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

<table>
<thead>
<tr>
<th>Point of Care Devices (aka Rapid Response Devices)</th>
<th>Types of Point of Care Testing Devices</th>
<th>Examples of Brand/Device</th>
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<tbody>
<tr>
<td></td>
<td>Molecular (nucleic acid amplification)</td>
<td>Abbott ID Now*</td>
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<td>Antigen</td>
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<td>• Quidel Sofia 2</td>
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<td>• BD Veritor™ System For Rapid Detection of SARS-CoV-2</td>
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<td>• BiNAX Now COVID Ag Card and NAVICA app</td>
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*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