Questions and Answers

COVID-19 Testing in Nursing Homes State Webinar

On September 3, 2020, the Department of Health and Human Services (HHS), in conjunction with Quidel Corporation and Becton, Dickinson and Company (BD), hosted a webinar to provide additional information regarding antigen testing in skilled nursing facilities.

The COVID-19 Testing in Nursing Homes State Webinar was open to skilled nursing facilities and state public health laboratories. The webinar was recorded and can be watched by clicking the link below. Presentations by Quidel and BD can also be accessed by clicking on the links below.

Webinar recording: https://www.youtube.com/watch?v=8oCRqlY1kJw

Quidel presentation: https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/Quidel-Sofia-HHS-Nursing-Home-Training-9-3-20.pdf

BD presentation: https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/BD-Veritor-HHS-Nursing-Home-Training-9-3-20.pdf

Abbreviations

CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
EMR	Electronic medical records
FDA	Food and Drug Administration
HCP	Healthcare personnel
HHS	Department of Health and Human Services
IFU	Instructions for Use
LIMS	Laboratory information management system
LLIS	Laboratory information system
NHSN	National Healthcare Safety Network
NP	Nasopharyngeal (swab)
POC	Point-of-care
RT-PCR	Reverse transcriptase polymerase chain reaction
SNF	Skilled nursing facility

Table of Contents

Section 1: *General initiative questions and answers*

Question 1

When are facilities expected to start using these point of care tests?

Response:
The point of care tests may be used upon receipt.

Question 2

Are both test machines being sent to nursing homes?

Response:
Both devices were procured by HHS for this initiative. Some facilities received the BD Veritor™ Plus System and others received the Quidel Sofia® 2 System.

Question 3

Who is responsible for covering cost of future test supplies if facilities do not have the funds?

Response:
The CARES Act provided funds to support COVID-19 testing in nursing homes. HHS Announces Allocations of CARES Act Provider Relief Fund for Nursing Homes (August 7): https://www.hhs.gov/about/news/2020/08/07/hhs-announces-allocations-of-cares-act-provider-relief-fund-for-nursing-homes.html

For more information visit the CARES Act Provider Relief Fund home page: https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html

Question 4

Do we use one machine for staff (BD) and the other machine (Sophia) for our residents? Or do we interchange?

Response:
Each facility received either a Quidel Sofia® 2 System or BD Veritor™ Plus System. On exception, an additional instrument from the same vendor was allocated to large facilities that were identified to receive 900 tests (facilities identified as major outliers). Allotments of instruments and test kits are determined by the estimated volume of tested needed for the facility to test all staff and residents at least once. Nursing homes should utilize these instruments to test staff and residents and have the authority to decide how to allocate tests among staff and residents.

Question 5

Why send facilities the BD Veritor which has a limited shelf life if CMS is requiring such extensive testing?

Response:
While the BD Veritor™ Plus System can only run 3,500 tests, it is a critical tool in congregate care settings to quickly identify positive COVID-19 cases. Additionally, instruments and tests provided by the

federal government to nursing homes were not intended to be the sole source of COVID-19 testing. Facilities can use CARES Act funds to purchase any additional PCR or point of care instruments and tests as long as CMS requirements are met.

Question 6

Will HHS send us a new machine after reaching 3,500 tests?

Response:
Replacement instruments can be purchased directly from the manufacturer or a distributor. For pricing and reordering visit the manufacturer websites.
https://togetheragain.quidel.com/#how-to-order-more-tests
https://www.bdveritor.com/long-term-care-facilities/order-tests/

Question 7

How do senior living facilities get testing equipment?

Response:
Senior living facilities were not part of this initiative. The CARES Act Provider Relief Fund will be used to protect residents of nursing homes and long-term care facilities from the impact of COVID-19.
https://www.hhs.gov/about/news/2020/08/07/hhs-announces-allocations-of-cares-act-provider-relief-fund-for-nursing-homes.html

Question 8

If a facility is not on the list to receive an instrument, where should we reach out for further support and assistance?

Response:
CMS-prioritized nursing homes who also held a valid CLIA Certificate of Waiver which were identified as recipients of testing instruments and tests in distribution waves starting in August 2020. Facilities who had acquired a Certificate of Waiver by September 30, 2020 will receive an instrument and tests to perform at least one round of testing for residents and staff.

Questions for the eligibility status of a facility with a CLIA Certificate of Waiver can be directed to COVID-19@cms.hhs.gov.

Section 2: *Regulatory questions and answers*

Question 1

What regulatory documents do we need to perform antigen testing in our facility? Does our CLIA Certificate of Waiver need to be updated?

Response:
Point-of-care tests can be performed in a facility that has a CLIA Certificate of Waiver. If you have a current CLIA Certificate of Waiver, there should be no update required.

Question 2

Where can we find the CLIA Certificate of Waiver allowing use of these devices for testing asymptomatic individuals?

Response:
Information to apply for a CLIA Certificate of Waiver for performing SARS-CoV-2 POC antigen testing can be obtained on the CMS website.
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf

Please refer to the FDA recommendations SARS-CoV-2 Diagnostic Tests for Screening Asymptomatic Individuals for COVID-19 and the Public Readiness and Emergency Preparedness Act (PREP Act) coverage which addresses administration of the test to symptomatic and asymptomatic individuals at congregate facilities.

