



Indiana
Department
of
Health

Long Term Care NEWSLETTER

Issue 2020-60
September 17, 2020

IMPORTANT NOTICE

- **Abbott BinaxNOW Test – *Distribution to Nursing Homes & Assisted Living Facilities***

The Department of Health & Human Services (HHS) has started distributing 150 million Abbott BinaxNOW COVID-19 Ag Card Point of Care (POC) SARS-CoV-2 diagnostic tests across the country. The first wave of the BinaxNOW test cards is being distributed this week to Nursing Homes and Assisted Living/Residential Care Facilities (AL/RCFs) facilities in designated counties, including 500 facilities in Indiana listed [here](#). Those facilities should have received the email below from HHS confirming eligibility for testing prioritization and relating important information about training for and use of the BinaxNOW tests.

Roughly 170 AL/RCFs and about 330 nursing homes in Indiana will receive BinaxNOW test cards during the first delivery wave. Each of these AL/RCFs will be expected to report its testing results to the Indiana Department of Health, using the same REDCap portal already being used by nursing homes for CMS-mandated testing.

More information about the reporting requirement will be available over the next few days, but if you have immediate questions please email the Long-Term Care Division's point person for test reporting, Michelle Donner, at MiDonner@isdh.IN.gov.

[Abbott BinaxNOW COVID-19 Ag Card Point of Care SARS-CoV-2 Diagnostic Test Distribution to Nursing Homes and Assisted Living Facilities](#)

[COVID-19 Point of Care Test Reporting](#)

HHS Email Sent to Nursing Homes and Assisted Living Facilities:

Good afternoon,

On August 27, 2020, the Trump Administration [announced](#) the purchase of 150 million rapid COVID-19 tests to be distributed across the country. You are receiving this email because your facility is scheduled to receive Abbott BinaxNOW COVID-19 Ag Card Point of Care (POC) SARS-CoV-2 diagnostic tests from the U.S. Department of Health and Human Services (HHS) within the week, having met HHS criteria regarding testing prioritization. Training videos, modules, and frequently asked questions (FAQs) for the

BinaxNOW test can be accessed [here](#) on Abbott's website. For questions regarding the BinaxNOW test, please call Abbott Technical Services at 1-800-257-9525 or email ts.scr@abbott.com. For shipment issues or questions, email ARDxUSGovernmentSupport@abbott.com.

Additional Information

Your facility's use of BinaxNOW COVID-19 Ag Card POC SARS-CoV-2 diagnostic tests will assist with testing of staff and enable adherence to ongoing testing practices according to public health guidelines. The attached one-pager addresses additional information about the test and other related items. Only those facilities with a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver will receive shipments of tests. For CLIA FAQs and information, click [here](#). For Centers for Medicare & Medicaid Services' (CMS) policy regarding laboratories performing antigen tests authorized by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) for use at the POC or in patient care settings operating under a CLIA Certificate of Waiver on asymptomatic individuals, click [here](#). When screening asymptomatic individuals, FDA has stated that health care providers may consider use of less sensitive POC tests, even if not specifically authorized for this indication (commonly referred to as "off-label"). For FDA recommendations for health care providers who are ordering authorized tests outside their authorization (e.g., antigen tests for asymptomatic individuals) – see [FDA's FAQ on Testing for SARS-CoV-2](#) ("Q: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19?") for further information. Lastly, for Public Readiness and Emergency Preparedness Act (PREP Act) coverage guidance for COVID-19 screening tests at nursing homes, assisted-living facilities, long-term-care facilities, and other congregate facilities, click [here](#).

External Affairs /HHS BINAX -Team

Testing and Diagnostics Work Group

COVID-19 Response Team