

# TOOLKIT FOR NURSING HOMES USING POINT OF CARE DEVICES FOR SARS-COV-2 TESTING

(OCT 5, 2020)

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### BACKGROUND

On July 14, 2020, the U.S. Department of Health and Human Services (HHS) announced the large-scale procurement of SARS-CoV-2 rapid point-of-care diagnostic tests and instruments for distribution to nursing homes with a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver as certified by the Centers for Medicare & Medicaid Services (CMS). These antigen tests, from Becton, Dickinson and Company (BD) and Quidel Corporation have been issued emergency use authorizations by the U.S. Food and Drug Administration (FDA).

In addition, on August 26, 2020 CMS announced sweeping regulatory changes that require Medicare and Medicaid-certified nursing homes to routinely test staff and offer testing to residents for coronavirus disease 2019 (COVID-19). Laboratories and nursing homes using point of care testing devices will be required to report diagnostic test results as required by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

Lastly, on August 27, 2020, HHS and the Department of Defense (DOD) awarded a contract to Abbott for the delivery of 150 million rapid, Abbott BinaxNOW COVID-19 Ag Card SARS-CoV-2 diagnostic tests to expand strategic, evidence-based testing in the United States. The Abbott BinaxNOW COVID-19 Ag Card received FDA emergency use authorization, does not require instrumentation, and delivers COVID-19 test results in 15 minutes or less.

### NURSING HOME DATA

- The Nursing Home COVID-19 Public File includes data reported by nursing homes to the CDC's National Healthcare Safety Network (NHSN) system COVID-19 Long Term Care Facility Module as well as Frequently Asked Questions.
- Nursing homes were prioritized for receipt of a testing instrument by CMS in their continuing effort to protect older adults.
- Allotments of instruments and amount of test kits for each facility were determined by the estimated volume of tests needed for the facility to test all staff and residents at least once.
- Following initial distribution, nursing homes can procure additional tests directly from the respective manufacturers and/or distributors.
- Nursing homes must meet [CMS requirements](#) for testing residents and staff.
- Procurement can also enable testing of visitors if appropriate for that facility.
- [COVID-19 Nursing Home Data](#)

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### FEDERAL TESTING GUIDANCE

[HHS] Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities (Aug 31<sup>st</sup>, 2020)

- U.S. Department of Health and Human Services, through the Assistant Secretary for Health, extended coverage under the Public Readiness and Emergency Preparedness Act (PREP Act) to licensed healthcare practitioners prescribing or administering point-of-care COVID-19 tests for screening in congregate facilities across the Nation.
- PREP Act coverage preempts any state and local law that prohibits or effectively prohibits such persons from administering COVID-19 tests authorized by the U.S. Food and Drug Administration (FDA) to symptomatic and asymptomatic individuals at congregate facilities, like nursing homes or similar settings.
- PREP Act coverage encompasses licensed healthcare practitioners prescribing or administering FDA-authorized COVID-19 tests, including for off-label (outside the authorization) use to screen asymptomatic individuals in congregate facilities.
- Prescribing providers in a congregate setting would be covered if prescribing for off-label use, as set forth in the guidance.
- [Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities](#)
  - Last update: August 31, 2020

[CMS] Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID-19 Focused Survey Tool (Aug 26<sup>th</sup>, 2020)

- Rule establishes long-term-care (LTC) facility testing requirements for staff and residents.
- Specifically, facilities are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the Secretary of Health and Human Services.
- [Interim Final Rule \(IFC\), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to COVID-19 Focused Survey Tool](#)
  - Last update: August 26, 2020

[CMS] CMS's policy regarding laboratories performing antigen tests for use at the point of care (POC) or in-patient care settings operating under a CLIA Certificate of Waiver on asymptomatic individuals

- 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.

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- [CMS's policy regarding laboratories performing antigen tests authorized by the Food and Drug Administration \(FDA\) under an Emergency Use Authorization \(EUA\) for use at the point of care \(POC\) or in patient care settings operating under a Clinical Laboratory Improvement Amendments of 1988 \(CLIA\) Certificate of Waiver on asymptomatic individuals](#)
  - Last update: August 28, 2020

### [CDC] Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes

- Provides a summary of considerations for use of SARS-CoV-2 antigen testing in nursing homes and is intended for nursing home providers and state and local public health departments.
- [Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes](#)
  - Last update: August 27, 2020

### [CDC] Interim Guidance for Rapid Antigen Testing for SARS-CoV-2

- Interim guidance is intended for clinicians who order antigen tests, receive antigen test results, and/or perform point-of-care testing, as well as for laboratory professionals who perform antigen testing in a laboratory setting or at the point of care and report those results.
- Purpose of this interim technical guidance is to support effective use of antigen tests for different testing situations.
- [Interim Guidance for Rapid Antigen Testing for SARS-CoV-2](#)
  - Last update: September 4, 2020

### [FDA] FDA's recommendations for healthcare providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals

- 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: [FAQs on Testing for SARS-CoV-2](#)
  - Last update: September 2, 2020

## CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability and timeliness of test results regardless of where or by whom the test was performed.

- CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. Please note that state, local, and accreditation requirements may be more stringent.

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- Skilled nursing facility / nursing facility needs a CLIA certificate, which can be a Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation, to perform COVID-19 testing on specimens cleared or authorized by the FDA to be used in point of care settings (i.e., in patient care settings operating under a CLIA Certificate of Waiver) or waived settings.
- Guidance for obtaining a CLIA Certificate of Waiver can be found on the CMS website.
- [How to obtain a CLIA Certificate of Waiver](#)

## DATA REPORTING

CDC's NHSN provides healthcare facilities, such as long-term care facilities (LTCF) with a customized system to track infection and prevention process measures in a systematic way

- Facilities eligible to report into all modules of the Long-term Care Facility Component include nursing homes, skilled nursing, chronic care, and developmental disability facilities.
- [CMS requires](#) all Medicare and Medicaid-certified nursing homes to report specific COVID-19-related data through CDC's NHSN COVID-19 Module for LTCFs.
- Reporting COVID-19 data through NHSN enables state and local health departments and the Centers for Medicare & Medicaid Services (CMS) to gain access to the COVID-19 data for LTCFs in their jurisdictions.
- [National Healthcare Safety Network \(NHSN\) - LTCF COVID-19 Module](#)

Testing sites must report data for all diagnostic and screening testing completed, which includes molecular, antigen, and antibody testing, for each individual tested

- CDC outlines the reporting requirements for COVID-19 testing sites such as who must report, how to report, what to report, and how to report using standard terminology.
- [Coronavirus Disease 2019 \(COVID-19\) - How to Report COVID-19 Laboratory Data](#)

Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) codes for reporting of SARS-CoV-2 antigen test results

- Public health surveillance for reportable and nationally notifiable diseases and conditions relies on laboratory criteria to support case definitions and classification. The mapping of test results for electronic laboratory reporting systems used by clinical laboratories is challenging due to the numerous test platforms available. The ability for computer systems to transmit data that is unambiguous and has shared meaning (semantic interoperability) is needed to harmonize the large volume of laboratory test data both within and especially between healthcare systems.
- LOINC and SNOMED CT together standardize and the reporting of the results of those tests to enhance interoperable and actionable laboratory data that can be effectively communicated electronically.
- [Division of Laboratory Systems \(DLS\) - LOINC In Vitro Diagnostic \(LIVD\) Test Code Mapping for SARS-CoV-2 Tests](#)

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Table 1: Point-of-Care Tests Procured by HHS to Support Enhanced Testing in Congregate Settings.

| Manufacturer                               | Test LOINC Code | Vendor Result Description                | Result SNOMED CT Code |
|--|-----------------|--|-----------------------|
| Abbott BinaxNOW                            | 94558-4         | Positive                                 | 10828004              |
|  |                 | Negative                                 | 260385009             |
|  |                 | Invalid                                  | 455371000124106       |
|  |                 | Specimen unsatisfactory for evaluation   | 125154007             |
| Becton, Dickinson and Company (BD) Veritor | 94558-4         | Positive Test for SARS-CoV-2             | 260373001             |
|  |                 | Presumptive Negative Test for SARS-CoV-2 | 260415000             |
|  |                 | Test Invalid                             | 455371000124106       |
|  |                 | Specimen unsatisfactory for evaluation   | 125154007             |
| Quidel Sofia 2                             | 95209-3         | Positive                                 | 260373001             |
|  |                 | Negative                                 | 260415000             |
|  |                 | Invalid                                  | 455371000124106       |
|  |                 | Specimen unsatisfactory for evaluation   | 125154007             |