- FDA FAQ regarding healthcare providers that use diagnostic tests for screening of asymptomatic individuals:
  - Question: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening of asymptomatic individuals for COVID-19? (Updated 9/2)
  - Answer: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general-screeningasymptomatic
- PREP Act (August 31, 2020): https://www.hhs.gov/sites/default/files/prep-act-coverage-for-screening-in-congregate-settings.pdf

Also, CMS will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals.
https://www.cms.gov/files/document/clia-poc-ag-test-enforcement-discretion.pdf

Question 3

Do facilities need to report all point-of-care test results?

Response:
Yes. Testing sites must report data for all positive and negative diagnostic and screening testing completed, which includes molecular, antigen, and antibody testing, for each individual tested. These data must be reported daily, within 24 hours of test completion, to the appropriate local, state, territorial or tribal health department, based on the individual's residence.

Laboratory data elements may be reported in the following ways:
- Submit laboratory testing data directly to state or local public health departments according to state/or local law or policy. Data must be sent using existing reporting channels to ensure rapid initiation of case investigations, and concurrent reporting of results must be shared with ordering provider or patient, as applicable.

- Submit laboratory testing data to state and local public health departments through a centralized platform (such as the Association of Public Health Laboratories' AIMS platform), where the data will then be routed to the appropriate state and local authorities and routed to CDC after removal of personally identifiable information according to applicable rules and regulations.
- Submit laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and then to CDC as directed by the state.

Public health departments will submit de-identified data to CDC on a daily basis, using either Health Level 7 (HL7) messaging or the CDC-provided CSV format.

Question 4

How often is the information on the website used to calculate county percent positivity rates updated ?

Response:
The county prevalence website is updated weekly and can be found on the CMS website.
https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/

Question 5

If our state has requirements that are more stringent than CMS for testing staff, can we use those? Will states have to adopt CMS/CDC guidance?

Response:
States must test at the minimum frequency set by CMS. If the state requires more frequent testing than CMS, then the state requirements should be followed, as long as CMS minimum requirements are being met.

Question 6

Can you clarify "one new case" as being in a staff member and/or resident?

Response:
One new case could be either a resident, staff or visitor who tests positive for COVID-19. Visitors who have had close contact (within 6 feet of an infected person for at least 15 minutes) with someone with confirmed COVID-19 should be tested.

Facility staff includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. For the purpose of testing individuals providing services under arrangement and volunteers, facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff.

Regardless of the frequency of testing being performed or the facility's COVID-19 status, the facility should continue to screen all staff (each shift), each resident (daily), and all persons entering the facility, such as vendors, volunteers, and visitors, for signs and symptoms of COVID-19.

Question 7

Who can perform testing?

Response:
Under a CLIA waiver certificate for the test and the institution, any trained personnel can perform the test. Proper recordkeeping of training must be maintained by the facility. To comply with CLIA when using a CLIA-waived test, the facility will need to ensure that testing personnel are following all manufacturers' instructions and complete the CMS training. CMS training can be accessed here: https://qsep.cms.gov/COVID-Training-Instructions.aspx.

Question 8

Is routine staff testing a recommendation or a requirement according to CMS?

Response:
Routine staff testing is required based on CDC's Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes.
https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

Routine testing should be based on the extent of the virus in the community; therefore, facilities should use their county positivity rate in the prior week as the trigger for staff testing frequency. The county prevalence website is updated weekly and can be found on the CMS website. https://data.cms.gov/stories/s/bkwz-xpvg.

Intervals for routine testing can also be found on the CMS website.
https://www.cms.gov/files/document/qso-20-38-nh.pdf

Question 9

Given that the county positivity rates on the CMS website used to make testing frequency decisions are based on incomplete data (specifically incomplete data on negative test results), is there a process for states to use more accurate locally available data (i.e., state data) for determining county positivity?

Response:
County level data from the county or state agencies may be used provided that it is recent and that the nursing home documents the date and source of data that they are using for purposes of decisions.

Question 10

Are the CMS positivity rates based off total numbers that accumulate as we go (cumulative), and updated every week? For example, if there were 20 tests done in our county in one week, with two testing positive, will that move us to 10% bracket even if our overall rate is much lower?

Response:
The data are based on the rate for the week versus cumulative with the idea being to address a recent change in status as soon as possible.

Question 11

When is this requirement by CMS supposed to be implemented? If the facility has not received their testing instrument, do the existing timelines for compliance apply? What protects a skilled nursing facility with non-compliance if the facility has not completed implementation of testing and reporting by the three-week grace period?

Response:
The requirement is intended to immediately protect the health and safety of nursing home residents thus every attempt should be made to perform testing as soon as possible. CMS recognizes that there may be challenges when performing and reporting testing. CMS is also working with CDC to streamline nursing home reporting of laboratory data through NHSN. When a facility is unsuccessful in meeting the guidelines, surveyors will consider documentation that demonstrates a facilities attempt to perform and/or obtain testing in accordance with the guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours) and use enforcement discretion.

Question 12

How are patient results reported to the public health department?

