



Technical Bulletin



Date: October 2, 2020
Topic: Discontinue the Use of Antigen Testing in Skilled Nursing Facilities Until Further Notice
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To: Health Care Providers and Long-Term Care Facilities

Urgent:

The Nevada Department of Health and Human Service's (DHHS) Chief Medical Officer, is issuing this directive in consultation with the Nevada State Public Health Laboratory (NSPHL) Director requiring Skilled Nursing Facilities (SNFs) to immediately discontinue the use of all COVID-19 point of care (POC) antigen tests until the accuracy of the tests can be better evaluated.

Background:

In August 2020, SNFs across the country received the Quidel Sofia and Becton Dickinson (BD) Veritor point of care (POC) antigen tests from the Center for Medicare and Medicaid Services (CMS). The Food and Drug Administration (FDA) reported these tests as having a high specificity and moderate sensitivity. This means that these antigen tests are accurate for detecting individuals with COVID-19, but less accurate for correctly detecting when someone does not have COVID-19. The recommendation from the FDA is not to confirm positive antigen results as they are likely to be true positives, but to perform confirmatory molecular testing on negatives as false negatives may occur. The formal FDA Emergency Use Authorization filing indicated that the sensitivity and specificity of these tests is as follows:

1. Quidel Sofia: 87% sensitivity and 100% specificity
2. BD Veritor: 97.5% sensitivity and 100% specificity

However, this was based on extremely limited data. Despite the sensitivity and specificity data provided to the FDA, DHHS recommended to perform confirmatory testing on all positives tests and distributed this guidance through a [Technical Bulletin](#) on August 28, 2020.

In mid-September DHHS started receiving anecdotal reports from SNFs that individuals with a positive antigen test were subsequently testing negative by confirmatory Reverse-Transcriptase Polymerase Chain Reaction test (RT-PCR). RT-PCR tests are considered the gold-standard for testing and the result of a PCR test is considered accurate. Such tests are based on nucleic acid detection which is a process of extreme sensitivity and specificity.

The SNFs were surveyed systematically in order to quantify the issue. The findings are as follows:

A total of 12 facilities were performing antigen testing:

- Total tests: 3,725 antigen tests were performed
- Positivity: 60 positive antigen test results were resulted

Of the 12 facilities that have performed testing, eight (8) facilities collected specimens for confirmatory RT-PCR testing on the positive individuals:

- Total confirmatory tests: Of the 60 positive antigen tests, 39 (60%) had samples collected and sent for confirmatory RT-PCR testing AND results were available at the time of survey response
- True positives: 16 (40%) were true positives (confirmatory RT-PCR result was positive)
- False positives: 23 (60%) were false positives (confirmatory RT-PCR result was negative)

Accuracy by test brand:

- BD Veritor: 30 tests (performed at six (6) different facilities) were positive using the BD Veritor. Fifteen were confirmed as positive and 15 did not confirm by RT-PCR
- Quidel Sofia: Nine (9) tests (performed at two (2) different facilities) were positive using the Quidel Sofia. One (1) was confirmed and eight (8) did not confirm by RT-PCR

Possible reasons for conflicting test results include lack of compliance with the manufacturer's protocols; inadequate training on the testing procedure, or false negatives with the confirmation RT-PCR test especially if the confirmatory PCR test could not be performed within 48 hours of the positive antigen test. Additionally, low prevalence and incidence of COVID-19 within a community may result in higher rates of false positive tests.

Next Steps:

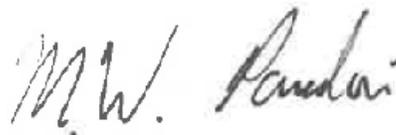
SNFs must continue to fulfill the testing efforts as outlined by CMS using molecular testing, such as RT-PCR or the Abbott IDNOW.

DHHS will continue to work closely with the NSPHL to further investigate the issue of discordant results between COVID-19 antigen testing and RT-PCR. Once more data is gathered and analyzed, formal updated guidance for the use of antigen testing in SNFs will be provided.

[NAC 449.74473](#) requires SNFs to maintain a program for control of infections. If the use of the outlined antigen tests continues within a SNF, the Bureau of Health Care Quality and Compliance will take necessary corrective action to ensure the safety of staff and residents within the facility.



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