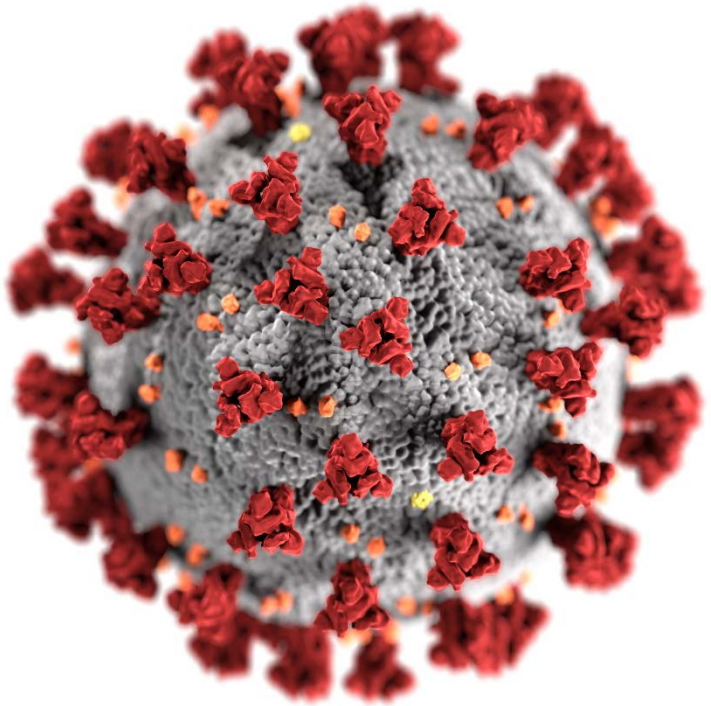
National Healthcare Safety Network (NHSN) COVID-19 Module Updates

Open Office Hours

National Healthcare Safety Network (NHSN) COVID-19 Module Updates for August 2020

Dates: Tuesday, September 1, 2020 and Thursday, September 3, 2020

Speaker: Angela Anttila, PhD, MSN, NP-C, CIC



cdc.gov/coronavirus

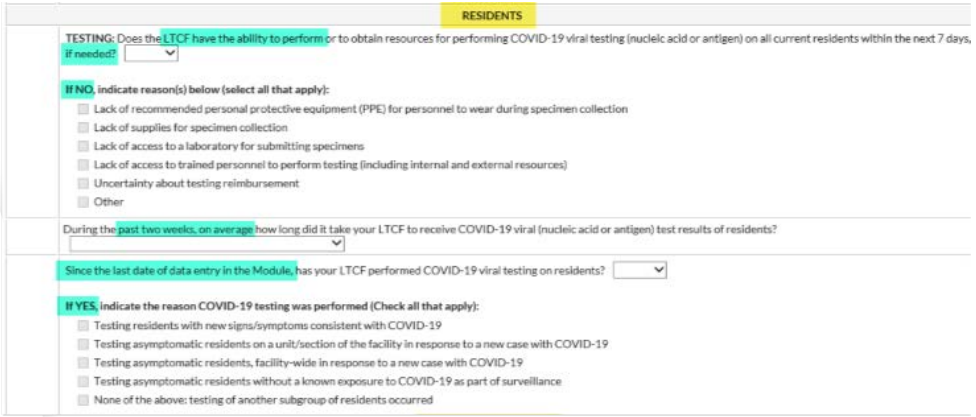
Objectives

- Review recent modifications to NHSN COVID-19 module
- Discuss common questions about the COVID-19 Module and NHSN response with justification to improve understanding
- Provide participants with resources
- Respond to participant questions

August 2020 Modifications

COVID-19 Updates in August 2020 (August 10 NHSN Release)

- New lab questions for residents and staff and personnel
  - Prioritize testing resources to facilities
- Frequency of testing and turn-around time for results are important for optimal control
  - Barriers to expanded viral testing
  - Timeliness of results
  - Characterize testing practices between residents and staff and personnel



RESIDENTS

TESTING: Does the LTCF have the ability to perform or to obtain resources for performing COVID-19 viral testing (nucleic acid or antigen) on all current residents within the next 7 days, if needed?