Response:
Results are not automatically reported from the instrument to the state department of health. Facilities must establish connectivity to a LIMS/EMR system to automatically report or must manually document the results and share with their state. Nursing homes have three different options for reporting test results. CDC recommends consulting with your health department for additional details on their protocols on reporting.
https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html
https://www.cdc.gov/publichealthgateway/healthdirectories/healthdepartments.html

Section 3: *Testing guideline questions and answers*

Question 1

If the tests are to be used on people within 5 days of being symptomatic, why are facilities supposed to use these devices to routinely screen staff regardless of symptomatic status?

Response:
Nursing home residents are at high risk for infection, serious illness, and death from COVID-19. Testing for SARS-CoV-2, the virus that causes COVID-19, in respiratory specimens can detect current infections (referred to here as viral testing) among residents in nursing homes.

Viral testing of residents in nursing homes, with authorized nucleic acid or antigen detection assays, is an important addition to other infection prevention and control (IPC) recommendations aimed at preventing SARS-CoV-2 from entering nursing homes, detecting cases quickly, and stopping transmission. This guideline is based on currently available information about COVID-19 and will be refined and updated as more information becomes available.

Please refer to the FDA recommendations *SARS-CoV-2 Diagnostic Tests for Screening Asymptomatic Individuals for COVID-19* and the *Public Readiness and Emergency Preparedness Act (PREP Act) Act* coverage which addresses administration of the test to symptomatic and asymptomatic individuals at congregate facilities.

- FDA FAQ regarding healthcare providers that use diagnostic tests for screening of asymptomatic individuals:
  - Question: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening of asymptomatic individuals for COVID-19? (Updated 9/2)
  - Answer: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general-screeningasymptomatic
- PREP Act (August 31, 2020): https://www.hhs.gov/sites/default/files/prep-act-coverage-for-screening-in-congregate-settings.pdf

CMS will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals.
https://www.cms.gov/files/document/clia-poc-ag-test-enforcement-discretion.pdf

Question 2

Previous CDC guidance stated that in order to open a facility to visitors all staff had to be tested, even if they previously tested positive. Updated CDC guidance does not recommend retesting a person if they have tested positive within the last 90 days. Can clarification be provided?

Response:
CMS published new guidance on nursing home visitation on September 17, 2020. For more information refer to this link: https://www.cms.gov/files/document/qso-20-39-nh.pdf

Question 3

Can you please explain for whom the antigen testing is appropriate? Symptomatic individuals? Asymptomatic Individuals? Since specificity and sensitivity were tested on symptomatic individuals, how will we know if the test is accurate for asymptomatic people? In what situation would a negative test require follow up PCR testing?

Response:
Both asymptomatic residents and staff can be tested using antigen tests. The performance of the BD Veritor™ Plus and Quidel Sofia® 2 SARS CoV-2 tests can be found in the manufacturer-specific IFU.

BD IFU: https://www.fda.gov/media/139755/download
Quidel IFU: https://www.fda.gov/media/137885/download

Please refer to the FDA recommendations SARS-CoV-2 Diagnostic Tests for Screening Asymptomatic Individuals for COVID-19 and the Public Readiness and Emergency Preparedness Act (PREP Act) Act coverage which addresses administration of the test to symptomatic and asymptomatic individuals at congregate facilities.

- FDA FAQ regarding healthcare providers that use diagnostic tests for screening of asymptomatic individuals:
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  - Answer: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general-screeningasymptomatic
- PREP Act: https://www.hhs.gov/sites/default/files/prep-act-coverage-for-screening-in-congregate-settings.pdf

CMS will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals. For more details refer to the following link:
https://www.cms.gov/files/document/clia-poc-ag-test-enforcement-discretion.pdf

For additional information for considerations for the use of SARS-CoV-2 antigen testing in nursing homes and considerations for interpreting antigen test results in nursing homes, refer to the following link:
https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf
https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

Question 4
What other disease parameters could be used to determine testing frequency? Would these influence the testing frequency?

Response:
Testing based on county positivity rate is the current requirement. County level data from the county or state agencies may be used provided that it is recent and that the nursing home documents the dates and source of data that they are using for purposes of decisions. CMS continues to evaluate data in real-time to determine if other metrics should be required.

Question 5

What's the sensitivity for the BD Veritor and Quidel Sofia tests on asymptomatic individuals?

Response:

Test specific sensitivity can be found here:

- Quidel Sofia® 2 System: https://www.fda.gov/media/137885/download
- BD Veritor™ Plus System: https://www.fda.gov/media/139755/download

FDA's updated guidance as of September 2, 2020 states: that although the current available literature suggests that symptomatic individuals with COVID-19 and asymptomatic individuals without known exposure may have similar levels of viral genetic material, there is limited data on the distribution of viral loads in individuals with and without symptoms across demographics, different settings, and specimen types. Therefore, when screening asymptomatic individuals, health care providers should consider using a highly sensitive test, especially if rapid turnaround times are available. If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (commonly referred to as "off-label"). For congregate care settings, like nursing homes or similar settings, repeated use of rapid point-of-care testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times.

