

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
	Molecular (nucleic acid amplification)	Abbott ID Now*
Point of Care	Antigen	Quidel Sofia 2
Devices (aka Rapid Response Devices)		BD Veritor™ System For Rapid Detection Start Salves
Response Devices;		of SARS-CoV-2BINAX Now COVID Ag Card and NAVICA
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*Per <u>Guidance—Proposed Use of Testing Platforms</u> , 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 <u>FDA's FAQ on Testing for SARS-CoV-2</u>.
- CLIA FAQs and information, available <u>here</u>.
- 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