Shasta County Health & Human Services Agency | Public Health Branch

Recommendations for use of Abbott BinaxNOW antigen tests

November 18, 2020

Antigen Test Overview and Performance

Antigen tests directly detect fragments of SARS-CoV-2 viral protein (as opposed to viral RNA detected by nucleic acid amplification tests [NAAT aka PCR tests]). Antigen tests are approved by the FDA for use on symptomatic individuals. No antigen test has yet been yet approved by the FDA for use on asymptomatic individuals.

The main drawbacks of antigen tests are lower sensitivity (more false negatives). Antigen tests are most reliable when used on symptomatic individuals in populations with a high prevalence of disease or high pre-test probability (e.g., symptomatic close contact to a confirmed COVID-19 case).

Positive results in symptomatic individuals are likely to reflect an active infection, but negative tests are presumptive negative and depending on level of clinical concern may need to be confirmed with a NAAT/PCR. A negative antigen test may not exclude infection and is of insufficient sensitivity to make decisions about isolation.

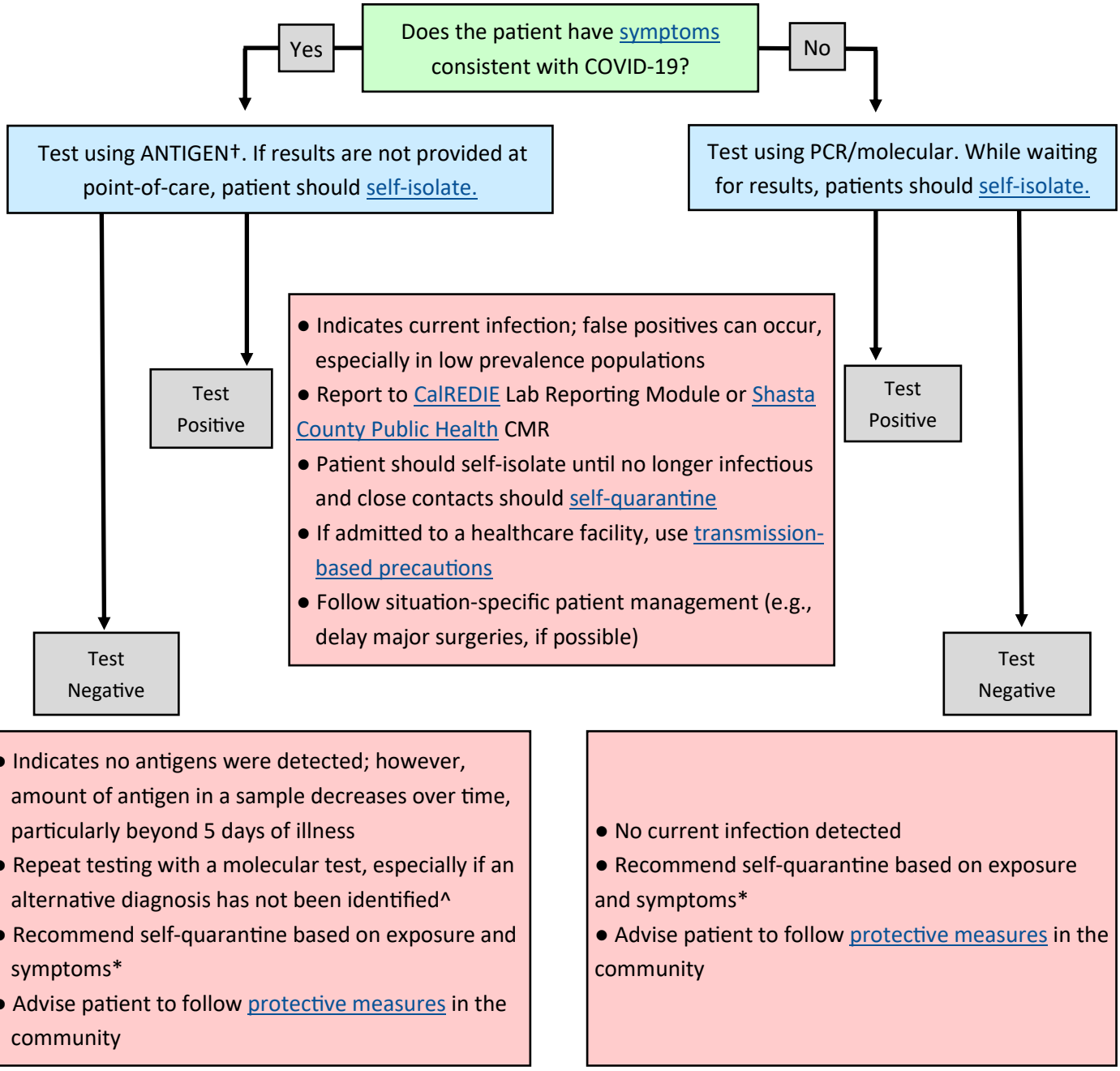
Any confirmatory test of an antigen test result should be performed within 48 hours of the original antigen tests. Confirmatory tests performed more than 48 hours after the original antigen test should be considered a separate test.

