**BinaxNOWTM Rapid Antigen Tests for Ohio’s ICF/IID**

The Ohio Department of Developmental Disabilities (DODD), in collaboration with our state partners, is currently able to secure 5,000 BinaxNOWTM Rapid Antigen Tests per week for distribution to Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs) whose residents may be the most vulnerable to contacting COVID-19. This is only committed through December 31, 2020.

* **Use of these tests is entirely voluntary**
* **This is not for surveillance testing**
* **The tests are for determining if symptomatic people are positive for COVID-19**
* **ICF/IIDs must have a Clinical Laboratory Improvement Amendments (CLIA) Waiver to use these tests**

The current limited supplies for distribution to ICF/IID facilities is for using the BinaxNOWTM tests for people with symptoms of suspected COVID-19. The BinaxNOWTM test is most accurate **when used to determine if a person with symptoms is positive for COVID-19.** This mitigates the risk of false positive results with asymptomatic individuals.

The BinaxNOWTM test should be used for the detection of COVID-19 in individuals who are determined to be suspected of COVID-19 **within the first seven days of onset of symptoms.**

* A healthcare provider needs to prescribe use of the test
* These can be standing orders for facility personnel and residents

The test can easily be performed at the ICF and takes 15 minutes to process after the sample collected from both sides of the nose is inserted in the test card.

**Symptomatic people who test positive do not need confirmation with a PCR test** (the molecular polymerase chain reaction test) unless indicated by their healthcare provider or the local health department.

Isolation and quarantine guidance are contained in the Long-Term Service and Support guidelines (LTSS)

[**https://dodd.ohio.gov/wps/portal/gov/dodd/about-us/communication/news/news-guidance-ltss**](https://dodd.ohio.gov/wps/portal/gov/dodd/about-us/communication/news/news-guidance-ltss)

Facilities must have a **CLIA Waiver to be able to administer the test.** The BinaxNOWTM has been authorized by the FDA under an Emergency Use Authorization for use at the Point of Care, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. (more information on CLIA Waiver can be found at <https://www.cms.gov/Regulations-and-guidance/legislation/CLIA/downloads/howobtaincertificateofwaiver.pdf>



**All tests must have results reported** (positive and negative) daily. See document below for more details. Facilities may start testing while they arrange for reporting. **All positive tests must still be reported to the Local Health Department.**



**Distribution:**

1. DODD will have a distribution list for all ICF/IIDs to receive an initial supply of test kits based on their size
	1. Each “kit” contains 40 test cards
	2. Initial distribution will attempt to make sure every ICF has access to tests as soon as possible (if no CLIA Waiver please do not accept tests for agency/facility)
	3. The Initial delivery of tests will be by agencies within counties; it will take at least 3 weeks to supply all ICFs in the state
2. Kits will be delivered to County Boards of DD for further distribution to the specific ICF as listed on the DODD distribution list
	1. The county contact will be sent shipping tracking information once tests have shipped
	2. The county board contact will notify each provider to arrange test pick-up after receiving the stock
3. After the original distribution waves each provider will contact their DODD Statewide Support Team representative to arrange for additional tests <https://dodd.ohio.gov/wps/portal/gov/dodd/about-us/support-team/Support-Team>

**Manufacturer Information about the BinaxNOWTM COVID-19 Test and NAVICATM mobile app**

* In data submitted to the FDA from a clinical study conducted by Abbott with several leading U.S. research universities, the BinaxNOW COVID-19 Ag Card demonstrated sensitivity of 97.1% (positive percent agreement) and specificity of 98.5% (negative percent agreement) **in patients suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.**
* **Testers must watch the training videos** before initiating testing procedures.

Training Link: [**https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html**](https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html)

* + Training videos
	+ Helpful documents for downloading including a fact sheet for patients in English or Spanish

Abbott Technical Services at 1-800-257-9525 or e-mail **ts.scr@abbott.com**

Although use f the NAVICATM app for mobile devices is not mandatory it can be used to provide encrypted results to participants allowing them to obtain a digital NAVICA Pass with negative test results. NAVICATMAdministratorapp sign up is done on the Abbott training page listed above. Participants must download the participant version of the app to receive the results.

* **Used test kit materials should be discarded as Biohazard waste.**
* **Storage:** Tests should be stored at room temperature (between 35- and 86-degrees Fahrenheit).
* **A Quality Control** element is built into each test with a blue control line that turns pink if test was completed correctly. Each box includes a positive test swab to do a quality control test with each shipment.
* **Specimen Collection:** Wear appropriate personal protection equipment and gloves in accordance with CDC guidance when running each test and handling patient specimens

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/broad-based-testing.html#:~:text=Gown%2C%20N95%20equivalent%20or%20higher,of%20the%20person%20being%20tested>

* Change gloves between handling of specimens suspected of COVID-19
* Use only the swab in the kit and process with test immediately – do not store or transport test swab; do not return the swab to the paper packaging

**Questions:**

About testing in ICF/IIDs can be sent to**:** DODDCR-ICF@DODD.OHIO.GOV

About use of the test: Abbott Technical Services at 1-800-257-9525 or e-mail **ts.scr@abbott.com**