

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

LEADING AMERICA TO HEALTHIER LIVES

ABBOTT BINAXNOW™ WEBINAR FOR ASSISTED LIVING FACILITIES

SEPTEMBER 18, 2020



NOTICE

This webinar is intended for assisted living facilities receiving Abbott BinaxNOW™ tests from the U.S. Department of Health and Human Services.

It is not intended for members of the media.

Agenda for today

Welcome

12:00 PM - 12:05 PM

Dr. Tammy Beckham, Lead for Testing and Diagnostics Working Group at HHS

Abbot BinaxNOW™ Overview

12:05 PM - 12:40 PM

Ashley Cilfone, *Director of Training and Development at Abbott*Amanda Simpson, *Director of Field Technical Operations at Abbott*David Kowalski, *Director of Global Marketing - Rapid Diagnostics*

CDC Update on Testing Guidance

12:40 PM - 12:50 PM

Dr. Nimalie Stone, Long Term Care Team Lead at the CDC

Q&A Session

12:50 PM - 1:00 PM

All panelists



ABBOTT RAPID DIAGNOSTICS

BinaxNOWTM COVID-19 Ag Card Test & NAVICATM App

HHS Assisted Living Webinar September 18, 2020

Agenda

- Introduce Testing Solution
 - BinaxNOW™ COVID-19 Ag Card Test
 - − NAVICA™ App
- Training Toolkit & Technical Resources
- Review FAQs

HHS ASSISTED LIVING WEBINAR

BinaxNOWTM COVID-19 Ag Card Test Overview

BinaxNOW™ COVID-19 AG CARD

A Breakthrough Antigen Test

SIMPLIFYING THE TEST PROCESS

- Cost-effective, high performing test designed for decentralized testing
- Simple test procedure
- Direct Nasal swab
- Onboard extraction allows the swab to be directly inserted into the test card
- Visually read results in 15 minutes (no instrument required)
- Emergency Use Authorization (EUA)
 supports testing in patient care settings
 operating under a CLIA Certificate of
 Waiver, Certificate of Compliance or
 Certificate of Accreditation*

PERFORMANCE

Sensitivity (PPA) 97.1%

Specificity (NPA) 98.5%

Direct nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.



Intended Use Key Points

- The BinaxNOW[™] COVID-19 Ag Card is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from **individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.**
- Antigen is generally detectable in nasal swabs during the acute phase of infection.
- Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay if necessary, for patient management, may be performed

Intended Use Resources for Questions

Resources for Intended Use Questions:

- For FDA recommendations for Health Care Providers who are ordering tests outside of their authorization (e.g. antigen tests for asymptomatic individuals) see FDA's FAQ on Testing for SARS-CoV-2
- <u>Refer to the PREP Act Coverage for COVID-19 Screening at Congregate</u>
 <u>Facilities document</u> for Guidance from the Department of Health and
 Human Services
- Direct any additional questions regarding BinaxNOW Ag Card Intended Use to the Abbott Technical Services Team at 1-800-257-9525 between 8 a.m. and 8 p.m. EST Monday-Friday or email ts.scr@abbott.com

BinaxNOW[™] COVID-19 Ag Emergency Use Authorization

The BinaxNOW COVID-19 Ag Card is only for use under the Food and Drug Administration's Emergency Use Authorization

What is Emergency Use Authorization (EUA)?

- FDA emergency access mechanism
- Health & Huan Services declare when circumstances exist to justify use of diagnostics under EUA for the diagnosis of COVID-19
- It is not full FDA clearance or approval and is temporary, until the declaration is terminated or revoked.

BinaxNOW[™] COVID-19 Ag Emergency Use Authorization Responsibility

Test Site Obligations:

- Notify relevant public health authorities on intent to run test
- Report all results to healthcare providers and include the Healthcare Provider Fact Sheet. Healthcare providers to include Patient Fact Sheet with results
- Ensure all operators are trained to perform and interpret the test
- Per Product Insert: Collect performance data and report via email to FDA/HHS and to Abbott Technical Support
- Retain all records associated with EUA until otherwise directed by FDA