General guidelines for use of Abbott BinaxNOW antigen tests

- The BinaxNOW test is authorized for use by the Food and Drug Administration (FDA) in patients with signs and symptoms consistent with COVID-19. Testing in asymptomatic individuals is considered an off-label use.
- For symptomatic individuals, the test must be administered using dry swabs **within 7 days of symptom onset**. Do not use the BinaxNOW test outside this window.
- The BinaxNOW test **should not** be used for screening asymptomatic individuals with no known exposure to a case of COVID-19.
- The test *may* be used in asymptomatic individuals who live or work in a high-risk congregate setting with confirmed COVID-19 cases within the last 14 days, however PCR testing is preferred over antigen testing if test results can be obtained within 48-72 hours.
- Review all training materials prior to implementing testing and follow the manufacturer's Instructions for Use
- Sites that perform Point of Care (POC) antigen tests are required to have a Clinical Laboratory Improvement Amendments (CLIA) Certificate or Certificate of Waiver.

COVID-19 Antigen Testing Algorithm

For healthcare providers to understand who to test and what recommendations to provide based on the results



Recommendations are based on CDC guidance, Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19, APHL's Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing, current FDA Emergency Use Authorizations for available tests, and FDA FAQ.

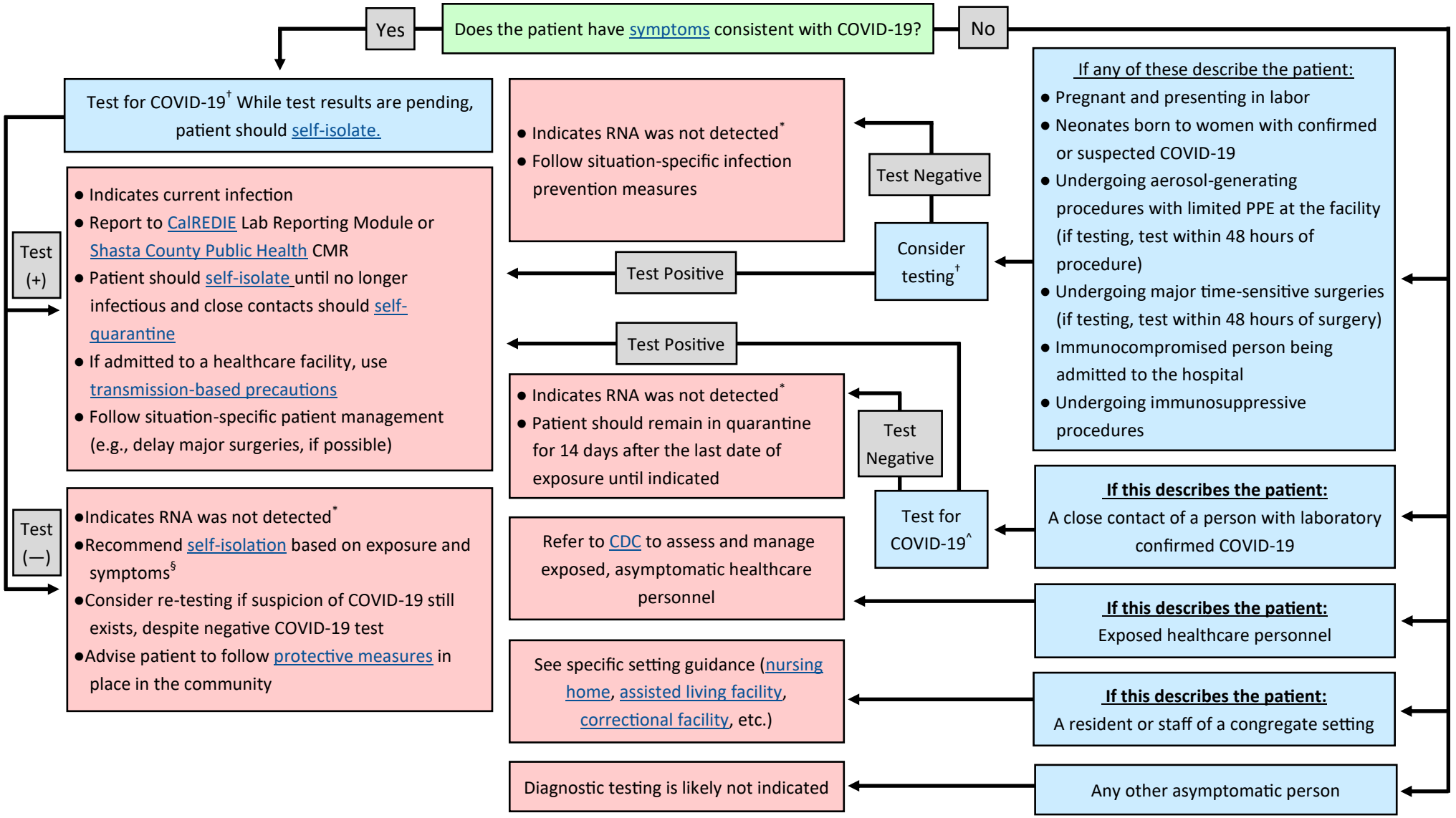
†Point-of-care (POC) tests must be performed at a CLIA-certified laboratory or testing site. If there is a known exposure, it is reasonable to test approximately one week after exposure based on the average incubation period and available evidence to date. Refer to long term care facility guidance for serial antigen testing among asymptomatic individuals in nursing homes.

