CDC Interim Guidance for Rapid Antigen Testing

AHCA/NCAL Member Summary

CDC has released interim guidance on rapid antigen testing for COVID-19. This document provides an explanation and summary of this guidance focusing on the elements that impact long-term care providers.

The key points that members should be aware of include:

- The two rapid antigen tests on the market (BD Veritor and Quidel Sofia2, which are being sent to all nursing homes by CMS) are currently intended for use in diagnostic testing of symptomatic patients within five days of symptom onset.
- The CDC expands use of these rapid antigen tests to include use as screening tool in congregate settings (such as a nursing home) for staff and residents.
- All long term care facilities must defer to state or local guidance on their use. If no such guidance exists, you may consider following CDC guidance.
- Evaluating the test results must be done in context with the person's symptoms and how likely COVID-19 is in the group of people getting the tests, which is usually similar to the community's rate of COVID-19.

Here is a further explanation of the interim guidance.

Definitions

- **Diagnostic Testing**: Testing performed on an individual who is symptomatic, suspect of having COVID-19 or has confirmed exposure to COVID-19.
- **Screening Testing**: Testing to identify asymptomatic individuals or individuals without known exposure to COVID-19 so that steps can be taken to prevent further transmission. Testing of staff or resident in long-term care facilities is an example of screening testing.
- **Surveillance Testing**: Public health testing of large groups or the population to understand the prevalence and spread.
- **Sensitivity**: % of all people with COVID-19 who test positive
- **Specificity**: % of all people without COVID-19 who test negative
- **Positive Predictive Value:** % of people who test positive who actually have COVID-19.
- **Negative Predictive Value**: % of people who test negative who actually do not have COVID-19.
- **Pretest probability**: Likelihood of a patient having COVID-19, which is based on:
    - the proportion of people in a community with COVID-19 (i.e., prevalence), commonly assessed as either the test positive rate in the community or the 7-day rolling average per 100,000
    - the clinical presentation of the patient (i.e. signs and symptoms of COVID-19)
    - their exposure risks (e.g. living with people who contracted COVID-19)

General Guidance

CDC outlines three situations in which antigen testing is particularly useful:

1. For a person with symptoms suggestive of COVID-19, particularly in early stages of COVID-19 when viral load is the highest.
2. For a person with a known exposure to COVID-19 to diagnose if they contracted COVID-19 (note a person may take up to 14 days to develop the infection after exposure).
3. Screening of individuals in high-risk congregate settings (such as a nursing home) who maybe asymptomatic or in a pre-symptomatic phase, in which rapid results and repeat testing afforded by point of care antigen tests can identify an individual with COVID-19 to help limit spread[1].

Regulatory Requirements

- Any antigen test device used must have an Emergency Use Agreement (EUA) from the FDA. The Quidel Sofia2 and the BD Veritor are currently the only two point of care antigen testing devices with an EUA from the FDA.
- Any nursing home conducting screening or diagnostic testing must comply with Clinical Laboratory Improvement Amendments (CLIA) regulations, which includes:
    - Obtaining a CLIA certificate
    - Meet all CLIA requirements to perform the testing. This includes assuring professionals conducting the test meet all training requirements for the test equipment used (training links available at the end of the document).

Specimen Collection

- The CDC states that the reliability of test results is impacted by proper specimen collection and handling. This could include:
    - Inadequate specimen collection
    - Inadequate quality assurance procedures
    - Delays from sample collection to testing
    - Biosafety measures and instructions for use not being followed
- Providers should refer to the CDC's guidance on Collecting, Handling, and Testing Clinical Specimens for COVID-19 and also follow the manufacturer's instructions.

Test Performance

- The sensitivity of a rapid antigen test is lower than a PCR test, which means the false negatives are about 10-15% higher with the antigen tests compared to PCR tests.
- The sensitivity can vary based on the viral load in a patient. A patient tested after five days of symptoms may drop their viral shedding load below the detection limit of the test.
- The specificity of a rapid antigen test is generally as high as a PCR test, which means that false positives are unlikely with both tests.
- Positive and negative predictive values of all diagnostic tests vary depending on pretest probability of the patient being tested.

