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Interim Recommendations for Use of SARS-CoV-2 Molecular Tests During COVID-19 Public Health Emergency

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Purpose

Rapid molecular tests such as the Abbott ID NOW are an important part of public health emergency response strategy as they are relatively inexpensive and can be used at the point-of-care. However, they are generally less sensitive than lab-based molecular testing. The purpose of these recommendations is to support effective use of rapid molecular tests for different testing situations, as proper interpretation of molecular test results is important for accurate clinical and public health management and new data has emerged to better inform decision making.

Recommended Use

- Use to test individuals associated with congregate facilities or settings when there is an outbreak in the area.
- Use to test individuals associated with congregate facilities or settings when there are no outbreaks in the area.
- Congregate facilities include nursing homes, assisted-living facilities, long-term-care facilities, and other health or social facilities such as day programs.
- Congregate settings include schools, colleges, universities and other educational settings, workplaces, and other sites where people gather.

All results must be reported to ECLRS.

Considerations When Testing Individuals Associated with Congregate Facilities or Settings When There Is an Outbreak in the Area (see attached flow chart):

- If a ***symptomatic*** individual has a ***positive*** ID NOW COVID-19 assay test result, ***no*** confirmatory testing is needed. The individual must be isolated, contact tracing must be initiated, and results must be reported to ECLRS.
- If a ***symptomatic*** individual has a ***negative*** ID NOW COVID-19 assay test result, perform confirmatory laboratory-based molecular test for SARS-CoV-2 immediately and test for other respiratory pathogens. Quarantine until confirmatory molecular results are obtained. If confirmatory laboratory-based molecular test is positive, continue isolation and initiate contact tracing. If confirmatory laboratory-based molecular testis negative, discontinue quarantine.
    - Regardless of the results of the laboratory test, both the ID NOW COVID-19 assay test result and the confirmatory test result must be reported to ECLRS.

- If an ***asymptomatic*** individual has a ***positive*** ID NOW COVID-19 assay test result, ***no*** confirmatory testing is needed. The individual must be isolated, contact tracing must be initiated, and results must be reported to ECLRS.
- If an ***asymptomatic*** individual has a ***negative*** ID NOW COVID-19 assay test result, due to the potential for a false negative result with the ID NOW in this setting, a confirmatory test with a laboratory-based molecular test for SARS-CoV-2 should be considered. Negative results should be considered in the context of a patient's recent exposures, and a detailed thorough history needs to be taken to ensure that the patient does not have clinical signs and symptoms consistent with COVID-19. Specimen collection for the confirmatory test should occur **on the same day** that the ID NOW COVID-19 assay was performed. If this is not possible, it can be collected **up to a maximum of 48 hours** later. If confirmatory laboratory-based molecular test is positive, isolate and initiate contact tracing. If confirmatory laboratory-based RT-PCR is negative, no quarantine or isolation is necessary.
    - Regardless of the results of the laboratory test, both the ID NOW COVID-19 assay test result and the confirmatory test result must be reported to ECLRS.

Considerations When Testing Individuals Associated with Congregate Facilities or Settings When There Is NOT Outbreak in the Area (see attached flow chart):

- If a ***symptomatic*** individual has a ***positive*** ID NOW COVID-19 assay test result, ***no*** confirmatory testing is needed. The individual is must be isolated, contact tracing must be initiated, and results must be reported to ECLRS.
- If a ***symptomatic*** individual has a ***negative*** ID NOW COVID-19 assay test result, perform confirmatory laboratory-based molecular test immediately and test for other respiratory pathogens. Quarantine until confirmatory results are obtained. If confirmatory laboratory-based molecular test is positive, continue isolation and initiate contact tracing. If confirmatory laboratory-based molecular test is negative, discontinue quarantine.
    - Regardless of the results of the laboratory test, both the ID NOW COVID-19 assay test result and the confirmatory test result must be reported to ECLRS.

- If an ***asymptomatic*** individual associated with a congregate facility or setting in an area without an outbreak a has a ***positive*** a ID NOW COVID-19 assay test result, due to the potential for a false positive result, a confirmatory test with a laboratory-based molecular test for SARS-CoV-2 should be performed on a specimen collected **within 48 hours** and **preferably the same day** that the ID NOW COVID-19 assay was performed. The individual should be quarantined until the PCR test results are obtained. If confirmatory laboratory-based molecular test is positive, isolate and initiate contact tracing. If confirmatory laboratory-based molecular test is negative, no quarantine/isolation is necessary.

- As more is learned about the test performance of the ID NOW COVID-19 assay when used in this setting, these recommendations might change. Regardless of the results, both the ID NOW COVID-19 assay test result and the confirmatory results must be reported to ECLRS.

- If an ***asymptomatic*** individual associated with a congregate facility or setting in an area without an outbreak has a ***negative*** ID NOW COVID-19 assay test result, ***no*** confirmatory testing is needed and results must be reported to ECLRS. However, negative results should be considered in the context of a patient's recent exposures, and a detailed thorough history needs to be taken to ensure that the patient does not have clinical signs and symptoms consistent with COVID-19.