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June 5, 2020

## **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.

### **COVID-19 PCR Swab testing**

Reagent volume continues to be a challenge to maintain. With all the surgeries beginning, most clients are requiring a negative COVID-19 test for pre-op. **Our reagent allocation cannot withstand this volume, which has again forced us to recreate a priority list.** Anything non-priority will be sent to Quest Diagnostics, who is currently seeing a 5-7 day TAT.

We are working closely with the local Urgent Cares trying to tackle this testing volume together. We are all facing the same reagent challenges. Therefore, we are asking that patients be tested **at least 4 working days** in advance before results are required. A protocol has been created. (As you all know, this changes weekly as the demand changes.)

### **Please indicate either on the requisition or on a separate paper placed with the order:**

- Symptomatic HCW
- High Risk
- Surgery

These patients will be performed in-house as long as reagents are available. We are only able to perform approximately 75 tests in-house per day due to reagent challenges and we are currently receiving orders for over 200 tests per day. Prioritizing specimens is important. Any priority specimens that we cannot perform will be sent to another reference lab that is offering a 72-hour turnaround time from the time they receive the specimen. Please work with us so that we can make the right decision on where testing should be performed.

### **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

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distancing inside and outside the building, so currently, we are only allowing a certain amount of patients inside at the same time.

### **Priority Collections**

Patients that need tolerance testing or specimen drop off will be priority and collected or assisted before other patients.

### **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 infer that the patient is immune from future infection. Clinical care decisions should be made using the PCR test.**

### **Direct To Consumer Testing**

Testing of both Coronavirus Total Antibody and PCR swab is allowed WITHOUT a doctor's order per CMS directives. Paid time of service pricing is listed below.

SPLH39448 Coronavirus Swab PCR testing \$145 (Price updated 6/15/2020)

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.