If less sensitive tests, such as some rapid point-of-care tests, are used, health care providers should be aware of the performance of the tests and may want to consider different testing approaches, such as serial testing. "Negative" results should be considered as "presumptive negative," and health care providers should consider them in the context of clinical observations, patient history, and epidemiological information. Thus, if there is a significant new outbreak in a congregate care facility or high clinical suspicion of an infection in an individual resident, a negative point-of-care test should be confirmed with a highly sensitive molecular test (refer to CDC guidelines). It is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with negative antigen test or other point-of-care test results if they are obtained during routine screening or surveillance.

Reference: FDA FAQ regarding healthcare providers that use diagnostic tests for screening of asymptomatic individuals (last updated 9/2/20).

- Question: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening of asymptomatic individuals for COVID-19? (Updated 9/2)
- Answer: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general-screeningasymptomatic

Question 6

Should point of care testing only be used for outbreak testing or should it also be used for routine testing?

Response:

Antigen testing can be used for both outbreak testing and routine testing for both symptomatic and asymptomatic individuals.

Question 7

What is the role of PCR testing along with antigen testing?

Response:

As the sensitivity of antigen tests is generally lower than RT-PCR, FDA recommends negative POC antigen tests be considered presumptive negative. Clinical staff in facilities should consider when confirmatory RT-PCR testing might be needed prior to making clinical decisions, cohorting residents, or excluding HCPs from work. It is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with a negative antigen test or other point of care test if they are obtained during routine screening or surveillance.
https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html
https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf

Question 8

Is there a recommendation to run a PCR test after a negative antigen test result?

Response:

Information on confirmatory test can be found on CDC's website.
https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html
https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf

Question 9

What should a facility do if an initial antigen test is positive and either another antigen test using the same specimen is negative or a new test using a second specimen is negative?

Response:

In general, if an antigen test is positive, confirmatory testing is not necessary. However, if a clinical decision suggests a confirmatory test is needed (e.g. asymptomatic worker in a county with low prevalence), CDC recommends use of RT-PCR for confirming a positive antigen test.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html
https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf

Question 10

How many samples should be collected to perform confirmatory testing?

Response:

Once a swab sample is used for an antigen test, it cannot be used for further testing. CDC recommends collecting additional samples employing preferably an NP swab to be used with RT-PCR when conducting confirmatory testing. When confirming an antigen test result with a RT-PCR test, it is important that the time interval between collection of samples for the two tests is less than two days, and there have not been any opportunities for new exposures in between. If more than two days

separate the two collections, or if there have been opportunities for new exposures, the nucleic acid test should be considered a separate test – not a confirmatory test.

Question 11

Have POC tests improved their false negative and positive rates so they can be used for surveillance and response testing in SNFs?

Response:

Laboratory and testing professionals who conduct SURVEILLANCE testing for SARS-CoV-2 with rapid antigen tests are not obligated to comply with FDA and CLIA requirements. However, CDC recommends that facilities that conduct surveillance testing for SARS-CoV-2 with antigen tests use an antigen test that has been authorized for use, which are listed on FDA's website. Surveillance testing for SARS-CoV-2 is intended to monitor for a community- or population-level infection and disease, or to characterize the incidence and prevalence of disease. Surveillance testing is used to gain information at a population level, rather than an individual level, and results of surveillance testing are only returned in aggregate to the requesting institution. Surveillance testing is performed on de-identified specimens, and thus results are not linked to individuals. Surveillance testing does NOT involve returning a diagnostic test result to an individual, or for individual decision-making. In addition, surveillance tests results are not reported. For more information, see this link:
https://www.fda.gov/media/139755/download

Section 4: *Training and laboratory questions and answers*

Question 1

What resources are available to train facility staff on sample collection? What types of specimens can be tested? Are anterior nasal swabs, oropharyngeal swabs, etc. sufficient?

Response:

See manufacturer websites for training related to sample collection and appropriate swab types:
https://www.bdVeritor.com/wordpress/wp-content/uploads/2020/08/BD-Veritor-System-for-Rapid-Detection-of-SARS-CoV-02.pdf

https://quickstart.quidel.com/docs/tests/swab/

Additionally, CDC has developed Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19.
https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Question 2

What is a patient ID and how does a patient receive one?

Response:

Patient ID is an identifier assigned to each sample to be tested. A protocol for sample processing should be established at each facility, where each sample is assigned a processing code (i.e., patient ID). This code should also be recorded on the patient record/chart, tube, cartridge/test cassettes and results reporting document.

Question 3

Do you write the patient ID or name on tube? On the cassette?

Response:

It is imperative to maintain proper record keeping of the sample throughout the process, especially if processing multiple samples at once. Each sample should be assigned an identifier or processing code (i.e., patient ID) that matches the patient chart/record and the same code used throughout the process. Tubes used to transport the swab prior to sample processing (if used), vials with extraction reagent vials and the test cassettes/cartridges might be labeled. Test cassettes/cartridges should be labeled before adding the sample, either on the backside or lateral sides, avoiding the sample drop area and the bar code. See other questions specific to the vendor-specific test.

Question 4

How do you prepare a one-liter solution of 10% bleach using 5.25% sodium hypochlorite solution?