HHS ASSISTED LIVING WEBINAR

BinaxNOWTM COVID-19 Ag Card Technical Overview

BinaxNOWTM COVID-19 Ag Card Product Overview

Test Summary	Rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2
Testing Environment	Point of Care settings with a CLIA Certificate of Waiver
Specimen Type	Direct nasal swab
Time to Result	Results visually read at 15 minutes *Results should not be read after 30 minutes
Reagent & Materials	40 test cards, extraction reagent, QC & patient collection swabs, Product Insert, Procedure Card & Fact Sheets
Waste Disposal	All components should be discarded as Biohazard Waste
PPE for Specimen Collection and Handling	Refer to CDC Guidelines for collecting, handling and testing clinical specimens (link in Product Insert)

Internal Quality Control

Internal Procedural Controls:

- BinaxNOW[™] COVID-19 Ag Card has built-in procedural controls
- In an untested card there will be a blue line at the Control Line position
- In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working



Note: If the blue line is not present at the Control Line position prior to running the test, do not use and discard

When is Quality Control Required?

External Positive & Negative Controls:

- Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working properly and that the test is correctly performed
- BinaxNOW[™] COVID-19 Ag Card kits contain a positive control swab and sterile swabs that can be used as a negative control

Required Frequency:

- New shipments received
- Untrained operators
- Conforming with local, state, and/or federal regulations, accrediting groups, or lab's standard QC procedures.

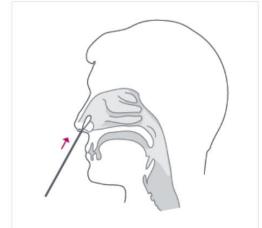


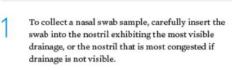
Note: If correct results are not obtained, contact the Abbott Technical Services Team at 1-800-257-9525 between 8 a.m. and 8 p.m. EST Monday-Friday before testing patient specimens

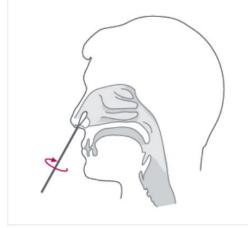
Nasal Swab Sample Collection

Sample Collection Key Points:

- Only the swab provided in the kit is to be used for nasal swab collection
- Insert swab until resistance is met
 - At the level of the nasal turbinates
 - less than 1 inch into the nostril
- Rotate the swab 5 times or more against the nasal wall
- Using the same swab, repeat sample collection in the other nostril





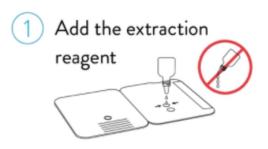


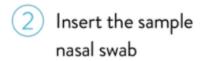
Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab 5 times or more against the nasal wall and then slowly remove from the nostril.

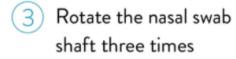
3 Using the same swab, repeat sample collection in the other nostril.

For optimal performance, test specimens immediately after collection

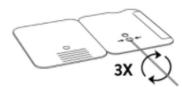
BinaxNOW[™] COVID-19 Ag Card Test Procedure Overview

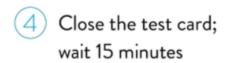




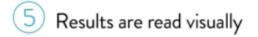


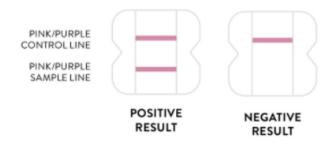












- To ensure proper test performance read results at 15 minutes and not before
- Results should not be read after 30mins

Additional Resources

Ordering Information

- 195-000: BinaxNOW™ COVID-19 Ag Card (40 Tests)
- 195-080: BinaxNOW™ COVID-19 Ag Control Swab Kit (10 positive swabs)
- 190-010: Optional COVID-19 Swab Transport Tube Accessory Pack (24 tubes)

Technical Support Line:

- US +1 800 257 9525, 8am-8pm EST M-F
- <u>ts.scr@abbott.com</u>

hhs assisted living webinar $NAVICA^{\mathrm{TM}}\,App$

Introducing NAVICA.

An end-to-end, secure, accessible COVID-19 Testing Solution



A digital COVID-19 application designed to create a personalized and seamless testing experience that is available to all

NAVICA[™] Has a Familiar Experience to Apps We Use Everyday

Simplicity

- Based on familiar consumer experiences
- Low learning required to setup and use without help
- Designed to scale rapidly

Availability

• Available on App Store and Google Play Store

Security

- Cloud based, scalable infrastructure with independent ongoing security assessments to maintain the security of the platform
- Data is fully encrypted at all times.



