to limit the volume of traffic in the office to minimize risk of transmission.

Any Covid-like symptoms will be triaged by phone and not be seen in the office. Only acute/subacute issues that arise will be considered for an office interaction and at my discretion as to the best course of treatment.

We continue to appreciate your patience and understanding as to the situation and restrictions. As always, my staff and I remain at your service for any of your health care needs.

R. Delgado, MD & Staff