Response:

Notes for preparing a 10% solution from sodium hypochlorite solution (bleach):

- Check the concentration on your bleach bottle. Use bleach containing 5.25%–8.25% sodium hypochlorite. Do not use a bleach product if the percentage is not in this range or is not specified.
- Check to ensure the product is not past its expiration date.
- Chlorine solutions gradually lose strength, and freshly diluted solutions must therefore be prepared daily.
- Use plastic containers for storing bleach solutions as metal containers are corroded rapidly and also affect the bleach.
- Put on protective gear (gloves and goggles) when diluting or using bleach as it irritates mucous membranes, the skin and the airway
- Never mix household bleach with ammonia or any other cleanser. This can cause fumes that may be very dangerous to breathe in.

To prepare a one liter (1000ml) of 10% bleach solution from a 5.25% bleach solution:

- Use a clean measuring cylinder.
- Add 900ml of water at room temperature
- Add 100ml of 5.25% sodium hypochlorite (bleach) solution

Stir and transfer to a storing container or containers used to spray and disinfect surfaces

For more information about chlorine solutions refer to: https://www.cdc.gov/coronavirus/2019-ncov/global-covid-19/make-chlorine-solution.html

Question 5

What safety precautions should be used and what PPE worn when performing these tests?

Response:

Follow standard precautions when handling clinical specimens, including hand hygiene and the use of PPE, such as laboratory coats, disposable gloves, and eye protection when specimens are collected and

evaluated. If needed, additional precautions can be used, such as a surgical mask or face shield, or other physical barriers, such as a splash shield to work behind.

Nursing homes implementing COVID-19 testing should follow the CDC Guidance for General Laboratory Safety Practices during the COVID-19 Pandemic:
https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-safety-practices.html

All procedures should take into consideration the CDC guidance Prepping for COVID-19 in Nursing Homes located here and Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes located.
https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html
https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html

Also, visit Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories for additional information:
https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html

Question 6

What is the proper way to dispose of test cartridges? Is disposed cartridge or test devices considered bio-hazardous waste?

Response:
The test device or cassette may contain biological waste from suspected or confirmed COVID-19 patient specimens and should be treated as biohazardous waste and disposed properly following the protocol established for used swabs and test cartridges/cassettes. Disposal of biohazardous waste can be found here: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html

Question 7

What instructions will be provided to ensure that there is NOT cross contamination of samples? Does the machine need to be cleaned between each individual test to prevent cross contamination and possible false results? How often do you clean the machine?

Response:
Nursing homes implementing COVID-19 testing should follow the CDC Guidance for General Laboratory Safety Practices located.
https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-safety-practices.html

Specifically, when using patient swabs, minimize contamination of the swab stick by placing the swab with the sample in a previously labeled clean tube or extraction reagent vial (refer to manufacturer instructions). Additional guidance can be found here: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html

Additional precautions should include the changing of gloves after adding patient specimens to the test device (cassette/cartridge) and decontamination of the work area between each sample or batch.

The instrument should be decontaminated after each run using a manufacturer-approved disinfectant following the manufacturer's recommendations.

Refer to CDC guidance on decontaminating working surfaces before and after sample processing with EPA-approved disinfectant for SARS-CoV-2.
https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

Section 5: *BD Veritor™ Plus System questions and answers*

Question 1

Does the Veritor come with a USB cord or printer?

Response:

The BD Veritor™ Plus Analyzer does not come with an ethernet cord or a printer. A USB cord is included with the BD InfoScan (additional barcode reader) that can be purchased separately. A printer can be purchased as an option to the device and is not included with the instrument provided by HHS. Email BD at: Ids.covidtests@bd.com to support the purchase of a printer.

Question 2

Where can I find training information for using the Veritor?

Response:

Visit the manufacturer website for training information.
https://www.bdVeritor.com/long-term-care-facilities/training/

Contact BD at Ids.covidtests@bd.com for questions specific to training.

Question 3

After I registered to eLearning, I didn't receive an email or a link. What am I missing? Should all our operators register and get trained online?

Response:

Registrants will receive a link to the training upon completion of the registration. If you do not receive a link, contact BD at: Ids.covidtests@bd.com.

Question 4

Is there a quiz to take before a certificate of completion is awarded?

Response:

To receive a competency certificate for training for use of the BD Veritor™ Analyzer, a user must complete a competency assessment for the online eLearning modules. Once all the modules are completed and training has been passed, the user will receive the competency certificate.

Question 5

How many controls are needed to validate each lot or new user?

Response:

Per the package insert and online training, controls (positive and negative) should be run:

- With each new kit lot
- With each new operator
- As required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements

Additional controls can be purchased to maintain quality.

Lot numbers of test kits should be recorded to ensure controls are run to maintain high quality control standards.

Question 6

What is the price for each test kit and how can they be reordered?

Response:

Visit the manufacturer website for pricing and reordering information.
https://www.bdVeritor.com/long-term-care-facilities/order-tests/

Question 7

How many kits does BD have prepared to ship?

Response:

BD is actively producing millions of kits to support BD-SARS-CoV-2 testing. BD continues to ramp up manufacturing and is estimated to increase capacity to 8 million tests per month starting in October. An investment from the U.S. Government will increase capacity to 12 million tests per month at the end of February 2021.

Question 8

What are the test's performance characteristics?

Response:

The positive percent agreement (indicator of sensitivity) and negative percent agreement (indicator of specificity) can be found in the package insert.
https://www.bdVeritor.com/wordpress/wp-content/uploads/2020/08/BD-Veritor-System-for-Rapid-Detection-of-SARS-Co-V-2-Instructions-for-Use.pdf

Question 9

Can influenza and SARS-Cov-2 tests be performed using the same specimen or at the same time?

