

The U.S. Department of Health and Human Services (HHS) has begun distribution of Abbott BinaxNOW™ COVID-19 Antigen (Ag) Card Point of Care (POC) SARS-CoV-2 diagnostic tests. Recipients include states, long term care facilities (LTCF), and historically black colleges and universities (HBCUs).

What requirements exist for those receiving the test kits?

- Recipients must:
 - ✓ Be a CLIA-waived facility
 - ✓ Use the tests per manufacturer's instructions
 - ✓ Report all test results to TN Department of Health
 - ✓ Counsel patients based on their results

How should stakeholders use these test kits?

1. Apply for a CLIA Waiver (if not already a CLIA-waived) facility

- Review CMS Guidance to apply for a CLIA Waiver:
<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf>
- Complete CMS Form 116:
 - <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>
- Request CLIA Waiver Electronically
 - Upload application to Email: CLIA.Health@tn.gov (recommended) or
 - Fax CLIA Application: (615) 532-2700 or
 - Mail application to:
Office of Health Care Facilities, CLIA Certification
665 Mainstream Drive, 2nd Floor
Nashville, TN 37243
- For more information, see <https://www.tn.gov/health/clinical-laboratory-improvement-amendments/clia/faq.html>
Phone: (615) 741-7023
Fax: (615) 532-2700
Email: CLIA.Health@tn.gov

2. Review the material included in the test kit, and use the kits appropriately

The Intended Use Statement from the manufacturer reads: *"The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from individual suspected of COVID-19 by their **healthcare provider within the first seven days of symptom onset**. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263A, that meet the requirements to perform moderate, high or waived complexity tests. **This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.**"*

3. Follow the directions provided in the product insert to test patients.

4. Counsel the patient based on their results.

- **What to do if you get a positive result?**
 - Use TDH's *Guidance for Cases* for counseling the patient: <https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/CaseGuidance.pdf>
 - Consider the possibility of a false positive, based on the patient's clinical presentation and exposure history.
 - Consider using confirmatory molecular test (*i.e.* PCR) for SARS-CoV-2
- **What to do if you have a negative result?**
 - Use TDH's *What to Do if You Test Negative* document to counsel the patient: <https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/what-to-do-if-you-test-negative.pdf>
 - Consider the possibility of a false negative, based on the patient's clinical presentation and exposure history.
 - Consider using confirmatory molecular test (*i.e.* PCR) for SARS-CoV-2
 - Consider an alternative diagnosis
 - If a patient has a known exposure to a COVID-19 case, they must adhere to quarantine recommendations. Refer to the TDH isolation and quarantine guidance for more details: <https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/Isolation-QuarantineRelease.pdf>
- **Additional information from CDC about Antigen Tests and interpreting results is available here:** <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

5. Report the results to TDH, following the guidance for reporting Point of Care Results posted here: <https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/POC-Reporting-Guidance.pdf>

How can I order additional BinaxNOW kits through the State?

- Additional test kits can be ordered online through TEMA's Survey123
- Follow the guidance here: https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/Request_Binax_Supplies.pdf

How can I order additional external Binax Quality Control kits?

- Test sites should email their request to HHS: HHSbinax@hhs.gov
- The same email needs to copy Col Mol on each request: MOL, ROSS A Lt Col US Air Force HAF AF/A4P <ross.mol@us.af.mil>
 - Binax QC kits have 10 positive controls/kit: 195-080: BinaxNOW™ COVID-19 Ag Control Swab Kit (10 Positive Swabs)