Frequently Asked Questions for Clinicians: Antigen testing for COVID-19

1. **What is antigen testing?**
   Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies current viral infection. Rapid antigen tests are commonly used in the diagnosis of respiratory pathogens, including influenza viruses and respiratory syncytial virus (RSV). The FDA has granted emergency use authorization (EUA) for antigen tests that can identify SARS-CoV-2. Antigen tests are currently authorized to be performed on nasopharyngeal or nasal swab specimens placed directly into the assay's extraction buffer or reagent.

2. **What antigen testing is currently available for SARS-CoV-2?**
   There are several different companies that produce antigen testing kits and reagents. Within the BILH, antigen testing is not yet available. However, an assay developed by Abbott called the BinaxNOW™, approved under emergency use authorization, and is being considered for point of care (POC) testing in symptomatic individuals when PCR testing is not available. Antigen tests are relatively inexpensive, and the currently authorized devices return results in approximately 15 minutes.

3. **How good is the test?**
   Antigen tests for SARS-CoV-2 are generally less sensitive than viral tests that detect nucleic acid using reverse transcription polymerase chain reaction (RT-PCR). Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest. Currently, the rapid antigen tests that have received EUAs from the FDA are authorized for diagnostic testing on symptomatic persons **within the first five to seven days of symptom onset.** The use of antigen testing is not recommended after 7 days of symptoms.

   The sensitivity of rapid antigen tests is generally lower than RT-PCR. The first antigen tests to have received FDA EUAs demonstrate sensitivity ranging from 84.0%-97.6% compared to RT-PCR. Antigen levels in specimens collected beyond 5-7 days of the onset of symptoms may drop below the limit of detection of the test. This may result in a negative test result, while a more sensitive test, such as RT-PCR, may return a positive result.

   There are limited data to guide the use of rapid antigen tests as screening tests on asymptomatic persons to detect or exclude COVID-19, or to determine whether a previously confirmed case is still infectious.

4. **What are the current clinical indications for testing?**
   Current indications for antigen testing within the BILH will be for symptomatic individuals at those clinical sites within the BILH network that do not have access to standard PCR COVID-19 testing. The tests can be performed on patients of any age and the specimen type will be either a nasopharyngeal swab or nasal swab.

5. What should I do if I have a high-degree of concern for COVID-19 and my patient had a negative antigen test?

A negative test result means that antigens from SARS-CoV-2 were not present in the sample above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or recommendations regarding self-isolation or use of personal protective equipment. Antigen tests are known to be less sensitive than molecular assays. Specimens collected after 7 days of symptoms are more likely to be negative when compared to PCR assays. In the setting of a negative result and high concern for COVID-19, the patient should be recommended to self-isolate and referral for COVID-19 PCR obtained.

6. What should I do if I have a low concern for COVID-19 and my patient had a positive antigen test?

A positive test should always be considered in the context of the clinical symptoms and epidemiological data. If the result is felt to most likely represent a false positive result (i.e. low probability, asymptomatic individual), the patient should be advised to self-isolate pending further evaluation. Referral for COVID-19 PCR testing, optimally via nasopharyngeal swab should be considered and in this context 2 samples separated by a minimum of 24 hours obtained.

7. Can an antigen test be used for the purpose of the MA Travel Order to end quarantine after return from a high-risk state?

No, a negative result from an antigen test must be confirmed by a negative result from an FDA EUA approved PCR test. Testing with a PCR test should be obtained no greater than 72 hours prior to arrival in Massachusetts or quarantine should be maintained upon return pending the availability of a negative test result.

8. Can an antigen test be used for the purpose of pre-operative or preprocedural screening?

No, at this time, a negative result from an antigen test must be confirmed by a negative result from an FDA EUA approved PCR test.

9. How do I order the test? At this time, SARS-CoV-2 antigen testing is not yet available in the BILH system however we are evaluating potential options for expanding access to this type of testing for symptomatic patients with a high degree of suspicion for COVID-19.

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