If NO, indicate reason(s) below (select all that apply):

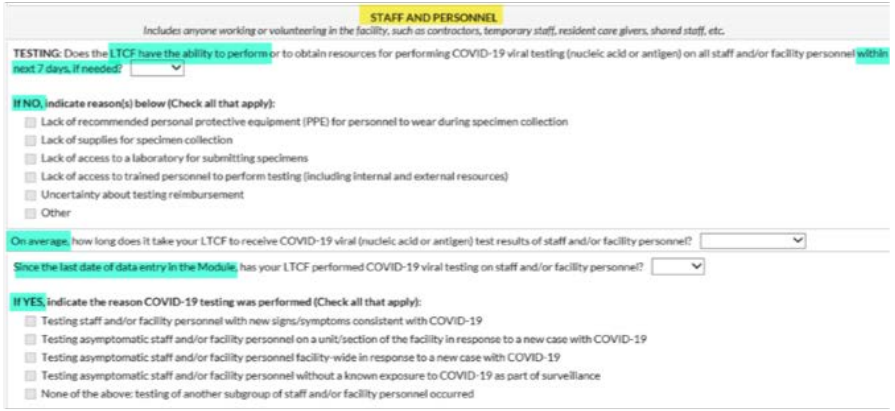
- Lack of recommended personal protective equipment (PPE) for personnel to wear during specimen collection
- Lack of supplies for specimen collection
- Lack of access to a laboratory for submitting specimens
- Lack of access to trained personnel to perform testing (including internal and external resources)
- Uncertainty about testing reimbursement
- Other

During the past two weeks, on average how long did it take your LTCF to receive COVID-19 viral (nucleic acid or antigen) test results of residents?

Since the last date of data entry in the Module, has your LTCF performed COVID-19 viral testing on residents?

If YES, indicate the reason COVID-19 testing was performed (Check all that apply):

- Testing residents with new signs/symptoms consistent with COVID-19
- Testing asymptomatic residents on a unit/section of the facility in response to a new case with COVID-19
- Testing asymptomatic residents, facility-wide in response to a new case with COVID-19
- Testing asymptomatic residents without a known exposure to COVID-19 as part of surveillance
- None of the above: testing of another subgroup of residents occurred



STAFF AND PERSONNEL

Includes anyone working or volunteering in the facility, such as contractors, temporary staff, resident care givers, shared staff, etc.

TESTING: Does the LTCF have the ability to perform or to obtain resources for performing COVID-19 viral testing (nucleic acid or antigen) on all staff and/or facility personnel within next 7 days, if needed?

If NO, indicate reason(s) below (Check all that apply):

- Lack of recommended personal protective equipment (PPE) for personnel to wear during specimen collection
- Lack of supplies for specimen collection
- Lack of access to a laboratory for submitting specimens
- Lack of access to trained personnel to perform testing (including internal and external resources)
- Uncertainty about testing reimbursement
- Other

On average, how long does it take your LTCF to receive COVID-19 viral (nucleic acid or antigen) test results of staff and/or facility personnel?

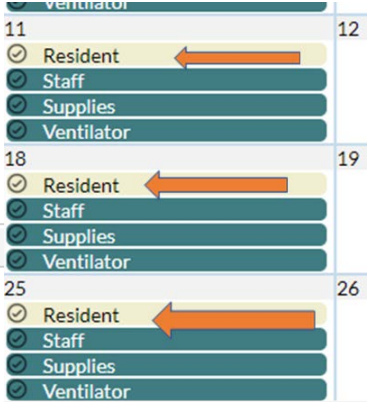
Since the last date of data entry in the Module, has your LTCF performed COVID-19 viral testing on staff and/or facility personnel?

If YES, indicate the reason COVID-19 testing was performed (Check all that apply):

- Testing staff and/or facility personnel with new signs/symptoms consistent with COVID-19
- Testing asymptomatic staff and/or facility personnel on a unit/section of the facility in response to a new case with COVID-19
- Testing asymptomatic staff and/or facility personnel facility-wide in response to a new case with COVID-19
- Testing asymptomatic staff and/or facility personnel without a known exposure to COVID-19 as part of surveillance
- None of the above: testing of another subgroup of staff and/or facility personnel occurred

COVID-19 Updates in August 2020 (August 29 NHSN Release)

- In-House, Point-of-Care COVID-19 Testing questions
  - Direct resources based on responses
  - Availability of Point-of-Care testing machines and test kits (*referred to as supplies*)
  - Impact on prevention/outcomes
- Questions are retro-active to August 10, 2020 – responses optional



IN-HOUSE, POINT-OF-CARE COVID-19 TESTING

Does the LTCF have an in-house point-of-care test machine (capability to perform COVID-19 testing within your facility)?

Since the last date of data entry in the Module, how many COVID-19 point-of-care tests has the LTCF performed on residents?

Since the last date of data entry in the Module, how many COVID-19 point-of-care tests has the LTCF performed on staff and/or facility personnel?

