TOOLKIT FOR NURSING HOMES USING POINT-OF-CARE DEVICES FOR SARS-COV-2 TESTING
(NOVEMBER 10, 2020)

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UPDATES

- Added HHS BinaxNOW™ COVID-19 Ag Card link to the Background section from press release.
- Updated the Nursing Home Data section to include specifics for the different antigen tests available under the HHS programs.
- Added CMS Interim Final Rule for updating requirements for reporting of SARS-CoV-2 test results by CLIA laboratories subsection under Federal Testing Guidance section.
- Added Payment Medicare Guidance for Testing section.
- Added the CDC's Guidance for SARS-CoV-2 Point-of-Care Testing website to the Laboratory Best Practices subsection under Guidance for General Laboratory Safety Practices during COVID-19 Pandemic section.
- Deleted HHS Strike team section and replaced with State and Local Support for Testing section.
- Relocated Instructions for Use (IFU) to a new section.
- Added NHSN training links to the Training section.
- Added new Batch Testing Process section.
- Added new supporting weblinks to Instrument Data Capture section.
- Added new details on how to order more Abbott BinaxNOW™ COVID-19 Ag Card tests under Reordering Tests section.

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. For more information, visit: https://www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html.

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LONG TERM CARE (LTC) FACILITY AND NURSING HOME SUPPORT

General Information for Antigen Testing Support

- Nursing homes were prioritized for receipt of testing instruments/devices by CMS in their continuing effort to protect older adults.
- The CMS COVID-19 Nursing Home data is a public file that includes data reported by nursing homes to the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) system COVID-19 Long Term Care Facility Module as well as Frequently Asked Questions and other resources.
    - https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/
- Long-term care facilities and nursing homes must have a CLIA Certificate of Waiver and be federally certified under Medicare as a Skilled Nursing Facility (SNF) and/or Medicaid as a Nursing Facility (NF).
    - https://www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html
- LTC facilities must submit point-of-care SARS-CoV-2 testing data, including antigen testing data, to CDC's NHSN. This requirement is responsive to the Coronavirus Aid, Relief, and Economic Security (CARES) Act requirement that "every laboratory that performs or analyzes a test that is intended to detect SARS-CoV2 or to diagnose a possible case of COVID-19" must report the results from each such test to HHS.
    - https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf
        - Last Update: October 19, 2020

BD Veritor™ System and Quidel Sofia 2 SARS Antigen FIA information

- 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.

Abbott BinaxNOW™ COVID-19 Ag Card information

- For the current nursing homes allocation strategy, refer to the HHS BinaxNOW™ website.
    - https://www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html
- Additional information can also be located on the HHS Abbott BinaxNOW™ COVID-19 Ag Card Fact Sheet.
    - https://www.hhs.gov/sites/default/files/abbott-binaxnow-fact-sheet.pdf

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

- U.S. Department of Health and Human Services, through the Office of the Assistant Secretary for Health (OASH), extended coverage under the Public Readiness and Emergency Preparedness Act (PREP Act) to licensed healthcare practitioners prescribing or and other personnel 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 other personnel 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.
- https://www.hhs.gov/sites/default/files/prep-act-coverage-for-screening-in-congregate-settings.pdf
    - 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

- Rule establishes 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.
- https://www.cms.gov/files/document/qso-20-38-nh.pdf
    - Last update: August 26, 2020

[CMS] Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

- Health care facilities using point-of-care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes (SNF/NF), pharmacies, or other settings will be required to report test results under this regulation.
- In addition, LTC facility enforcement requirements have been revised to include requirements specific to the imposition of a Civil Money Penalty (CMP) for nursing homes that fail to report requisite COVID-19 related data to the CDC's NHSN.

- https://www.cms.gov/files/document/qso-20-37-clianh.pdf
    - Last updated: August 26, 2020

[CMS] CMS's Policy Regarding Laboratories Performing Antigen Tests for Use at the Point-of-Care 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 point-of-care antigen tests on asymptomatic individuals.
- Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 point-of-care antigen tests are performed on asymptomatic individuals.
- https://www.cms.gov/files/document/clia-poc-ag-test-enforcement-discretion.pdf
    - 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.
- https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html
    - 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.
- https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
    - Last update: September 4, 2020

[FDA] FDA's Recommendations for Healthcare Providers Using SARS-CoV-2 Diagnostic Tests for Screening Asymptomatic Individuals and Addressing Potential False Positive Results.

- FDA Frequently Asked Question (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
        - Last update: September 2, 2020
- Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers

- https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory?utm_medium=email&utm_source=govdelivery
  - Last Updated: November 3, 2020

MEDICARE PAYMENT GUIDANCE FOR TESTING

- CMS released information to help states, nursing facilities, and other providers better understand the sources of Medicare and Medicaid coverage and payment for COVID-19 testing, including a flow chart detailing testing coverage for nursing facility residents.
- https://edit.cms.gov/files/document/covid-medicare-payment-covid-19-viral-testing-flow-chart.pdf
  - Last Update: September 18, 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.
- A SNF/NF needs a CLIA certificate, which can be a Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation, to perform COVID-19 testing. Facilities operating under a Certificate of Waiver can only use tests that have been authorized by the FDA for testing in waived settings such as a point-of-care site (e.g., a nursing home operating under a CLIA Certificate of Waiver can use rapid antigen tests that have been authorized by FDA for use in waived settings).
- Guidance for obtaining a CLIA Certificate of Waiver can be found on the CMS website.
  - https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf

DATA REPORTING

CDC's National Healthcare Safety Network (NHSN) Provides Healthcare Facilities, Such as LTC Facilities, 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.
  - https://www.cdc.gov/nhsn/ltc/covid19/index.html
- CMS requires all Medicare and Medicaid-certified nursing homes to report specific COVID-19-related data through CDC's NHSN COVID-19 Module for LTC facilities. Reporting COVID-19 data through NHSN enables state and local health departments and CMS to gain access to the COVID-19 data for LTC facilities in their jurisdictions.