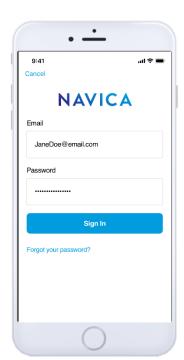


Downloading and sign-up is quick, simple, and secure





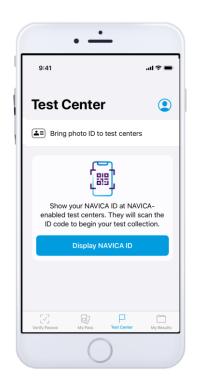






NAVICA[™] App for Test Participants BinaxNOW [™] COVID-19 Test Results Quickly and Securely Shared

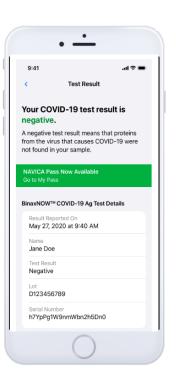
NAVICA



Find Testing Sites



Use NAVICA ID To Get Tested



Receive Test Results Electronically



Use NAVICA Pass To Show Status

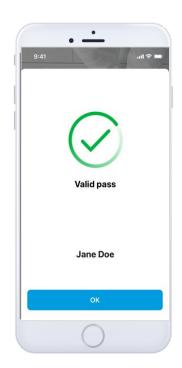


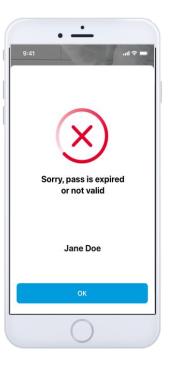
NAVICA[™] Verifier Verification of an Authentic and Secure NAVICA Pass

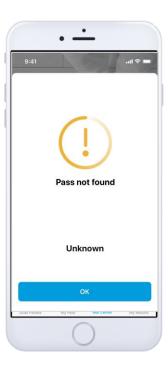
NAVICA











Status Can Be Confirmed Using NAVICA Verifier Available in NAVICA Application

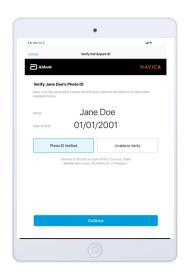


NAVICA Administrator guides the test operator through the process of capturing the test result*



Ease of Use

- · Intuitive Design
- · Simple Log in Processon
- Focus on Patient/Participant



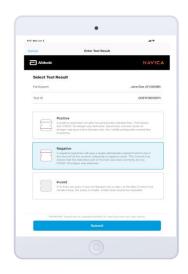
Workflow Confirmations

- App guides admin through process
- Verify NAVICA ID with Photo ID



Accurate and Secure.

 Connects NAVICA ID with BinaxNOW COVID-19 test card



Connected and Private

- NAVICA ID and test card connection confirmed by rescanning test card
- Results visually interpreted and then securely communicated to NAVICA test participant

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*NAVICA Administrator app is designed be used with an Apple or Android tablet



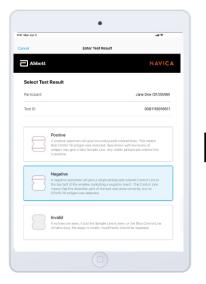
NAVICA[™] Administrator Verify Test is Authentic, Unused, and Will be Matched to the Participant



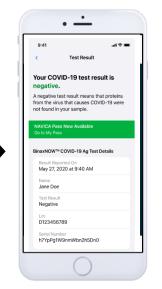
Intuitive workflow for reporting results digitally



Scan the test to securely retrieve the right test record



Tap to report the results to the participant electronically



Automatically updates NAVICA participant

NAVICA APP AND BINAXNOW COVID-19 AG CARD

Training Toolkit

Training Toolkit Homepage

Step 1:

BinaxNOW® COVID-19 Ag Card Demo Video

The BinaxNOW demo video provides an overview of the BinaxNOW test process. This video can be viewed prior to the more detailed training to see a brief demonstration of the testing process from start to finish.



