



COUNTY OF YOLO

Health and Human Services Agency

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Health Advisory

Date: December 17, 2020

To: Yolo County Health Care Providers

From: Aimee Sisson, MD, MPH, Health Officer

Subject: Use of BinaxNOW Antigen Tests in Asymptomatic Persons

SUMMARY

Yolo County is authorizing the use of Abbott BinaxNOW point of care antigen test kits in asymptomatic individuals. Providers wishing to use BinaxNOW kits may request them from the MHOAC by contacting 530-321-3620 or EMSDutyOfficer@yolocounty.org

BACKGROUND

The virus that causes COVID-19, SARS-CoV-2, can be transmitted by persons without symptoms. In order to slow disease transmission, it is important to be able to identify persons infected with SARS-CoV-2 and isolate them before they transmit virus to others. Testing is the only reliable way to diagnose COVID-19. Testing strategies that focus on testing persons with symptoms will miss the large number of cases of COVID-19 in individuals without symptoms. It is critical that we expand testing options for asymptomatic persons.

On August 26, 2020, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for the Abbott BinaxNOW COVID-19 Ag Card. The EUA allows labs with a CLIA Certificate of Waiver, Compliance, or Accreditation to use the test for individuals suspected of COVID-19 within the first 7 days of symptom onset. The BinaxNOW test kit detects viral nucleocapsid protein in direct nasal swabs, requires no laboratory instrumentation, and provides results within 15 minutes. The U.S. government has purchased large quantities of BinaxNOW cards and distributed the cards to states and directly to skilled nursing facilities. The U.S. Centers for Medicare and Medicaid Services (CMS) allows skilled nursing facilities to use BinaxNOW kits as part of required weekly screening testing for facility staff despite the absence of FDA authorization for use in asymptomatic persons. Off-label use of diagnostic tests and therapeutics (i.e., use outside formal FDA approval) is common and legal. For example, one in five prescriptions written today is for off-label use according to the Agency for Healthcare Research and Quality.

Several concerns about accuracy of results have been raised about the use of Abbott BinaxNOW antigen tests in asymptomatic persons. A test's performance depends both on the test's inherent ability to detect antigen as well as the prevalence of disease in the population the test is being used in. Because the Abbott BinaxNOW lateral flow immunoassay technology does not employ an amplification step, it is inherently less sensitive than methods like PCR testing that amplify target RNA sequences. The reduced sensitivity of the BinaxNOW means that false negative results are more likely with the BinaxNOW than with PCR. To compensate for the increased likelihood of false negative results with BinaxNOW testing, more frequent testing can be utilized. If someone is tested multiple times during their infectious period using the BinaxNOW, the likelihood of detecting the infection increases. In most cases, this means that screening

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testing of asymptomatic persons using the BinaxNOW should be done at least twice weekly. Every other day testing would further improve sensitivity compared to twice weekly.

The Abbott BinaxNOW antigen card has high specificity, but the specificity is less than that of PCR testing. When a test with less specificity is used in an asymptomatic population (with inherent lower pre-test probability), the positive predictive value of the test (likelihood of someone having COVID-19 given a positive test) decreases. The reduced positive predictive value means that false positives are more likely when the BinaxNOW card is used in asymptomatic persons compared to use in symptomatic persons. A recent study done in California found that false positives associated with use of the Abbott BinaxNOW card in asymptomatic persons could be reduced by modifying the manufacturer's criteria for classifying test results as positive. Counting only bands that extended across the full width of the testing strip, regardless of the band's intensity, reduced false positives from the BinaxNOW card compared to PCR.

GUIDANCE

The volume of testing currently conducted in Yolo County falls below the statewide median testing volume, indicating that we are testing less than other counties. At the same time, Yolo County's testing positivity rate is increasing, providing further evidence that testing is currently insufficient. Turnaround times for PCR test results are becoming slower as labs across the state and county struggle to keep up with the large volume of specimens submitted for testing. The longer it takes for test results to be available, the longer an asymptomatic individual who is not in isolation will have to transmit virus to others. Finally, many providers in Yolo County are not currently able to offer testing to persons without symptoms due to limited laboratory resources. Given all these considerations, and evidence that the Abbott BinaxNOW can provide accurate results in asymptomatic persons, as Yolo County Health Officer, **I authorize providers in Yolo County to use the Abbott BinaxNOW antigen testing card in asymptomatic persons.** Providers who choose to use BinaxNOW test kits in asymptomatic person are encouraged to use the [modified interpretation guidance](#) developed by United in Health based on research in California.

From a clinical perspective, a positive antigen test result in an asymptomatic person *may* be a false positive result. Providers are encouraged to collect another specimen and conduct confirmatory PCR testing in an asymptomatic person with an initial positive antigen test result. The person being tested is required to isolate while awaiting the results of PCR testing.

From a disease-reporting perspective, all COVID-19 test results, including antigen test results, whether positive or negative, must be reported to the local health department. An individual with a positive COVID-19 antigen test only will be counted as a probable case of COVID-19 and will not be included in State or local counts of confirmed cases. However, probable cases receive the same case investigation and contact tracing follow-up by public health personnel as confirmed cases.

Abbot BinaxNOW Antigen Cards are available to providers in boxes of 40 cards through Yolo County's Medical and Health Operational Area Coordinator (MHOAC). Contact the MHOAC at 530-321-3620 or EMSDutyOfficer@yolocounty.org to request test kits.

RESOURCES

[Pilarowski et al.](#), Performance characteristics of a rapid SARS-CoV-2 antigen detection assay at a public plaza testing site in San Francisco, November 12, 2020. Preprint available at medRxiv.

[Abbott BinaxNOW Training Videos](#)

[FDA EUA for Abbott BinaxNOW Ag Card](#)

[United In Health BinaxNOW Interpretation Guidance](#)