AMPATH
LABORATORIES

SEROLOGICAL TESTS FOR COVID-19

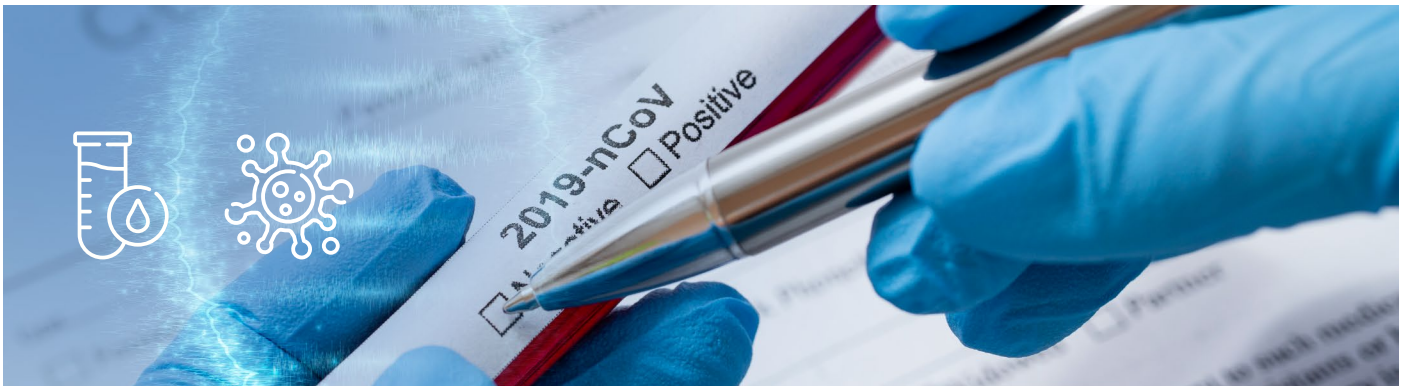
8 April 2020

Dear Colleagues

Why we do not test healthy people for Coronavirus/COVID-19

With all the media coverage, Ampath has been receiving many queries about performing serological tests for COVID-19 antibodies. We would therefore like to update you regarding our current stand with respect to testing for COVID-19 antibodies.

Ampath's current stance on serology assays for COVID-19, is that it likely has a limited role to play in diagnosis of acute infections, where the gold standard remains the more sensitive and specific PCR assays. In essence, antibody development differs from person to person. From the current literature, it seems that most persons seroconvert 7 to 11 days after the onset of illness, but there are individuals who have detectable antibodies earlier and later. This, together with issues of serology sensitivity and specificity hampers the use of serology in the acute diagnosis of COVID-19. A positive result may turn out to be false positive (whether IgA or IgM) and a negative certainly does not exclude infection, and therefore would not make any difference in terms of the individual still being required to isolate.



Where we do see a potential role regarding serology assays, will be for determining previous exposure to the virus (for example cases who suspect they may have had the illness some time ago, but who by now are again asymptomatic and PCR is no longer helpful), or if one needs to determine whether persons are immune to the disease. In both these instances, we would be looking at the presence of IgG antibodies. It must be stressed, that although this may be where we are heading with serology, we don't have full knowledge about the implications of having detectable IgG yet; it seems as if the presence of IgG antibodies may protect against re-infection, but there have been isolated cases reported of possible re-infection with COVID-19. We don't have a guarantee of fully protective immunity yet. In addition, we don't know what the duration of this antibody response will be, and whether (as with many other viral respiratory infections) the immunity may be inclined to wane over time, with susceptibility again a year or two down the line. These are questions we will probably only get answers to as the pandemic goes on.

There may also be a role for IgG in convalescent serum to confirm diagnosis if, for some reason, there was concern over the positive or negative PCR result's validity. And then finally serology will likely be used for sero-epidemiological evaluations in populations, as well as to screen for convalescent plasma (plasma from recovered patients) as potential treatment, should this be proven to be a useful treatment modality.

There are also a few antigen detection assays coming onto the market. These may, in fact, be more useful in acute diagnosis, especially if there is a global shortage of PCR test kits. The problem with antigen detection is that although it is much more specific than antibody assays, it is much less sensitive than PCR. If patients test negative they would still require to have a PCR test done, but at least then positive results can be viewed with more trust to confirm COVID-19 infection.

We are currently in the process of validating a variety of serology assays within Ampath, but these assays are not being offered yet. We are also hoping that the WHO and NICD will provide further guidance in terms of how these assays should be utilised going forward. We shall continue updating you.

For any further queries, please contact Dr Marieke Brauer - brauerm@ampath.co.za