
Information on Availability of Point of Care Antigen Tests for COVID-19

December 31, 2020

Purpose: To notify health care providers of the availability of BinaxNOW Antigen Tests as part of an organization's surveillance testing protocol.

A. 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.

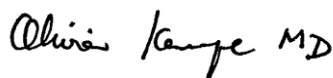
On August 26, 2020, the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for the Abbott BinaxNOW COVID-19 Ag Card. The EUA allows labs with a CLIA Certificate of Waiver, Compliance, or Accreditation to use the test for individuals suspected of COVID-19 within the first 7 days of symptom onset. The BinaxNOW test kit requires no laboratory instrumentation and provides results within 15 minutes. 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.

B. Guidance

Given evidence that the Abbott BinaxNOW can provide accurate results in asymptomatic persons, providers in Sacramento County are authorized 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.

For additional information including requirements for testing, how to request BinaxNow tests locally, and reporting results refer to the attached document "[BinaxNOW COVID-19 Rapid Antigen Test Kit – Guidance.](#)"

Sincerely,



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Health Officer