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 is publishing the list of nursing homes prioritized to receive the instrument, along with a list of frequently asked questions, on the CMS NHSN data site. CMS is constantly adding to the list of nursing homes as more shipments become available.

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 CDC Interim Guidance for Rapid Antigen Testing to Understand the Limitations and Cautions of these devices.**
   The CDC interim guidance on rapid antigen testing provides important information on appropriate use of these antigen test devices. AHCA has also published a summary of this guidance which covers the relevant points for long term care providers.

3. **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.

4. **Complete required training to ensure proper use of test devices and compliance with your CLIA certificate.**
As stated, the FDA and CLIA requires that facilities performing waived tests follow the manufacturer's instructions. An individual at the facility must have proper knowledge and training to utilize the device, and should also have proof of completing the training. Proper use and maintenance of the test device and specimen collection will also improve the accuracy of the results.

One day prior to receiving the device, providers will receive an email from the company with links to training information. Training information can also be accessed on each company's website below:

Quidel Sofia 2
https://togetheragain.quidel.com/
This website is the source for all information regarding the Sofia 2 SARS Antigen FIA test. You can access:

- Training – both online and live virtual training resources
- Kit reordering instructions
- Technical support
- FAQ's

This site was developed to ensure the success of the implementation of the Quidel Sofia 2 testing in your facility.

BD Veritor™ System
https://www.bdveritor.com/
This website provides access to all training and information long term care providers need to get started with the BD Veritor. Providers must log into the BD website to access training resources. If you need to establish an account, please complete the registration form by clicking on "Register yourself!"

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. You may need to purchase a printer for your device to print the results of each test performed.

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.