Point-of-Care Antigen Test Devices

On July 14, Centers for Medicare and Medicaid (CMS) announced an initiative to distribute of point-of-care (POC) antigen COVID-19 testing devices to nursing homes across the country. Nursing facilities will receive one of two testing devices:

- Quidel Sofia 2 SARS Antigen FIA
- BD Veritor System for Rapid Detection of SARS-CoV-2

CMS has published the list of nursing homes that are prioritized to receive the instrument first, as well as a list of FAQs that providers are encouraged to review.

Here are six steps providers must take before using these testing devices.

1. Check with your state public health department or state epidemiologist to verify what, if any, requirements, guidelines or limitations are in place for using these POC Antigen tests.
   Due to the lower sensitivity and specificity of these test devices, not all state public health departments allow for their use, and many have certain requirements in place for using these tests appropriately.

2. Review CARES Act reporting requirements and establish a process to report ALL test results.
   The CARES Act requires all laboratories with a Clinical Laboratory Improvement Amendments (CLIA) certificate to report the results of every COVID-19 tests that they conduct (positives and negatives) to the appropriate state or local public health department. This applies to CLIA waived tests such as the POC tests being distributed. This includes any provider settings offering point-of-care testing. This is in addition to the reporting completed through the CDC NHSN website and other state reporting requirements.

   Nursing homes should contact their state/local health departments to identify options to align existing reporting to those agencies with these CARES Act reporting requirements for CLIA laboratories.

   Providers should also review the HHS laboratory reporting guidance and related FAQ’s for more information, including what specific information must be submitted. Providers can also refer to the guidelines CDC laboratory reporting website for information.

3. Develop a plan, in accordance with state and local guidelines, to perform any follow up tests with PCR for those that test negative using the POC testing devices.
   The FDA and CLIA guidelines require providers follow the FDA-approved manufacturer instructions for the CLIA waived tests you are performing. The instructions for use on both test devices state “negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions”
In their FAQ’s, CMS states: “Negative results should generally be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. If necessary, confirmation with a molecular assay for patient management may be performed. Negative results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.”

4. **Make sure you have personnel trained to collect the specimen and use the test properly to be compliant with your CLIA certificate.**
   As stated, the FDA and CLIA requires that facilities performing waived tests follow the manufacturer’s instructions. Proper use and maintenance of the test device and specimen collection will improve the accuracy of the results. Facilities must review the entire package insert and seek additional training. According to the CMS FAQ’s, “Quidel and BD will provide training materials to nursing home staff. Training documentation will be made widely available for all nursing homes that are receiving supplies. Quidel training information can be found at quideltogetheragain.com. BD is offering training services through their Learning Management System (LMS) platform to all BD Veritor System customers at no additional cost. The eLearning training platform is available online.”

5. **Make sure you have process to record all test results and notify the person of the results.**
   Results for residents will be documented in their medical record. Results for staff should be documented in an appropriate location determined by the facility.

6. **Incorporate the use of these testing devices into your facility infection prevention & control program and facility assessment.**
   Finally, facilities should be sure to incorporate these new elements (point of care testing onsite, training & competency, reporting requirements, plans for interpreting results) into existing facility infection prevention and control program, as well as into their facility assessment. Engage your Medical Director and other key personnel in this process.