Training Toolkit Homepage

Step 2:

BinaxNOW® COVID-19 Ag Card Training Videos

The BinaxNOW training video provides a detailed step by step guide to the BinaxNOW test process. The training video, divided into modules, should be completed in its entirety before performing tests on individuals.

- Module 1: Getting Started
- Module 2: Quality Control
- Module 3: Specimen Collection & Handling
- Module 4: Patient Test

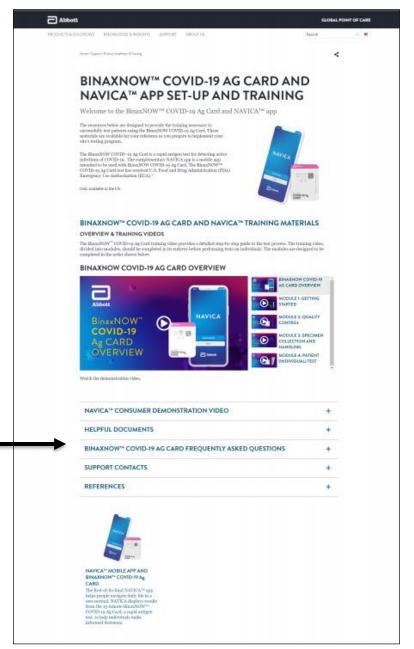


Training Toolkit Homepage

Step 3:

Review Support Documents & Contacts

- NAVICA™ Demonstration Video
- BinaxNOW® COVID-19 Ag Card Training Document
- Product Insert
- Procedure Cards
- Clinical and Laboratory Standards Institute (CLSI)
 Documents
- Introduction to CLIA-Waived Testing
- Support Contacts: Technical Service Phone and Email
- FAQs



Proprietary and confidenti

Technical Services

For any questions pertaining to the BinaxNOW COVID-19 Ag Card or NAVICA, please contact the Abbott Technical Services Team

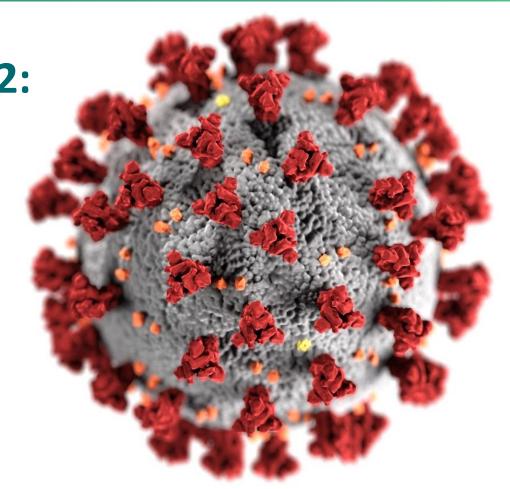
1-800-257-9525 between 8 a.m and 8 p.m. EST Monday-Friday Email ts.scr@abbott.com.



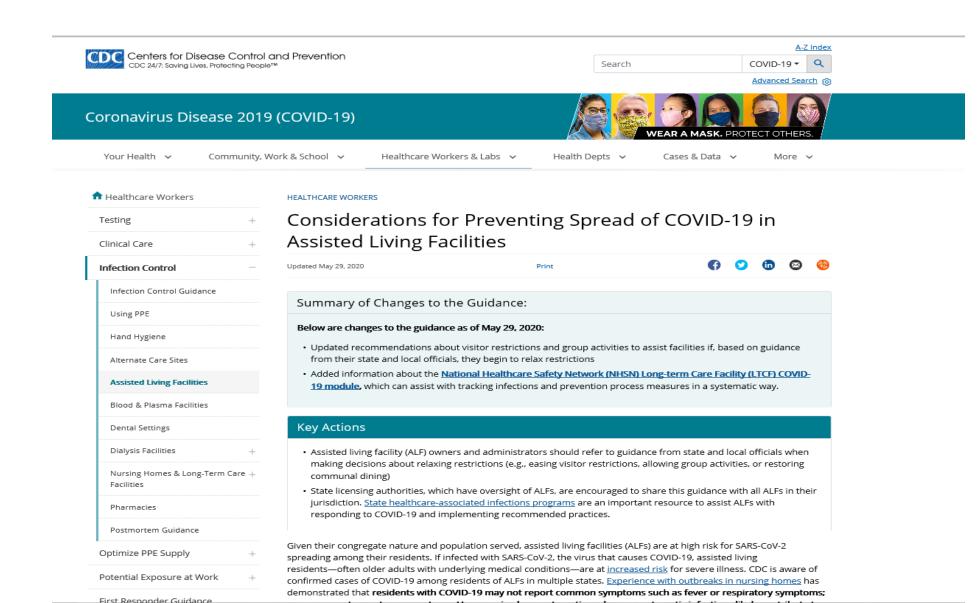
Detecting/Responding to SARS-CoV-2: Considerations for Assisted Living/ Residential Care Facilities

