February 2023

FDA Required Labeling Update SARS-CoV-2 Antigen Tests

On Tuesday, November 1, 2022, the FDA revised the authorized uses and performance data for all COVID-19 antigen tests. This revision comes with required updates to product labeling for all manufacturers for current SARS-CoV-2 antigen tests under Emergency Use Authorization (EUA). The labeling will impact the following Abbott products:

BinaxNOW COVID-19 Ag Card (195000): Prior labeling did not have an asymptomatic claim or require serial testing. New labeling includes an asymptomatic claim and serial test requirement regardless of symptomatic state.

BinaxNOW COVID-19 Antigen Self-Test (195160): Prior labeling required serial testing only if asymptomatic. New labeling requires serial testing regardless of symptomatic state and modifies the serial testing interval.

The two labeling changes are:

1. **Serial Testing Requirement**: Serial testing should be performed in individuals with negative results at least twice over three days (with at least 48 hours between tests) for symptomatic individuals and at least three times over five days (with at least 48 hours between tests) for asymptomatic individuals.

2. **Updated Performance Data**: The clinical performance section in the product inserts is updated to include the results of a supplemental study conducted by the National Institutes of Health (NIH) that pooled the results of several manufacturer's tests when individuals were serially tested. The data shows that repeat COVID-19 antigen testing after a negative test result can increase the chance of detecting COVID-19 in people with and without symptoms.

The new labeling is effective immediately. Distributors can continue to sell existing product that contains the prior labeling while Abbott updates the electronic and printed material, but should refer to the updated product insert available on the Abbott website www.eIFU.abbott.

Distributor partners will be required to update their electronic and print materials specific to BinaxNOW COVID-19 products including but not limited to Product Descriptions, Product Insert, Patient Fact Sheet and Health Provider Fact Sheet, reflecting the new product labeling. Please contact your Corporate Account representative to assist with this product transition.

The BinaxNOW COVID-19 Antigen Self Test and BinaxNOW COVID-19 Ag Card have not been FDA cleared or approved, but have been authorized by the FDA under an emergency use authorization. They have been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens, and are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.