[1] CDC states that currently there is limited data to specifically guide the use of rapid antigen tests as screening tests on asymptomatic individuals to detect or exclude COVID-19.

- The positive predictive value (PPV) and negative predictive value (NPV) varies based on the pretest probability. For example, assuming the antigen test has a sensitivity of 85% and specificity of 99%, the table below explains the predictive values for different pretest probability:

Assumes Sensitivity 85% and Specificity of 99%				
pretest probability	**PPV**	**NPV**	**# of False Negatives per 1,000 tests**	**# of False Positives per 1,000 tests**
20.0%	96%	96%	30	8
15.0%	94%	97%	23	9
10.0%	90%	98%	15	9
5.0%	82%	99%	8	10
2.5%	69%	99%	4	10
1.0%	46%	>99%	2	10

- CDC recognizes that controlling an outbreak depends on the frequency of testing and receiving rapid results, so serial antigen testing which is more possible with antigen tests may improve the positive predictive value in low prior probability situations, but how much is not yet known.

Evaluating the Results

- Interpreting rapid antigen tests should be based on the positive and negative predictive value of the tests which, as noted above, varies depending on the prevalence of infection in the community as well as the person's clinical signs, symptoms, and history.
- When using a rapid antigen test for **diagnostic purposes**:
  - Positive test results do not need to be confirmed, unless clinical suspicion of a false positive is high.
  - Negative diagnostic test results are considered "presumptive negative" and should be confirmed with a PCR test when the pretest probability is relatively high (especially if the patient is symptomatic or has known exposure) because of the higher number of false positives (see table above).
    - Consider the length of time the patient has been experiencing symptoms. Remember that a patient tested after five days of symptoms may drop below the detection limit of the test and produce false negative result.
    - If PCR testing is not available, the CDC indicates that clinical discretion can be used in whether to recommend the patient isolate. However, they do not recommend using antigen tests to decide when to discontinue isolation. Instead, providers should follow a time based strategy.
- When using rapid antigen testing for **screening purposes:**
  - Test results positive and negative are generally considered presumptive and may need to be confirmed with a PCR. The CDC outlines a few exceptions to this, including:

- You do not need to confirm a positive test result when the pretest probability is high (especially if the patient is symptomatic or has known exposure). However, when pre-test probability is low, you may want to confirm with another tests, but the individual should still be isolated until the positive test result is confirmed.
- It may not be necessary to confirm a negative test if the pretest probability is low (especially if the person is asymptomatic and has no known exposures) or is part of a cohort (of people) that will receive rapid results on a recurring (e.g. weekly) basis such as in nursing homes.

Reporting Results to Health Departments and Patients

- All CLIA laboratory sites have to report results of antigen tests (negative and positive) to local or state health departments under the CARES Act.
- HHS guidance on reporting laboratory data under the CARES act specifies what data should be collected and reported.

Additional Guidance from CDC:

- Overview of Testing for SARS-CoV-2.
- Testing Guidelines for Nursing Homes,
- Collecting, Handling, and Testing Clinical Specimens for COVID-19
- Quarantine and Isolation
- Discontinuation of Transmission-Based Precautions of Patients in Healthcare Settings
- Return to Work for Healthcare Personnel
- FAQ on Testing in Nursing Homes

Additional Testing Guidance from AHCA/NCAL:

- Testing in Long Term Care
- COVID-19 Testing Vendors for LTC
- Algorithm for Testing and Cohorting Nursing Home Residents
- Point-of-Care Antigen Tests in SNFs

Rapid Antigen Point of Care Devices- Training for Long Term Care Providers

- Quidel Sofia2: https://togetheragain.quidel.com/
- BD Veritor™ System: https://www.bdveritor.com/