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To: All Clients

**Re: Antibody Testing for Coronavirus**

The Path Lab is not yet performing Coronavirus antibody testing in-house, but as of last week, we do have the option to send immunochemistry antibody testing (SPLH39504) to Quest Diagnostics. Their test is IgG only and is not yet FDA authorized. As of today Labcorp also has a IGG test (LC164055) available. Labcorp has not been able to provide our lab with data regarding testing, but their disclaimers are very similar to those on the Quest reports.

**Please review the information below before making a decision to order this test.**

The test reports will include the following disclaimer:

#### **Part 1**

SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Immunoassay-Detection IgG antibodies may indicate exposure to SARS-CoV-2 (COVID-19). It usually takes at least 10 days after symptom onset for IgG to reach detectable levels. An IgG positive result may suggest an immune response to a primary infection with SARS-CoV-2, but the relationship between IgG positivity and immunity to SARS-CoV-2 has not yet been firmly established. Antibody tests have not been shown to definitively diagnose or exclude SARS-CoV-2 infection. Positive results could also be due to past or present infection with non-SARS-CoV-2 coronavirus HKU1, NL63, OC43, or 229E. Diagnosis of COVID-19 is made by detection of SARS-CoV-2 RNA by molecular testing methods, consistent with a patient's clinical findings.

#### **Part 2**

This test has not been reviewed by the FDA. Negative results do not rule out SARS-CoV-2 infection particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results could also be due to past or present infection with non-SARS-CoV-2 coronavirus strains. This test is not to be used for the screening of donated blood.

**Why isn't The Path Lab performing this test in-house? We have considerable reasons listed below:**

- What do these results mean for patients? Immunity or infectious? No one really knows yet.
- Cross reactivity. Does a positive result mean it is only COVID-19? In most cases, that is not true.
- Should antibody testing reflex to PCR test? Most test kits state they should reflex to molecular testing.
- Why do some patients get re-infected with COVID-19, despite forming antibodies? Patients may form neutralizing and non-neutralizing antibodies. The only one that would confer "immunity" would be neutralizing ones. The antibody tests currently available cannot distinguish between the two. Therefore, the most that any current antibody test can show is that a patient has been infected previously. No comment can be made as to whether they are now immune from re-infection. Therefore, the information produced is epidemiologic, and not clinically actionable in any given patient.

We are reviewing all antibody testing on the market and are interested in a **FDA authorized** test; however, there are very few that have received this authorization. Specificity and sensitivity data is being carefully reviewed. While it is important to properly validate any kit before bringing it in-house, this must be done by thoroughly taking the history of a patient's infection and performing the test using PCR and antibody methods to create an accurate picture of the disease state. Positive PCR first, IgM second, and IgG third – this is the order that each true positive patient should show as an infection. For more information, please review the Coronavirus in-house memo on our website at [www.thepathlab.com](http://www.thepathlab.com)

If you have any questions, please contact Nicho Bourque, Clinical Lab Manager at 337.312.1280 or [nbourque@thepathlab.com](mailto:nbourque@thepathlab.com).

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