> Nimalie D. Stone, MD Long-term Care Team Lead





For more information: www.cdc.gov/COVID19





Core Activities: Maintaining COVID-19 Readiness

- Identify a point of contact at the local health department to facilitate prompt notification
- Educate residents, family members, and personnel about COVID-19
- Have a plan for visitor and personnel restrictions
- Encourage source control / Encourage social (physical) distancing
- Provide access to supplies and implement recommended infection prevention and control practices
- Rapidly identify and properly respond to residents with suspected or confirmed COVID-19
- Report COVID-19 cases, facility staffing, and supply information to the <u>National</u> <u>Healthcare Safety Network (NHSN) Long-term Care Facility (LTCF) COVID-19</u> <u>module</u> (optional surveillance resource)



Core Activities: Maintain Supplies to Implement IPC

- Access to hand hygiene using alcohol-based hand sanitizer to make it easier to incorporate hand hygiene into workflow and during high risk activities (e.g., PPE doffing)
- Use of <u>appropriate products</u> for cleaning and disinfection of shared equipment and environmental surfaces
- Personal protective equipment (PPE)
 - Continuing to monitor PPE use (burn-rate) and maintain supplies
 - Ensure ongoing familiarity with PPE equipment selection and handling, especially if supplies change
 - Resources on PPE selection/use and conservation strategies
 - https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html
 - https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html

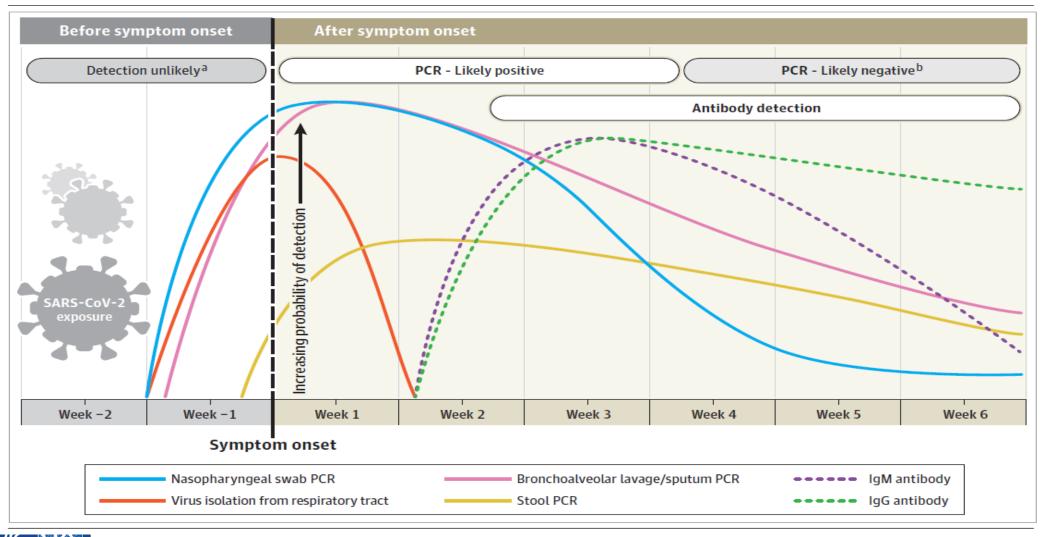


SARS-CoV-2 Testing Considerations



COVID-19 Infection Timeline and Testing

Figure. Estimated Variation Over Time in Diagnostic Tests for Detection of SARS-CoV-2 Infection Relative to Symptom Onset





