

The Tennessee Department of Health has begun distribution of Professional Use 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), health departments, healthcare facilities, etc.

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(s) reads: *"The BinaxNOW/QuickVue 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 five or seven days of symptom onset (depending on Test Kit)**. 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 should adhere to exposure guidance. Refer to the CDC recommendations for cases and contacts 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 Lab Reporting Guidance posted here:

<https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/TDH-COVID-Lab-Reporting-Guidance.pdf>

How can I order additional Professional Test 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_covid_ag_cards.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)