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Re: Coronavirus collection and testing

As you all know, the virus has caused a lot of disruption to our daily routines. The Pathology Lab feels the same way. How our workflow once was, is no longer. We have gone from collecting all patients outside, under a tent, to now moving asymptomatic patients back inside the lab in a social distancing fashion. Our goal is to keep the patients safe and be efficient at the same time. These changes are complicated at times, but we need to do it the best way possible. We would like to share how we are currently functioning.

Outside collections

The only patients collected outside the building are *SYMPTOMATIC* patients that are exhibiting signs of respiratory, gastro, or coronavirus symptoms. Symptomatic patients that require a urinalysis will be required to wear a mask, and collection occurs inside the building.

Inside collections

ASYMPTOMATIC patient collections will occur inside the building, including COVID swabs for presurgery. Patients will be driving through the tent for a symptom and temperature screen, and then they will be instructed to park and enter the building. Masks will not be required but are encouraged. We are practicing social distancing inside and outside the building, so currently, we are only allowing a certain amount of patients inside at the same time.

Priority Collections

Patient's that need tolerance testing or specimen drop off will be priority.

Antibody Testing

Beginning May 13, 2020, we started COVID-19 Total (IGM/IGG) antibody testing in-house. We are using the Roche Elecsys Anti-SARS-CoV-2 reagent on the Roche 8000 instrument. This test is FDA authorized and has a sensitivity of 100% and specificity of 99.8%. Positive Predictive Value (PPV) is 96.5%, and Negative Predictive Value (NPV) is 100%. If serology testing is going to be used to guide individual actions around patient health and safety, it will be critical that both sensitivity and specificity are as high as possible to avoid false-positive and false-negative results. In addition to specificity and sensitivity, which are both independent of the disease prevalence in the population, PPV and NPV need consideration. In the context of serological testing, PPV refers to how likely an individual is to have detectable antibodies given a positive test result, and NPV represents the likelihood that an individual that receives a negative test result does not have detectable antibodies. The intended use of the test is as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The test should not be used

to diagnose acute infection, nor confer that the patient is immune from future infection. Clinical care decisions should be made using the PCR test.

COVID-19 PCR Swab testing

Currently, we are testing in-house and are only validated for 48-hour refrigerated stability. After this weekend, we will be validated for 72 hours refrigerated and this will allow specimens from Friday afternoon to be delivered to us Monday morning for testing.

Direct To Consumer Testing

Testing of both Coronavirus Total Antibody and PCR swab is allowed WITHOUT a doctor's order per CMS directives.

SPLH39448 Coronavirus Swab PCR testing \$80

8706 Coronavirus Total Antibody Testing \$45

State Reporting of Coronavirus PCR swabs and Antibody testing

Also, the state is requesting us to provide them with each patient's race and ethnicity. Please provide this information to the lab when submitting COVID-19 swabs or antibody testing.

Use the options below.

Patient's race

Asian

Black or African-American

American Indian or Alaska Native

Native Hawaiian or Other Pacific Islander

White

Other

Unknown

Patient's ethnicity

Hispanic

Non-Hispanic

Unknown

If you have any questions, contact Nicho Bourque at 337.312.1280 or nbourque@thepathlab.com.