Response:

The tests are run separately with a new patient sample for each test. On the BD Veritor™ Plus test device, each performed test (SARS-Cov-2 or influenza) would count towards the 3500 maximum tests/device.

Question 10

How many samples can be tested at one time?

Response:

BD has developed a workflow that batches tests (groups of multiple tests). For more information, complete the eLearning module on batching/workflows.

https://www.bdVeritor.com/long-term-care-facilities/training/

Question 11

When batch testing, once the sample is collected, how long is the specimen viable for testing? how much time can pass from the time the sample is collected, until it must be run through the machine?

Response:

Freshly collected nasal swab specimens should be processed as soon as possible, but no later than one hour after specimen collection. For more information please visit: https://www.bdveritor.com/wordpress/wp-content/uploads/2020/09/589_US_0820_Veritor_SarsCov2_AnalyzeNow_BatchTestingGuide_FINAL.pdf.

Question 12

When a patient/resident is tested, they may be tested at bedside. Having the nurse swab and perform the sample processing at bedside increases risk of error and will take significant time. Further, transporting cassette back to the 'lab' area could also be an issue. Does the cassettes need to be positioned horizontally or is it acceptable if the cartridge/test cassette is placed in a bag where it may land upside down?

Response:

The nasal swabs can be processed right away in the extraction reagent vial at bedside, or be placed safely in a clean labelled transport tube, and transported in a rack to the processing/testing area. Freshly collected nasal swab specimens should be processed as soon as possible, and no later than one hour after specimen collection. If the nasal swab is deposited in the extraction reagent vial at bedside, the contents of the vial must be added to the test cartridge within 30 minutes. BD Veritor™ test cartridges should lay flat on a surface for incubation and not be transported.

Question 13

How long can the specimen remain in the reagent tube before testing? How long stable once on cartridge? How long is the swab with the sample good for?

Response:

Freshly collected nasal swab specimens should be processed as soon as possible and no later than one hour after specimen collection. The nasal specimen is expressed in the extraction reagent vial, and the extraction reagent vial must be used within 30 minutes to inoculate the test device (cartridge). The test device can be directly placed in the instrument on the WALK AWAY mode, or must be incubated for 15 minutes on the bench top for ANALYZE NOW mode. The cartridge must be read at the 15 minute mark.

Question 14

Does the BD Veritor™ Plus Analyzer require validation or monthly calibration?

Response:

No monthly calibration is required. Instructions on validating the instrument are in the online eLearning module.

https://www.bdVeritor.com/long-term-care-facilities/training/

Additional instructions for how to use the verification cartridge are also included in the package insert, section 5.1.1 on page 28.

Dedicated support is also available at 1-844-823-5433.

Question 15

Does the BD Veritor™ Plus Analyzer track how many tests it has performed? How do we know when we have completed 3500 tests? Does the analyzer just not power back on any more? Does it give an error code? When reaching 3500 tests and the BD machine has to be replaced, Is there a discount on reorders?

Response:

The instrument can be used for up to 3,500 tests or for 24 months, whichever comes first. A countdown mode is activated when the device is turned on or when there are 300 remaining tests. When the device is nearing its end of life it must be replaced. Contact your distributor to find out how to replace your instrument. The distributor will support the facility in identifying options for replacement. Several distribution partners offer different purchasing plans for replacement instruments.

Question 16

Can patient information be entered into the Veritor?

Response:

Information can only be added into the BD Veritor™ Plus Analyzer with the optional BD InfoScan (not included on the devices procured by HHS). The InfoScan is barcode reader that can used to scan 1D barcodes of up to 40 characters. It can be used to capture specimen ID, kit/lot number, and also operator ID information. Without InfoScan, no information can be entered into the BD Veritor™ Plus Analyzer.

Question 17

How are results collected from the instrument?

Response:

Results can be captured in four ways.

- Manual read and download. The device will display test result, and time and date of test which can be manually recorded.
- Purchase the optional BD InfoScan, which allows for a CSV download of test results
- Print results by attaching a printer (specifications for printer are included in the e-learning modules);
- Connectivity through BD Synapsys informatics, which is a full service informatics solution that allows for automated results reporting to your EMR or LIS.

For more information on connectivity options please attend the BD webinar on connectivity. Register here: https://go.bd.com/BD-Veritor-webinars.html. For questions specific to training, please contact BD at Ids.covidtests@bd.com.

Question 18

Does electronic reporting have to be connected to a LIMS system? Most LTCFs will not have this technology.

Response:

The BD Veritor™ Plus Analyzer requires BD Synapsys informatics to automate result reporting. Automated result reporting can be done with either a LIMS or EMR system. Electronic reporting can be uploaded directly into an EMR system like PointClickCare® if a facility does not use a LIMS system. Without BD Synapsys informatics, results will need to be documented manually in the EMR system.

Question 19

Can the Veritor™ be used for surveillance testing?

