COVID-19 Test Performance – April 17, 2020 1120

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Situation

There is ongoing concern about the accuracy of COVID-19 laboratory tests.

Background

COVID-19 (SARS-CoV-2 virus) testing is currently being performed by Spectrum Health laboratories on four different platforms: the CDC assay on the ABI 7500 Dx instrument, Abbott m2000, Cepheid GeneXpert, and Abbott ID NOW assays. These are all molecular methods that utilize nucleic acid amplification for viral detection from respiratory specimens.

Because all these tests received Emergency Use Authorization by the FDA, but were not evaluated through the normal approval process, there is no clinical trial data available regarding the performance of these tests. However, there is no inherent concern about their quality since they use gold standard testing methodologies and contrived studies by each manufacturer have shown near perfect sensitivity and specificity.

Test platform	Preferred Collection	Location	Time on Instrument
ABI 7500 (CDC method)	NP swab in UTM or saline BAL, sputum, etc	Molecular lab	3 hours
m2000	NP swab in UTM or saline	Molecular lab	6 hours
GeneXpert	NP swab in UTM or saline	Microbiology Lab	45 minutes
ID NOW	Dry NP swab	Microbiology Lab Regional Labs	15 minutes

Assessment

During test validation, the CDC performed 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. 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.

To assess test performance of the ID NOW rapid assay at Spectrum Health, 50 confirmed positive specimens (by either CDC or m2000 methods) were tested by ID NOW. Of these, 5 were negative for a sensitivity of 90%. The most important metric for providers is a test's negative predictive value which addresses the question "how confident can I be in a negative result truly being negative?" With a test positivity rate around 10% for symptomatic patients in our community, the **negative predictive value for the ID NOW test is 99%**. When testing mild or asymptomatic patients, the negative predictive value improves further. Despite this reasonable performance for such a rapid test, as of 4/20/20, due to concerns of reduced sensitivity based on diluting the specimen in transport media, Abbott will be revising their ID NOW swab collection requirements. Dry swabs without transport media must be submitted for testing.

Repeat testing: Over one month of testing at Spectrum Health (3/18/20 – 4/17/20), there were 484 instances of a patient with a negative result for which a repeat test was later ordered. Of these repeats, only 5 produced a positive result (average 9.2 days later), demonstrating a change in results for only 1% of repeats.

Recommendation

The strong analytical performance of COVID-19 molecular testing depends on 1) specimen collection during acute symptoms and 2) proper NP swab collection technique. Improper collection may lead to false negative results, however, there is low utility in repeat COVID-19 testing. Current re-testing guidelines may be found on InSite.

For rapid ID NOW testing, dry swabs must be collected and distributed to testing labs as quickly as possible.