



Technical Bulletin



Date: October 9, 2020

Topic: **REMOVAL OF DIRECTIVE** to Discontinue the Use of Antigen Testing in Skilled Nursing Facilities Until Further Notice

Contact: Melissa Peek-Bullock, State Epidemiologist, Office of Public Health Investigations and Epidemiology

To: Health Care Providers and Long-Term Care Facilities

Urgent:

Effective immediately, the Nevada Department of Health and Human Services' (DHHS) Chief Medical Officer's (CMO) directive 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, will be removed as directed by the United States Department of Health and Human Services (HHS), Office of the Secretary. This effectively allows the use of such tests in all SNFs.

Background:

On October 2, 2020, DHHS's CMO in consultation with the Nevada State Public Health Laboratory Director, issued a directive to stop the use of antigen testing in SNFs until the accuracy can be better evaluated. This directive was issued in response to high rate of false positive results reported by SNFs.

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 initial 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

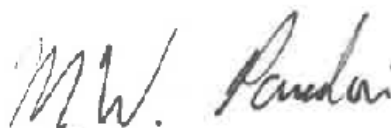
confirmatory PCR test could not be performed within 48 hours of the positive antigen test. Additionally, low prevalence and incidence of COVID-19 within a community may result in higher rates of false positive tests.

DHHS recommends that Skilled Nursing Facilities (SNFs) using POC antigen tests continue to perform confirmatory RT-PCR testing for both positive and negative antigen results. Since these tests are intended to have an immediate infection control and prevention measure applied, the concern is moving a false positive vulnerable individual into a unit with known positive COVID-19 patients. Alternatively, there is concern with leaving a false negative individual (COVID positive individual) in the general facility population (COVID-19 negative area) and potentially expose individuals. Both of these scenarios could result in causing harm to a population that we have collectively worked so hard to protect.

Again, the directive to discontinue the use of POC antigen tests has been removed. DHHS and NSPHL will continue to evaluate and investigate the discordant results to better understand the root cause and to provide guidance based upon those findings.



Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer



Mark Pandori, Ph.D., HCLD (ABB)
Director, Nevada State Public Health Laboratory



Lisa Sherych, Administrator
Division of Public and Behavioral Health