Response:

Laboratory and testing professionals who conduct surveillance testing for SARS-CoV-2 with rapid antigen tests are not obligated to comply with FDA and CLIA requirements. However, CDC recommends that facilities that conduct surveillance testing for SARS-CoV-2 with antigen tests use an antigen test that has been authorized for use, which are listed on FDA's In Vitro Diagnostics EUA webpage. Surveillance testing for SARS-CoV-2 is intended to monitor community- or population-level infection and disease, or to characterize the incidence and prevalence of disease. Surveillance testing is used to gain information at a population level, rather than an individual level, and results of surveillance testing are only returned in aggregate to the requesting institution. Surveillance testing is performed on de-identified specimens, and thus results are not linked to individuals. Surveillance testing does not involve returning a diagnostic test result to an individual, or for individual decision-making. For more information on surveillance testing for SARS-CoV-2, see https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html.

Question 20

What is the accuracy of a positive test uncorrected for population infection rates?

Response:

Accuracy is usually equated with the sensitivity (positive percent agreement) and specificity (negative percent agreement) of an assay. We are interpreting this question as addressing the ability of an assay to correctly predict whether a positive result is actually a true positive (positive predictive value).

The IFU contains the positive predictive value (likelihood that a positive test result is correct) for a positive test result at the disease prevalence encountered in the study (13.7%). The IFU also includes a table that adjusts that positive predictive value to inform interpretation at different varying prevalence rates.

Question 21

What is the accuracy of these machines? How frequent are false positives or false negatives? Can we see the specificity and sensitivity results of your test?

Response:

The PPA (positive percent agreement, indicator of sensitivity) and NPA (negative percent agreement, indicator of specificity) are in the IFU for BD Veritor™ System for Rapid Detection of SARS-CoV-2. For further information please review the IFU at: https://www.bdVeritor.com/wordpress/wp-content/uploads/2020/08/BD-Veritor-System-for-Rapid-Detection-of-SARS-Co-V-2-Instructions-for-Use.pdf. Additional information on interpreting test results can also be found here: https://www.bdveritor.com/long-term-care-facilities/system-overview/.

Question 22

What is the website address for the microsite?

Response:

Visit the manufacturer website for training information.
https://www.bdVeritor.com/long-term-care-facilities/system-overview/

Section 6: *Quidel Sofia® 2 Immunoassay Analyzer questions and answers*

Question 1

Does the Sofia® 2 come with USB cord?

Response:

A USB cord is not included with the Sofia® 2 analyzer installation pack. A facility may purchase a FAT 32 Formatted USB from a local electronics store.
For formatting instructions, visit https://connectme.quidel.com/docs/myquidel/.

Question 2

Where can I find training information for using the Sofia® 2?

Response:
Visit the manufacturer website for training information.
https://togetheragain.quidel.com/

Question 3
Who receives a user ID after completing the training?

Response:
When the instrument ships, the default Supervisor ID is 1234. Each facility may set up operators with unique operator IDs. Entering the operator ID and patient ID is an optional setting on the instrument. Please refer to the online manual for more information regarding management of patient and operator IDs.

Question 4
How many controls are needed to validate each lot or new user?

Response:
Per the package insert and online training, controls (positive and negative) should be run:

- With each new kit lot
- With each new operator
- As required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements

Additional controls can be purchased to maintain quality.

Lot numbers of test kits should be recorded to ensure controls are run to maintain high quality control standards.

Question 5
What is the price for each test kit and how can they be reordered?

Response:
Visit the manufacturer website for pricing and reordering information.
https://togetheragain.quidel.com/#how-to-order-more-tests

Question 6
What are the test's performance characteristics?

Response:

The performance data in the package insert for the Sofia® SARS Antigen FIA has a positive percent agreement of 96.7% and a negative percent agreement of 100% with RT-PCR using direct nasal swabs. The clinical samples were collected from patients with a symptom onset of 5 days or less. For more information, see the package insert:
https://www.quidel.com/sites/default/files/product/documents/EF1438903EN00.pdf

Question 7

Do you write the patient ID or name on tube? On cassette?

Response:

It is imperative to maintain proper record keeping of the sample throughout the process, especially if processing multiple samples at once. Each sample should be assigned an identifier or processing code (i.e. Patient ID) that matches the patient chart/record and the same code used throughout the process. Tubes used to transport the swab prior to sample processing (if used), vials with extraction reagent and the test cassettes/cartridges should be labeled. Test cassettes/cartridges should be labeled before adding the sample, either on the backside or lateral sides, avoiding the sample drop area and the bar code. Do not write on the top of the Quidel Sofia® 2 Test Cassettes.

Question 8

How many samples can be tested at one time?

Response:

There is an option to run tests in batch mode (READ NOW mode on the instrument), meaning the reaction in the cassette is timed (with a timer/stopwatch purchased from a local vendor) on the counter rather than using the instrument in WALK AWAY mode. In the WALK AWAY mode the device runs an internal timer for the results. Once the test cassettes have incubated for 15 minutes, set the instrument in READ NOW mode. Enter the user/patient ID (optional), insert the test cassette, and the unit will read the test cassette in less than 1 minute. Please note the user must time (using a timer/stopwatch) during the 15-minute incubation period prior to running the test cassette in READ NOW mode.

Question 9

Should specimens be processed at the patient's bedside or should they be transported back to the "laboratory" and then processed?

