Abbott Rapid ID NOW Lab Diagnostic Test for SARS-CoV-2

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Background: MercyOne is committed to providing widespread access to testing for SARS-CoV-2. Some locations are using the Abbott Rapid ID Now test platform to complement traditional RT-PCR allowing greater access to testing with near immediate results. However, like all SARS-CoV-2 tests there are limitations and unknowns.

The Abbott rapid test, ID NOW™ COVID-19, approved under the FDA's emergency use authorization (EUA), employs isothermal nucleic acid amplification technology. It is one of likely others that offer rapid point-of-care assays for SARS–CoV-2, the virus that causes COVID-19. It has analytic times ranging from 5 to 13 minutes and is approved solely for specimen collection by **dry nasal swabs**. The Abbott rapid test has an estimated Limit of Detection (LOD) of 3,200 viral copies per ml, whereas the Abbott M2000, a standard, traditional RT-PCR platform has an LOD of 100 viral copies per ml. The use of the Abbott rapid test depends on whether the patient is asymptomatic or symptomatic and whether the symptoms are clinically compatible with COVID-19 infection.[1-3]

In symptomatic patients, a negative result does not exclude infection with SARS-CoV-2 regardless of what platform was used to perform the test. False negative results have been seen with the traditional RT-PCR technology and may reflect collection techniques, the presence of inhibitors, or varying levels of the virus. Nasal specimens such as those commonly used with the Abbott rapid test are vulnerable to reduced sensitivity from poor collection techniques.

We recommend strict adherence to proper collection techniques to ensure maximal harvest of viral particles. Refer to System, *Diagnostic Testing for SARS-CoV-2*, for more details.

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.[4]

Nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, the swab can be held at room temperature (15-30°C) for up to two (2) hours prior to testing.[4]

Testing & Interpretation of Rapid Test Results in Symptomatic Patients:

- It has been reported that SARS-CoV-2 levels vary, sometimes unpredictably, during the course of illness and even after recovery. In a patient with symptoms clinically suspicious for COVID-19 and a negative viral test for SAR-CoV-2, a negative viral test regardless of the methodology does not exclude COVID-19 infection.
- **For a symptomatic patient with a negative Abbott rapid test, clinical triage and assessment should be performed according to clinical suspicion for COVID-19 and additional testing should be performed with a more sensitive test.**

- **A negative test (Abbott rapid or standard RT-PCR) for SARS-CoV-2 in the presence of symptoms does not exclude COVID-19. Patients with negative rapid test who the clinical care team suspects as having COVID-19 should be considered and cared for as a PUI.**

- **A symptomatic patient with a positive Abbott rapid test the patient should be managed as a laboratory confirmed case of SARS-CoV-2.**

Testing and Interpretation of Rapid Test Results in Asymptomatic Patients:

The situation and use of the Abbott rapid test for those who may be pre-symptom or asymptomatic is less clear than in symptomatic patients. The presence of false positive test results for SARS-CoV-2 is thought to be rare.

- **There is insufficient data to stratify risk in an apparently asymptomatic patient based on a negative Abbott rapid test.**
    - As more experience with the rapid Abbott test is acquired, further recommendations will be forthcoming.
- **Hospitals may pursue screening of asymptomatic patients and those who have an immediate need for urgent care, e.g., delivery of a newborn or emergent surgery, with the Abbott rapid test, but should proceed with caution in partnership with clinical stakeholders.**
- **Clinicians need to be aware of possible false negative Abbott rapid test result in asymptomatic patients. Therefore, risk stratification involving use of isolation precautions and any therapeutic/clinical care by the provider and other members of the care team receiving this result should cautious and aware of possibility this may be a falsely negative test result.**
- **Asymptomatic patient with a positive Abbott rapid test should be managed as a laboratory confirmed case of SARS-CoV-2.**

References:

1. CDC. Presymptomatic Transmission of SARS-CoV-2 — Singapore, January 23–March 16, 2020. MMWR 2020: 69(14);411–415.
2. CDC. Asymptomatic and Presymptomatic SARS-CoV-2 Infections in Residents of a Long-Term Care Skilled Nursing Facility — King County, Washington, March 2020. MMWR 2020; 69(13);377–381.
3. Sutton D, et al. Universal Screening for SARS-CoV-2 in Women Admitted for Delivery N Engl J Med 2020 April 13, 2020. DOI: 10.1056/NEJMc2009316
4. Abbott. ID NOW™ COVID-19 PRODUCT INSERT. IN190000 Rev.2 2020/04.