

Interim Point-of-Care Antigen Testing Guidance** for Long Term Care Facilities

*** Point of care antigen tests are authorized under FDA EUA. This guidance is subject to change as more data are available.*

Point-of-care (POC) antigen tests are available for diagnostic testing of SARS-CoV-2. POC antigen tests have a rapid turnaround time which allows for quick implementation of infection prevention strategies. In general, when compared to reverse-transcriptase polymerase chain reaction (RT-PCR), point of care antigen tests have a lower sensitivity but similar specificity. South Carolina nursing homes should follow the CDC nursing home [POC antigen testing algorithm](#).

Considerations when Interpreting POC Antigen Test Results and Use of Confirmatory RT-PCR Testing

Because the sensitivity of antigen tests is generally lower than RT-PCR, the FDA recommends that negative POC antigen tests be considered presumptive. When interpreting the results of negative antigen test results, consideration should be given to the following:

- **Which testing platform is being used.** There are several antigen testing platforms available with varying sensitivities and specificities.
- **Factors that increase the probability of infection,** to include having symptoms, recent exposure to a COVID-19 positive individual, whether testing is conducted in a nursing home with an outbreak, and if the facility is in a high prevalence community.

These considerations can inform the decision to use confirmatory testing by RT-PCR following a negative POC antigen test. If RT-PCR confirmatory testing is done:

- It **must be collected within 48 hours** of the antigen test.
- Individuals should be assumed infectious until confirmatory test results are available.
- Symptomatic residents should remain in transmission-based precautions (TBP) until RT-PCR tests are completed.

Although the specificity of POC tests is high (generally considered >99%), there have been national reports of false positive antigen tests. In the face of a discrepancy between a positive POC antigen and a negative PCR test, considerations must be given to the:

- Time of collection between the 2 specimens.
- Quality of specimens collected.
- Appropriate specimen handling.
- Incidence of COVID-19 in the community. (When county positivity is very low, even highly specific tests will have lower positive predictive value.) County incidence can be viewed [here](#).

Recommendations for Specific Situations

If **asymptomatic** nursing home staff tests antigen positive in a nursing home **without an outbreak** and in a county with **low community** prevalence, they should be excluded from work until a confirmatory RT-

PCR test result is available. (Also see [CDC staffing strategy](#)). The incidence of COVID-19 in the community can help interpret the likelihood of a false positive antigen test.

When testing **asymptomatic** staff or residents **in a nursing home outbreak** no confirmatory RT-PCR test is needed. The positive POC antigen test is considered adequate evidence of infection, and protocols for exclusion and isolation should be followed.

When testing **symptomatic** staff or residents, confirm all **negative** antigen test results with a RT-PCR test immediately. Exclude staff from work and isolate residents with transmission-based precautions until RT-PCR results are complete.

Additional Recommendations

If you believe you are experiencing false positive results from your antigen testing:

- Contact the manufacturer
- File a complaint with [FDA](#)
- Send an email to HAI_section@dhec.sc.gov with the following information:
 - How many total antigen tests were performed in your facility?
 - How many positive antigen tests were followed up within 48 hours of collection with a negative RT-PCR?
 - How many positive antigen tests did you think were true positives?
 - Were the same specimen types used between RT-PCR and antigen tests?
 - Do you know which RT-PCR platform was used for the confirmatory tests?
 - Was testing focused on asymptomatic staff in facilities without an outbreak?
 - Do you know if any control samples were run on the antigen machines?
 - What have you/facility decided to do with these individuals? Excluded from work/place in transmission-based precautions (if staff or resident)? Initiated an outbreak response (if index case)?
 - Was viral transport media used in any of these antigen tests? (That is now against the instructions for use and could be a cause of false positives.)

Note: The CMS Division that oversees nursing homes has provided guidance indicating a path for confirmation or refutation of COVID results from on-site tests. Specifically, when an asymptomatic individual tests positive using an antigen machine, a facility may conduct a PCR (confirmatory) test for a final result. In view of the issues outlined above, DHEC recommends referring to the [CDC algorithm](#) to consider local circumstances regarding outbreak and county incidence of COVID-19. It is not mandatory that the facility perform a PCR test under all situations.

Reporting of Antigen Test Results

All COVID-19 lab results, including positive, negative and indeterminate results, must be reported to DHEC. Positive tests should be reported to your regional DHEC office by phone within 24 hours. All test results must also be submitted to DHEC using an approved reporting method. To inquire about electronic reporting options, please contact SCIONHELP@dhec.sc.gov. For details on disease reporting in South Carolina, see the [South Carolina List of Reportable Conditions](#).