- https://www.cms.gov/files/document/qso-20-29-nh.pdf
  - Last Update: May 6, 2020

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.
  - https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html
    - Last Update: November 2, 2020
- The CARES Act Section 18115 requires CMS-certified long-term care facilities shall submit point-of-care SARS-CoV-2 testing data, including antigen testing data, to CDC's NHSN. This requirement to submit data to CDC's NHSN applies only to CMS-certified long-term care facilities. Test data submitted to NHSN will be reported to appropriate state and local health departments using standard electronic laboratory messages. Other types of LTC facilities may voluntarily report testing data in NHSN for self-tracking or to fulfill state or local reporting requirements, if any.
  - https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf
    - Last Update: October 19, 2020

Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) Codes to be Used 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.
  - https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html

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™ Plus	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 SARS Antigen FIA	95209-3	Positive	260373001
		Negative	260415000
		Invalid	455371000124106
		Specimen unsatisfactory for evaluation	125154007

TESTING 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.
    - https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-safety-practices.html
        - Last Update: August 15, 20202
- Guidance addresses the general testing guidance for point-of-care testing.
    - https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html
        - Last Update: August 14, 2020
- All facilities 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.

CLIA Self-Assessment Checklist for CLIA Waived Point-of-Care 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.
- https://www.cdc.gov/labquality/docs/waived-tests/self-assessment-checklist-good-testing-practices.pdf

STATE AND LOCAL SUPPORT FOR TESTING

Nursing homes and other LTC facilities with a CLIA Certificate of Waiver that are performing point-of-care testing for COVID-19 should contact their State Survey Agency or state/local health department if they have testing issues or challenges.

INSTRUCTIONS FOR USE (IFU)

- Quidel Sofia 2 SARS Antigen FIA: https://www.fda.gov/media/137885/download
- BD Veritor™ Plus: https://www.fda.gov/media/139755/download
- Abbott BinaxNOW™ COVID-19 Ag Card: https://www.fda.gov/media/141570/download

TRAINING MODULES

General Training

- CMS training for nursing homes: https://qsep.cms.gov/COVID-Training-Instructions.aspx
- NHSN training modules for data reporting: https://www.cdc.gov/nhsn/ltc/covid19/index.html

Manufacturer Training Modules

- Recorded manufacturers webinar through HHS (September 3, 2020): https://www.youtube.com/watch?v=8oCRqlY1kJw
    - BD presentation: https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/BD-Veritor-HHS-Nursing-Home-Training-9-3-20.pdf
    - Quidel presentation: https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/Quidel-Sofia-HHS-Nursing-Home-Training-9-3-20.pdf
- Quidel Sofia 2 system training information: https://togetheragain.quidel.com/
- BD Veritor™ system training information: https://www.bdveritor.com/long-term-care-facilities/training/
- Abbott BinaxNOW™ system training information: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

BATCH TESTING PROCESS

Procedural steps have been developed to support accurate processing of more samples in a set, timed period. The batch testing processing is not currently authorized under the IFU for COVID-19 antigens tests.

Quidel Sofia 2 SARS Antigen FIA System

- Coming soon

BD Veritor™ Plus System

- Coming soon

INSTRUMENT DATA CAPTURE

Quidel Sofia 2 System

- 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 nursing home's Laboratory Information Systems (LIS)/Electronic Health Record (EHR)/commercial data management system vendor for the availability of a commercial interface for data transfer.
- https://www.quidel.com/sites/default/files/product/documents/TB202991200EN00.pdf

BD Veritor™ Plus System

- 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.
- https://www.bdveritor.com/long-term-care-facilities/reporting-long-term-care-facilities/

Abbott BinaxNOW™ COVID-19 Ag Card System

- NAVICA™ Administrator App (from iPad or tablet) will communicate encrypted BinaxNOW™ COVID-19 Ag Card test results to individuals using the NAVICA™ patient App on their smartphone.
- Manual transfer of data from app to patient chart.
- https://www.globalpointofcare.abbott/en/product-details/navica-binaxnow-covid-19-us.html

ACQUISITION OF ADDITIONAL TESTS

- Quidel: https://togetheragain.quidel.com/#how-to-order-more-tests
- BD: https://www.bdveritor.com/long-term-care-facilities/order-tests/
    - Nursing Homes are responsible for the purchase of additional tests to support testing with the BD Veritor™ and the Quidel Sofia 2 instruments.
    - Reordering amounts should be representative of future needs on a monthly basis. Multi-month orders may present challenges to fulfill if manufacturer inventories are limited.
    - Reorder calculator: coming soon
- Abbott:
    - Nursing homes must request supplemental BinaxNOW™ COVID-19 Ag Card tests from their state.
    - HHS BinaxNOW™ COVID-19 Ag Card program will continue through December 2020 or until the 150 million tests purchased by HHS have been distributed.

POINTS OF CONTACT

- Quidel technical support: technicalsupport@quidel.com
- BD technical support: technical_services@bd.com
- Abbott technical support: ts.scr@abbott.com
- HHS regulatory support: NHTesting@hhs.gov
- CMS regulatory support: COVID-19@cms.hhs.gov

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