## LABORATORY BEST PRACTICES

### Guidance for General Laboratory Safety Practices during the COVID-19 Pandemic

- Guidance addresses the general workflow safety concerns of laboratory personnel during the COVID-19 pandemic.
- All laboratories should perform site- and activity-specific risk assessments to determine the most appropriate safety measures to implement for particular circumstances.
- In addition, facilities should adhere to local policies and procedures as well as all applicable federal, state, and local regulations and public health guidelines.
- [Coronavirus Disease 2019 \(COVID-19\) - Guidance for General Laboratory Safety Practices during the COVID-19 Pandemic](#)

### CLIA self-assessment checklist for CLIA waived POC tests

- The self-assessment checklist emphasizes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. This can be used as a voluntary tool to help ensure good testing practices and reliable, high-quality test results.
- [Self-Assessment Checklist for Good Testing Practices](#)

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Sample Processing Guidance – Coming soon

- Coming soon

## HHS NURSING HOME STRIKE TEAMS

In March 2020, CDC and CMS developed an operational plan to support implementation of infection control strategies that can reduce the transmission of SARS CoV-2 in nursing homes. As part of that broader concept of operations, CDC, CMS and their state partners use both remote and on-site strategies to assess and strengthen nursing homes' preparedness and response capabilities. HHS Strike Teams, which CMS has led in partnership with CDC and OASH / US Public Health Service since July, are one such strategy.

- Typically deployed to facilities experiencing, or at risk of experiencing, significant outbreaks.
- Risk and status determinations are based on data submitted by facilities through the National Healthcare Safety Network's COVID-19 LTC Module, as well as consultation with state partners.
- State and Local Public Health Departments (PHD) staff are also invited to join the visits, but State Survey Agency staff are not involved in the visit.

Visits are usually scheduled for a half-day and organized around the following aims:

- Understand how the COVID-19 outbreak unfolded; summarize current situation and the facility's response.
- Identify critical actions that will help the facility contain the current COVID-19 outbreak and/or prevent COVID-19 transmission in the future.
- Identify best practices and lessons learned that could benefit other facilities or inform state/federal support activities.

If issues related to diagnostic SARS-CoV-2 testing are identified, the teams will engage other state partners, such as the State Survey Agency and Healthcare-Associated Infections Program, to relay this information to Public Health Laboratory partners and other key contacts within the state.

## TRAINING MODULES

- Recorded manufacturers webinar through HHS (September 3, 2020): [YouTube - Nursing Home COVID-19 Testing Webinar](#)
  - BD presentation: [BD Veritor Training Presentation](#)
  - Quidel presentation: [Quidel Sofia 2 Training Presentation](#)
- [Quidel Sofia 2 System Training Information](#)
- [BD Veritor System Training Information](#)

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- [Abbott BinaxNOW System Training Information](#)
- CMS training for nursing homes: [QSEP - Targeted COVID-19 Training for Nursing Homes Instruction](#)

## INSTRUMENT DATA CAPTURE

### Quidel: Sofia 2

- Manual transfer of data from instrument to patient chart.
- Attach a printer (see compatible printer specifications).
- Attach a formatted USB drive to the instrument (see user guide for formatting instructions).
- Inquire with the NH's Laboratory Information Systems (LIS)/Electronic Health Record (EHR)/commercial data management system vendor for the availability of a commercial interface for data transfer.
- See IFU for more details: [FDA - Quidel Sofia SARS Antigen FIA](#)

### BD: Veritor

- Manual transfer of data from instrument to patient chart.
- Attach a printer (see compatible printer specifications).
- BD Veritor Plus System Connect Intel NUC (additional purchase) for wireless data transfer.
- Please see IFU for more details: [FDA - BD Veritor System](#)

### Abbott: BinaxNOW

- Use the NAVICA™ Administrator App to communicate encrypted BinaxNOW COVID-19 Ag Card test results to individuals.
- Manual transfer of data from app to patient chart.
- Please see IFU for more details: [FDA - BinaxNOW COVID-19 Ag CARD](#)

## REORDERING TESTS

- Reordering amounts should be representative of future needs on a monthly basis.
- Reordering calculator worksheet: Appendix C
- Quidel: [Quidel - How To Order More Tests](#)
- BD: [BD - How To Order More Tests](#)

## POINTS OF CONTACT

- Quidel technical support: [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com)



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- BD technical support: [technical\\_services@bd.com](mailto:technical_services@bd.com)
- Abbott technical support: [ts.scr@abbott.com](mailto:ts.scr@abbott.com)
- HHS regulatory support: [NHTesting@hhs.gov](mailto:NHTesting@hhs.gov)
- CMS regulatory support: [COVID-19@cms.hhs.gov](mailto:COVID-19@cms.hhs.gov)