Response:

The swab containing the patient sample should be placed safely in a clean, labeled tube, and transported in a rack to the processing area. CDC guidelines for COVID-19 sample collection and testing can be found here: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html. Patient samples placed in a clean tube are stable for 48 hours after collection at room temperature or refrigerated (2-8°C) before processing. Future lots of Sofia SARS® FIA test kits will include transport tubes. Each facility that received a Sofia® 2 will receive a package of dry transport tubes and a batch processing guide. It is anticipated that mailing will take place in 3-4 weeks. Reordering of the dry transport tubes will be completed through the primary distributor.

Question 10
How should samples be stored before they are tested?

Response:
Sample swabs can be placed in a clean sealed dry tube and stored at room temperature or refrigerated (2-8°C) for up to 48 hours. Samples should not be stored in the reagent tubes.

Question 11
How long can the specimen remain in the reagent tube before testing? How long stable once on cartridge? How long is the swab with the sample good for?

Response:
When ready to process samples, the patient swab is placed into the reagent tube, mixed and left for 1 minute. The swab is then removed and the preparation in the reagent tube should be immediately added to the cassette sample well. If batch processing in READ NOW mode, let the cassette sit for a minimum of 15 minutes but no longer than 30 minutes before inserting in the Sofia® 2 for analysis. If using the analyzer in WALK AWAY mode insert the cassette into the reader and low 15 minutes for the result. Results must be interpreted within 30 minutes of adding the preparation to the cassette. A swab placed in a dry tube is stable for 48 hours after collection at room temperature or when refrigerated (2-8°C).

Question 12
When a patient/resident is tested they may be tested at bedside. Having the nurse swab and perform the sample processing at bedside increases risk of error and will take significant time. Further, transporting cassette back to the 'lab' area could also be an issue. Do the cassettes need to be positioned horizontally or is it acceptable if the cartridge/test cassette is placed in a bag where it may land upside down?

Response:
The swab containing the patient sample should be placed safely in a clean, labeled tube, and transported in a rack to the processing area. Patient samples placed in a clean dry tube are stable for 48 hours after collection at room temperature or 2-8C before processing. Each nursing home that received a Quidel Sofia® 2 will receive a package of dry transport tubes and the batch processing guide. It is anticipated that the mailing will take place in 3-4 weeks. Reordering of the dry transport tubes will be completed through the primary distributor. The cassettes should lay flat on a surface for incubation.

Question 13
Does the Sofia® 2 require validation or monthly calibration?

Response:
Monthly calibration is recommended using the calibration cassette included with the kit. The instrument will prompt the user when it is time to calibrate. Calibration takes less than 1 minute.

Select training and review Module 2 – Calibration.

https://togetheragain.quidel.com/

Question 14

Is there a maximum number of tests that can be performed before needing to purchase a new instrument?

Response:

The instrument has no expiration date nor a limitation on the maximum number of tests that can be performed.

Question 15

How is the test cassette linked to a patient?

Response:

The sample or patient ID should be handled by the facility following the proper labelling protocol that the facility implemented per State, CMS, or CDC reporting guidance. Once each sample is labelled accordingly, the sample or patient ID is entered into the device following the device prompted commands.. Do not write on the top of the Quidel Sofia® 2 test cassettes. Please visit Sofia® 2 manual for more details

Question 16

Can patient demographics/identifiers be entered into the Quidel instrument since the new CMS requirement includes 18 fields?

Response:

The Quidel Sofia® 2 has the built-in capability of a barcode scanner that allows the scanning of the test cassette barcode. Once the cassette barcode is scanned by the machine, the Patient ID can be manually typed to be linked with the test cassette. Patient demographics, LOINC code, etc. will need to be entered into the LIMS system or other test results reporting document as required by CMS.

Question 17

How are results collected from the instrument?

Response:

Data can be recorded from the Quidel Sofia® 2 in four ways.

- Manual transfer of data from instrument to patient chart.
- Attach a printer (not provided, see compatible printer specifications in the user manual)
- Insert a formatted USB drive to the instrument (see user guide for formatting instructions). The USB must be inserted into the Sofia® 2 before conducting testing as data cannot be exported after the test is performed.
- Establish a link to the nursing home's laboratory information systems (LIS) or electronic health record (EHR) or purchase a commercial interface from a commercial data management system vendor for data transfer. For more information, visit: https://connectme.quidel.com/docs/myquidel/update-sofia-2/

Question 18
Are the current electronic health record (EHR) links the only connections available for the Quidel instrument? Will connections to other EHRs be considered? If so, at what cost?

Response:
Refer to https://connectme.quidel.com for more information regarding interfacing with various vendors.

Question 19
Please clarify EHR compatibility. How is reporting to local health departments performed by the Quidel Sofia® 2 instrument?

Response:
Currently, Quidel includes both ASTM and POCT1a interfaces in the instrument platform. These interfaces are included without any additional charge from Quidel. The Quidel Connectivity Team is available to support all EHR or EMR vendors to assist with their interfacing of the instrument. As always, instrument interface implementation to the EMR/EHR are completely dependent on the resources of the vendor.

Question 20
Does electronic reporting have to be connected to a LIMS system? Most LTCFs will not have this technology.

Response:
To send data to the EMR, the instrument would need to be connected to the network. To send data to the state Department of Health, facilities should follow your local state guidance for required reporting pathways.