Understanding SARS-CoV-2 tests

Table 2. Comparison of In Vitro SARS-CoV-2 Tests Granted Emergency Use Authorizations by the U.S. FDA

	Molecular	Antigen	Serology
Test Type	Viral	Viral	Antibody
Diagnostic Test	Yes	Yes	No
Description	Nucleic acid amplification test to detect viral RNA	Detects viral proteins in the nasal cavity	Detects the presence of IgA, IgM & IgG antibodies against SARS-CoV-2
Measure	Current infection with SARS- CoV-2	Current infection with SARS- CoV-2	Past exposure to SARS-CoV-2
Platform Technology	RT-PCR, LAMP, CRISPR	Lateral Flow	Lateral Flow, ELISA, CIA
Sample Type	Nasal or throat swab, Saliva, Bronchoalveolar lavage fluid	Nasal or throat swab	Blood draw (plasma, serum, whole blood) or Finger Stick
Testing Window	Days 1-28 after symptom onset, Optimal days 3-12	Days 1-28 after symptom onset, Optimal days 3-12	IgA/IgM: From day 5 after symptom onset, Optimal days 14-21; IgG: From day 14 after symptom onset up to 6 weeks
Result Turnaround Time	Same day or up to a week (depending on location); Point- of-care option available (within 1-2 hours)	Rapid, point-of-care (within 15 minutes)	Same day or up to 1-3 days (depending on location); Point-of-care option available (within 15-30 minutes)

 Only viral diagnostic tests (molecular "PCR" or antigen) can be used to determine presence of active COVID-19 infection

 Serology, or "antibody" testing is used to determine previous infection



Chau CH et al. Pharmacotherapy 2020 Jul 8;10.1002/phar.2439. doi: 10.1002/phar.2439 https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html

Factors that can impact test results

- Quality of the specimen collection
 - Inadequate sampling or mishandling of the specimen prior to running the diagnostic test can impact detection
- Proper use of the testing platform
 - Personnel should be trained and proficient in sample handling and running the tests
 - Use of positive and negative quality controls
- Clinical presentation at the time of the test (e.g., recent exposure or symptoms)
- Prevalence of COVID-19 in the center and community



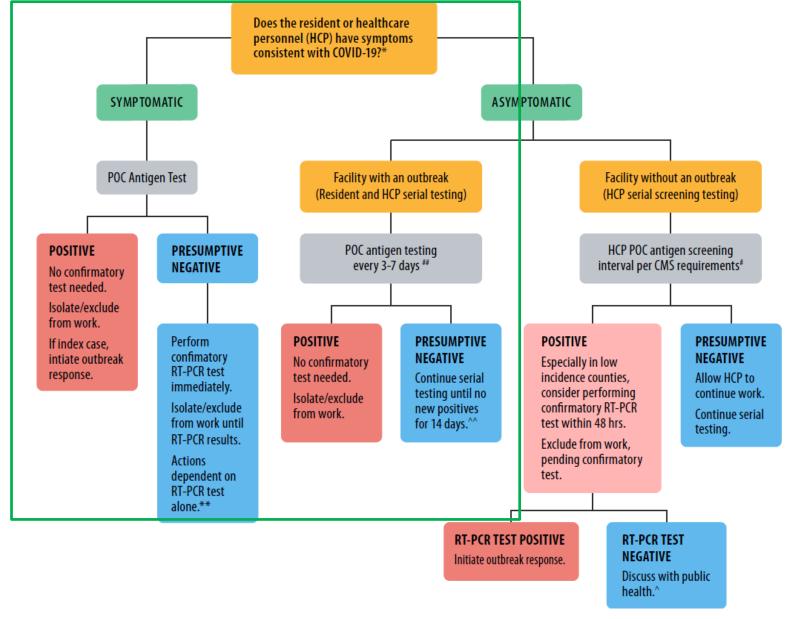
SARS-CoV-2 Testing in Response to a Case

- A new SARS-CoV-2 infection in any healthcare personnel (HCP) or any facilityonset SARS-CoV-2 infection in a resident should prompt investigation
- Expand diagnostic testing for all residents and healthcare personnel
 - Prioritize symptomatic residents and healthcare personnel
 - If testing supplies or capacity is limited, perform unit-based testing or testing other high-risk residents (e.g., roommates of COVID-19 infected residents)
- Perform repeat testing of all previously negative residents and HCP
 - Testing should be performed every 3-7 days until no new positive results are found for at least 14 days since last positive test result
 - If testing capacity is limited, prioritize testing for residents with known exposure to a case, residents and HCP on affected units

