Nevada Division of Public and Behavioral Health

October 22, 2020

Skilled Nursing Facilities (SNFs) - Point of Care (POC) Testing Devices

POC BD Veritor Plus and Quidel Sofia2 Testing Machines have been shipped to all Nevada SNFs from CMS.

Of the 65 SNFs in Nevada:

- *(61)– Have confirmed receipt of device*
- *(3) – Receipt unknown, email and phone messages were left but no response received yet*
- *(1) – Lost device. UPS records showed facility signed off on delivery of 4 boxes including the device. Facility lost their device and are working on replacing*
- *(29) Have used the device*

Main barriers to use include facilities not receiving their CLIA waiver, the cost of supplies and that supplies have been back-ordered for a while. Health Care Quality and Compliance Med Lab inspectors under DPBH are working to address this with facilities.

General info on lab certification process and process for CLIA

All laboratory tests that are performed by laboratories licensed in the State of Nevada are required to have an inspection before they are allowed to perform any patient testing. For CLIA Waived tests (simple tests like fingerstick glucose and urine pregnancy tests), the inspector will ensure that the laboratory is following the manufacturer's instruction for the performance of the test, review documentation of testing personnel training and competency, ensure that the test disposables are monitored for storage conditions (temperature/humidity) and laboratory safety policies are established and maintained for the staff and the patients/clients that the laboratory serves.

For CLIA Non-Waived tests, the inspector will ensure that the tests are performed according to the information provided for Waived tests, but it will also include required daily Quality Control, enrollment in Proficiency Testing (blind samples that are sent to the laboratory for test evaluation) and an evaluation of the validation or verification of the data that is produced for all new Non-Waived testing to determine if the tests will meet the Accuracy, Precision and Linearity criteria that is established by the laboratory. The inspector also needs to ensure that the tests performed by the laboratory meet the Federal CLIA requirements.

COVID-19 Point of Care (POC) Tests

Currently, there are four (4) POC tests available under the Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

1. Abbott IDNOW: nucleic acid amplification (molecular) test, 91.3% sensitivity and 100% specificity
2. Quidel Sofia: antigen test, 96.7% sensitivity and 100% specificity
3. Becton Dickinson Veritor: antigen test, 84% sensitivity and 100% specificity
4. Abbott BinaxNOW COVID-19: antigen test, 97.1% sensitivity and 98.5% specificity

Point of Care Molecular Test:

The Abbott IDNOW is the only Food and Drug Administration (FDA) authorized POC molecular test. A positive result is indicative of the presence of SARS-CoV-2 RNA and should be considered diagnostic. A negative result should be considered presumptive. In the event of a negative result, a subsequent specimen should be collected and sent to a laboratory for molecular testing if the patient has clinical signs and symptoms of COVID-19 and/or a known exposure to COVID-19.

Reporting of Abbott IDNOW results: We are still working with several entities that received the Abbott IDNOW machines to obtain reporting compliance. We are working with entities individually to ensure they are reporting all results, in the specified format, and with all variables required by HHS.

Point of Care Antigen Test:

Use of these tests should be reserved for instances where a positive result would direct immediate clinical decisions or infection control measures. For example, in a long-term care facility, a positive result should trigger isolation of the patient and corresponding COVID-19 mitigation procedures.

The 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 FDA published sensitivity and specificity of these tests is as follows:

1. Quidel Sofia: 96.7% sensitivity and 100% specificity
2. Becton Dickinson Veritor: 84% sensitivity and 100% specificity

However, this is 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 began receiving reports from SNFs of false positive antigen tests. The SNFs were surveyed systematically in order to quantify the issue. The initial findings revealed a 60% false positive rate and 40% true positive rate.

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.

In response to these finding, DHHS's Chief Medical Officer, in consultation with the Nevada State Public Health Laboratory Director, issued a directive through a Technical Bulletin on 10/2/2020 to discontinue the use of all POC antigen testing in SNFs until the accuracy of the test can be better evaluated.

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, a false negative individual would not be moved to a COVID-19 unit and have opportunity to expose other vulnerable people. Both of these scenarios could result in causing harm to a population that we have worked so hard to protect.

SNFs were directed to 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.

On October 9, 2020, Dr. Brett P. Giroir with the U.S. Department of Health and Human, Office of the Secretary, issued a letter directing Nevada DHHS to rescind the directive for SNFs to discontinue the use of POC antigen tests until the accuracy of the test can be better evaluated. Dr. Giroir stated that Nevada's directive was in violation of federal law under the PREP Act. Nevada DHHS rescinded the directive, however further investigation into the accuracy of the antigen tests is ongoing. To date the findings are as follows:

Overview:

A total of nine (9) skilled nursing facilities (SNFs) have reported point of care (POC) antigen results to Nevada Department of Health and Human Services (DHHS). The data below represents the total findings among these SNFs.

Overall Results:

Total positive POC antigen tests performed and reported: 50

- Total symptomatic = 12
- Total asymptomatic = 38

Total with confirmatory RT-PCR: 36

- Negative RT-PCR = 32 (89% false positive rate)
  - 21 had RT-PCR sample collected the same day of the antigen test.
  - Two (2) had RT-PCR sample collected within one (1) day of the antigen test.
  - Three (3) had RT-PCR sample collected within two (2) days of the antigen test.
  - Six (6) have blanks field for date of antigen test performed.
  - 30 persons were asymptomatic
  - Two (2) persons were symptomatic
    - All had antigen test performed within 5-7 days of onset date
- Positive RT-PCR = 4 (11% true positive rate)
  - Two (2) had RT-PCR sample collected the same day as the antigen test was performed.
  - Two (2) had RT-PCR sample collected within one (1) day of the antigen test.
  - One (1) person was symptomatic.
    - Onset date unknown
  - Three (3) persons were asymptomatic.

Breakdown by Staff and Patients/Residents:

Total positive POC antigen tests performed and reported: 50

- Total performed on staff: 28
  - Symptomatic = 4
  - Asymptomatic = 24
- Total with confirmatory RT-PCR: 24
  - Negative RT-PCR = 20 (83% false positive rate)
    - 18 had RT-PCR sample collected the same day of the antigen test.
    - Two (2) had RT-PCR sample collected within one (1) day of the antigen test.
    - All 20 persons were asymptomatic.
  - Positive RT-PCR = 4 (17% true positive rate)
    - Two (2) had RT-PCR sample collected the same day as the antigen test was performed.
    - Two (2) had RT-PCR sample collected within one (1) day of the antigen test.
    - One (1) person was symptomatic.
    - Three (3) persons were asymptomatic.

- Total performed on patients/residents: 22
  - Symptomatic = 8

- Asymptomatic = 14
- Total with confirmatory RT-PCR = 12
  - Negative RT-PCR (false positive) = 12 (100% false positive rate)
    - Three (3) had RT-PCR sample collected the same day of the antigen test.
    - Three (3) had RT-PCR sample collected within two (2) days of the antigen test.
    - Six (6) have blanks field for date of antigen test performed.
    - Two (2) patients/residents were symptomatic
    - 10 patients/residents were asymptomatic
  - Positive RT-PCR = 0

Performance by Device:

1. BD Veritor:
   - Total tests performed: 36
   - Total with confirmatory RT-PCR performed: 24
     - Negative RT-PCR = 21 (87.5% false positive rate)
     - Positive RT-PCR = 3 (12.5% true positive rate)
2. Quidel Sofia:
   - Total tests performed: 14
   - Total with confirmatory RT-PCR performed: 12
     - Negative RT-PCR = 11 (92% false positive rate)
     - Positive RT-PCR = 1 (8% true positive rate)