^When confirming antigen test result with a molecular test, it is important that the time interval between the two sample collections is less than two days, and there have not been any opportunities for new exposures between the two tests.

*If the person had known exposure to someone with COVID-19, the person should continue to self-quarantine until 14 days after the last known exposure. Infection may take up to 2 weeks after exposure to occur. If the person did not have a known exposure to someone with COVID-19, the person should isolate until at least 24 hours after symptoms resolve (if symptomatic) or follow protective measures in the community (is symptomatic).

COVID-19 Molecular Testing Algorithm

For healthcare providers to understand who to test and what recommendations to provide based on the results



Recommendations are based on CDC guidance, Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19.

†For known specimen collection locations in Shasta County, see here.

^If there is a known exposure, it is reasonable to test approximately one week after exposure based on the average incubation period and available evidence to date. If testing is not readily available for all close contacts, prioritize symptomatic close contacts or those at increased risk for severe COVID-19.

§If the person had known exposure to someone with COVID-19, the person should continue to self-quarantine until 14 days after the last known exposure. Infection may take up to 2 weeks after exposure to occur. If the person did not have a known exposure to someone with COVID-19, the person should isolate until at least 24 hours after symptoms resolve (if symptomatic) or follow protective measures in the community (if symptomatic).

*A negative molecular test result for SARS-CoV-2 means that at the time of collection, RNA from this virus was not present in the specimen above the limit of detection.

Acceptable Uses

Refer to General Antigen Test Guidance for when to use antigen tests.

Reporting

All facilities receiving BinaxNOW antigen tests are required to do the following:

1) Record results via the NAVICA App for patient notification purposes.
2) Report all antigen test results (positive, negative, and indeterminate) and patient demographics including race/ethnicity, sexual orientation, and gender identity to Shasta County Health and Human Services Agency, Public Health Branch, using the CalREDIE Lab Reporting Module within 8 hours of the test result. Instructions for access are available at the following link: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/CalREDIE_Manual_Laboratory_Reporting_Module.pdf

Regulatory requirements

Sites that perform Point of Care (POC) antigen tests are required to have a Clinical Laboratory Improvement Amendments (CLIA) Certificate. There are four different types of CLIA certificates, any one of which is appropriate for POC testing. See this Centers for Medicare & Medicaid Services (CMS) document that describes the different types of CLIA certificates. A CLIA Certificate of Waiver is appropriate for POC testing and can be obtained as follows:

1. Complete an application (Form CMS-116), available on the CMS CLIA website or from the California Department of Public Health (CDPH).
2. Send the completed application to CDPH.
3. Pay the CLIA Certificate of Waiver fee, following instructions provided by CDPH.

Further information on obtaining a CLIA Certificate of Waiver may be found here. POC testing may be performed after the testing site has received a CLIA certificate number. The testing site must keep its certificate information current. CDPH should be notified of any changes in ownership, name, address, or director within 30 days.

Process for Request of BinaxNOW POC Testing Devices

1. Medical provider to submit the request to the DOC45 email address (**DOC45@co.shasta.ca.us**). The provider must include completed Situation Status Report and Resource Request documents as part of the request.
2. Medical Health Ordering will review and process the request and if necessary:
    a. Contact the provider via email to address any questions or issues
    b. Contact *COVID19@co.shasta.ca.us* with the subject line BinaxNOW or designated contact person if there is a BinaxNOW POC medical related questions
3. Once the review process is complete, the Medical Health Ordering team will contact the provider regarding the decision and schedule pick up and/or delivery date and time.

Medical providers are encouraged to contact the Medical Health Ordering team by email (DOC45) or by phone (245-7372) if there are questions regarding the process.

For more information on BinaxNOW, please email COVID19@co.shasta.ca.us with "BinaxNOW" in the subject line.

Resources

BinaxNOW COVID-19 Ag Card and Navica App Set-Up and Training. Abbott Diagnostics. NAVICA and BinaxNOW COVID-19 Ag Card Training Site

BinaxNow COVID-19 Ag Card Instructions for Use. https://www.fda.gov/media/141570/download

BinaxNOW Fact Sheet for Healthcare Providers. Abbott Diagnostics. https://www.fda.gov/media/141568/download

California Department of Public Health Guidance on the Use of Antigen Tests for Diagnosis of Acute COVID-19. https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/CDPH-Guidance-on-the-Use-of-Antigen-Tests-for-Diagnosis-of-Acute-COVID-19.aspx#

Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing. Association of Public Health Laboratories. https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf

Considerations for Interpreting Antigen Test Results in Nursing Homes. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf

Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. Centers for Disease Control. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Guidance for SARS-CoV-2 Point-of-Care Testing. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html

Providers and Local Officials. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-shelters/unsheltered-homelessness.html