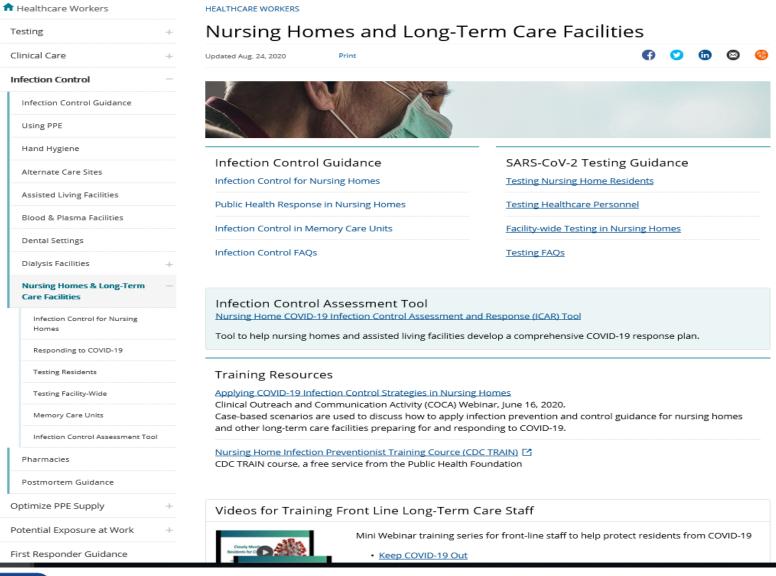


Considerations for interpreting antigen testing results

 New CDC guidance to support use of point of care antigen tests



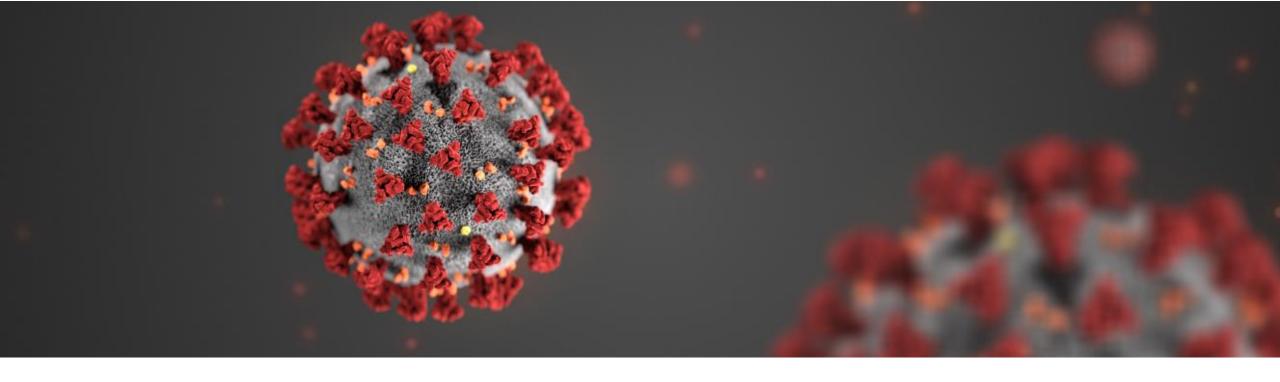




- CDC COVID-19Resource Page
 - Infection Control
 Guidance
 - Testing guidance
 - Assessment tools
 - Training materials



https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-home-long-term-care.html



For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



ABQ

To ask a question of the panelists, please submit your question through the Zoom Q&A Chat Box



For further questions, please contact Abbott at ts.scr@abbott.com.



Retail pharmacy contacts



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Other pharmacy partners



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CPESN Local Network Contact Information:

https://www.cpesn.com/media/1200/cpesn-usa-local-network-

contact-information.pdf



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Jennifer Zilka: jzilka@amerisourcebergen.com

For additional questions to our presenters, please reach out directly

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CDC

https://www.cdc.gov/cdc-info/index.html (800)-232-4636



Thank you!