COVID-19 Test Performance March 26 1107

COVID-19 (SARS-CoV-2 virus) testing is currently being performed by the Spectrum Health laboratory on two different platforms, the CDC assay on an ABI 7500 Dx instrument and the Abbott m2000 assay. Both assays are real-time reverse transcriptase PCR (RT-PCR) molecular methods for the qualitative detection of COVID-19 viral nucleic acid from respiratory specimens. This type of molecular RT-PCR assay is regarded as the gold standard testing method.

Test Performance
To date, the CDC has tested thousands of symptomatic patients with their assay. During the early phase of test validation, the CDC performed more extensive comparison of their test with two additional RT-PCR assays that targeted separate and independent genetic sequences of COVID-19. Of 117 respiratory specimens tested by all 3 methods, the CDC assay had both a 100% positive and negative percent agreement. While the clinical data set is small, this type of test for other respiratory viruses such as influenza has similar near 100% performance values. The specificity of this test has been assessed, and no cross-reactivity observed with other coronaviruses (including MERS and SARS), influenza, respiratory syncytial virus, rhinovirus, parainfluenza, etc.

There was a recent communication to Spectrum Health providers stating that “the COVID tests are 65% accurate”. This misleading statement likely originates from a recent Chinese publication which reported a 65% positive predictive value in the ability of abnormal chest CT imaging to predict the positivity of COVID-19 laboratory results, indicating that there are non-COVID-19 explanations for abnormal lung findings. The strong analytical performance of COVID-19 molecular testing requires 1) proper selection of symptomatic patients and 2) proper nasopharyngeal (NP) swab collection technique. Improper collection may lead to false negative results. A negative test cannot 100% rule out current or future infection, but a retesting process for COVID-19 has not been established.

Our test positivity rate is currently 5-7% and has been gradually increasing as prevalence within our community increases.

Other Test Considerations
Please see the latest Inpatient Workflow on Insite for additional testing and isolation precaution considerations.

In general, if COVID-19 positive, the addition of Influenza PCR testing may inform anti-viral therapeutic support. If COVID-19 negative, additional Influenza PCR or respiratory FilmArray testing may be considered to guide diagnosis.

Co-infections
There is currently limited data available regarding co-infections – being simultaneously infected with COVID-19 alongside another respiratory virus, however, in general co-infections with multiple respiratory viruses are fairly common. Here at Spectrum Health for the year 2020 to date, we have observed an 8% co-infection rate based on FilmArray respiratory panel testing. The rate of co-infection relates to overall viral prevalence within a population, so the co-infection rate with COVID-19 is probably similar. A recent study from Wuhan China observed as high as a 40% co-infection rate among pediatric patients.

References
- InSite COVID-19 Clinical Resources: [https://spectrumhealth.sharepoint.com/sites/disaster-preparedness/SitePages/COVID-19-Clinical-resources.aspx](https://spectrumhealth.sharepoint.com/sites/disaster-preparedness/SitePages/COVID-19-Clinical-resources.aspx) (accessibly only to Spectrum Health employees)
- Influenza PCR: [https://spectrumhealth.testcatalog.org/show/LAB3255-1](https://spectrumhealth.testcatalog.org/show/LAB3255-1)
- FilmArray Respiratory Panel: [https://spectrumhealth.testcatalog.org/show/LAB3359-1](https://spectrumhealth.testcatalog.org/show/LAB3359-1)