

USET Tribal Epidemiology Center Recommendations for Tribal Consideration

USET TEC COVID-19 Guidance 2020:003:

Abbott ID NOW COVID-19 Diagnostic Testing

(Issued 4/14/2020, updated 7/23/2020)



Background

In response to the COVID-19 pandemic, Indian Health Service (IHS) purchased and distributed several point-of-care type laboratory instruments called ID NOW, manufactured by Abbott Diagnostics. The instruments have been given Emergency Use Authorization by the Food and Drug Administration (FDA). This instrument measures a unique piece of viral nucleic acid of the coronavirus that causes COVID-19. Due to the technology utilized by ID NOW, it can produce results within 15 minutes. Prior to having these instruments on site, facilities had to rely on tests being sent to a reference laboratory to wait several days for test results.

As with all lab tests, there are inherent limitations of the test, and both false-negative and false-positive results may occur. All lab tests must be interpreted by qualified medical personnel in conjunction with other information, such as the patient's symptoms, environment, possible exposures, physical findings, imaging results, other lab test results, and other considerations. The USET Tribal Epidemiology Center (TEC) has reviewed the most recent available data and offers the following updated recommendations which replaces our previous *Recommendations for Tribal Consideration: Abbott ID NOW COVID-19 Diagnostic Testing* issued on April 14.

ID NOW SARS-CoV-2 Test

The ID NOW lab instrument is not new and untried technology; it has been previously used to test for other infectious diseases: group A streptococcus, influenza A and B, and respiratory syncytial virus. The test is a nucleic acid amplification test, similar to a polymerase chain reaction (PCR), but it uses an isothermal process that allows the test to be run in 5 to 15 minutes (the usual reverse transcription PCR test employs multiple heating and cooling cycles, and can take several hours to run). The test is designed to recognize the RdRp gene of the SARS-CoV-2 virus.

ID NOW SARS-CoV-2 Test Performance

Performance testing done originally with the Abbott ID NOW to obtain Emergency Use Authorization from the FDA was with contrived specimens of known concentration; the instrument was able to detect 100% of specimens at 2 to 5 times the theoretical limit of detection for the test (claimed to be 125 copies/mL of the sample). It also gave a negative result on 100% of 30 negative specimens. However, when the test received EUA, the performance of the test in the field was unknown. Since the instrument has been in widespread use, several studies have been done at academic centers to try to determine the actual sensitivity and specificity of the test in clinical practice. In reviewing seven such studies, the sensitivity has ranged from a low of 55% to a high of 94% when compared to a PCR reference, the current "gold standard" diagnostic test. Specificity in these studies has been 98.6% to 100%. In several studies sponsored by Abbott (and so far unpublished), use of the test in urgent care clinics in five states has shown a sensitivity of 94.7% and specificity of 98.6%, in a nursing home setting sensitivity was 91.3% and specificity 100%, and in a hospitalized patient study the sensitivity was 83.3% and specificity of 96.5%.

What has emerged from the performance studies to date is the following:

- The Abbott ID NOW performs well in situations where the patient has a high viral load, and poorly when the viral load is low. In the studies that did a quantitative analysis, the ID NOW had poor sensitivity at low viral loads, but very good sensitivity at moderate to high viral loads.
- The sensitivity is better when patients are tested early in the course of illness (symptom onset within a few days) than later in the course of the illness (a week or more since the onset of symptoms). This is presumably because patients have a higher viral load in the upper respiratory tract the first few days after symptom onset.
- The specificity of the test has been good in all settings.

The USET Tribal Epidemiology Center (TEC) is charged under the Indian Health Care Improvement Act with providing epidemiologic and public health support to federally recognized Tribal Nations in the Nashville Area. The USET TEC is a designated public health authority.



Recommendations

The major advantages of the Abbott ID NOW are (1) the rapid time of the test (5 to 15 minutes), and (2) the fact that it is CLIA-waived and can be used as a point-of-care test. The major disadvantage is the poor sensitivity of the test in situations where the patient has a low viral load and/or is later in the course of illness. Although a positive test gives a very high probability that the patient has COVID-19, a negative test does not rule out the diagnosis of COVID-19 and should not be used as the sole basis of patient management decisions. Clinicians must interpret test results along with other clinical data, such as patient symptoms and exposure history, and prevalence of the infection in the community. If there is clinical suspicion of COVID-19 with a negative ID NOW test, the patient should be tested by another method, such as sending a specimen to a reference lab for real-time polymerase chain reaction (PCR) testing. It is not recommended that the ID NOW test be used for mass screening due to its low sensitivity.

For more information, please refer to the Package Insert for the ID NOW instrument at <https://www.alere.com/en/home/product-details/id-now-covid-19.html>.