

Memorandum

Date: May 12, 2019

To: Physicians at New Hanover Regional Medical Center, Orthopedic Hospital, ED North, and Pender Hospital.
From: Dr. Kevin M. McNabb, Director Microbiology, Immunology, and Molecular Testing and Christopher D. McKinney, M.D., NHRMC Laboratory Medical Director

Re: Current Status of Antibody Testing for SARS-CoV-2 at NHRMC

The Department of Pathology and Laboratory Services has looked at all available testing for SARS-Cov-2 (COVID-19) and currently offers in-house molecular testing (RT-PCR) for rapid detection of RNA in symptomatic patients.

Other possible testing includes serology testing for detection of antibodies to SARS-CoV-2 in the patient's serum. These antibodies can take up to 3 weeks to form and are not considered useful for diagnosis of current infection. Antibodies produced in response to the viral infection includes IgM (current or recent infection), IgG (past infection, possible immunity) and IgA (possible mucosal immunity).

At this time, serology testing will only detect the presence or absence of antibody and not the amount (titer). The Food and Drug Administration (FDA) does not require an emergency use authorization (EUA) for serology assays and has left submission of data for EUA by manufacturers voluntary. In a typical infection, IgM is produced first in response to the infection and later IgG is produced as the infection begins to resolve. IgG antibody generally provides some degree of immunity from reinfection with the same pathogen. However the level of protective immunity, if any, from the presence IgG antibody in response to SARS-CoV-2 is currently unknown.

Since most of the serology tests available today are not evaluated for cross reactivity to other viruses, and specificity is also not well characterized, the results of serology testing will be difficult to interpret. A patient with IgG antibodies to SARS-CoV-2 may or may not have immunity. A person with IgM antibodies may have a current infection or they may not, since some patients don't produce these antibodies for weeks (older and immune compromised).

Based on the above, we are not currently planning to offer SARS-CoV-2 serology testing from NHRMC laboratory, at the present time. Until test performance can be better validated, serology testing results may be more misleading than helpful. It is estimated that 30% of the assays available now will likely cross-react with antibodies to endemic strains of Coronavirus (non-Covid-19) that are commonly found in the United States. Our laboratory team will continue to evaluate serology testing for SARS-CoV-2 and if a suitable test is found, we will consider adding it to our in-house testing menu.

Serology testing for IgG is available through our reference laboratory (LabCorp) with a turnaround time (TAT) of 3 to 5 days. Performance of this test and the clinical significance of the results have not been established.

Please contact the Director of Microbiology, Immunology, and Molecular Testing, Dr. Kevin M. McNabb, with any concerns or questions about this change at 910-667-7078 or via email at Kevin.McNabb@nhrmc.org.