NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Resource Compendium for Point of Care Testing Device Use in Long-term Care Settings

10/20/2020

## Point of Care COVID-19 Devices Summary Description

| | Types of Point of Care Testing Devices | Examples of Brand/Device |
|---|---|---|
| **Point of Care Devices (aka Rapid Response Devices)** | Molecular (nucleic acid amplification) | Abbott ID Now* |
| | Antigen | • Quidel Sofia 2<br>• BD Veritor™ System For Rapid Detection of SARS-CoV-2<br>• BiNAX Now COVID Ag Card and NAVICA app |
| *Per *Guidance—Proposed Use of Testing Platforms*, CDC/Office of the Assistant Secretary for Health | | |

## Policy Guidance Related to Point of Care Testing Devices

**NC DHHS Guidance:**

- *Antigen Testing* Memo, available here.

**Federal Guidance:**

- Centers for Disease Control and Prevention (CDC)'s Point of Care Testing Resource page here.
- For policy guidance regarding performance of antigen tests authorized by the FDA under an Emergency Use Authorization (EUA) at the point of care or in patient care settings operating under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver, please refer to Centers for Medicare & Medicaid Services' (CMS) policy here and PREP Act guidance here.
- For FDA recommendations to health care providers who are ordering authorized tests outside their authorization (e.g., antigen tests for asymptomatic individuals), please see FDA's FAQ on Testing for SARS-CoV-2.
- CLIA FAQs and information, available here.
- FAQs about CMS' Distribution of Point of Care Antigen Testing Devices, available here.

**Additional Resource:**

- APHL's *Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing*, available here.

## POC Device Training Resources

- For BD Veritor Devices
- For Quidel Sofia 2 Devices
- For Binax NOW COVID Ag Card

## POC Supply Chain Questions

- Troubleshooting on POC supply chain issues/providing guidance on resources available: NHTesting@hhs.gov