Based on this week's inventory, do you have enough supplies to test all staff and/or facility personnel for COVID-19 using the point of care test machine?

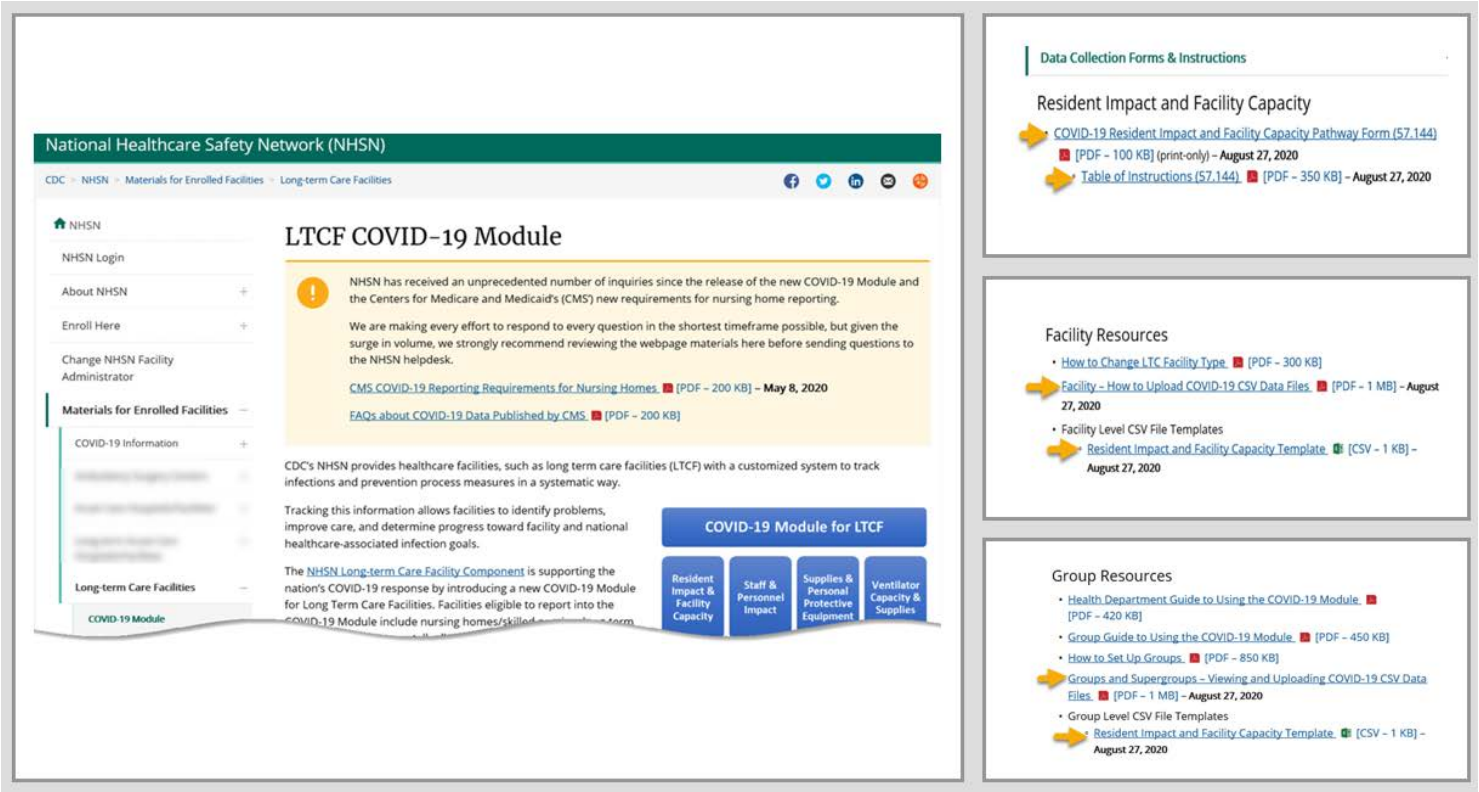
COVID-19 Updates in August 2020 (August 29 NHSN Release)

- In-House, Point-of-Care COVID-19 Testing questions, *continued*

❗ NHSN testing questions do **NOT** satisfy reporting requirements under the CLIA waiver

  - Questions related to CLIA: LabExcellence@cms.hhs.gov
  - Question related to LTC Enforcement: DNH_Enforcement@cms.hhs.gov
  - Questions related to the nursing home testing requirement: DNH_TriageTeam@cms.hhs.gov

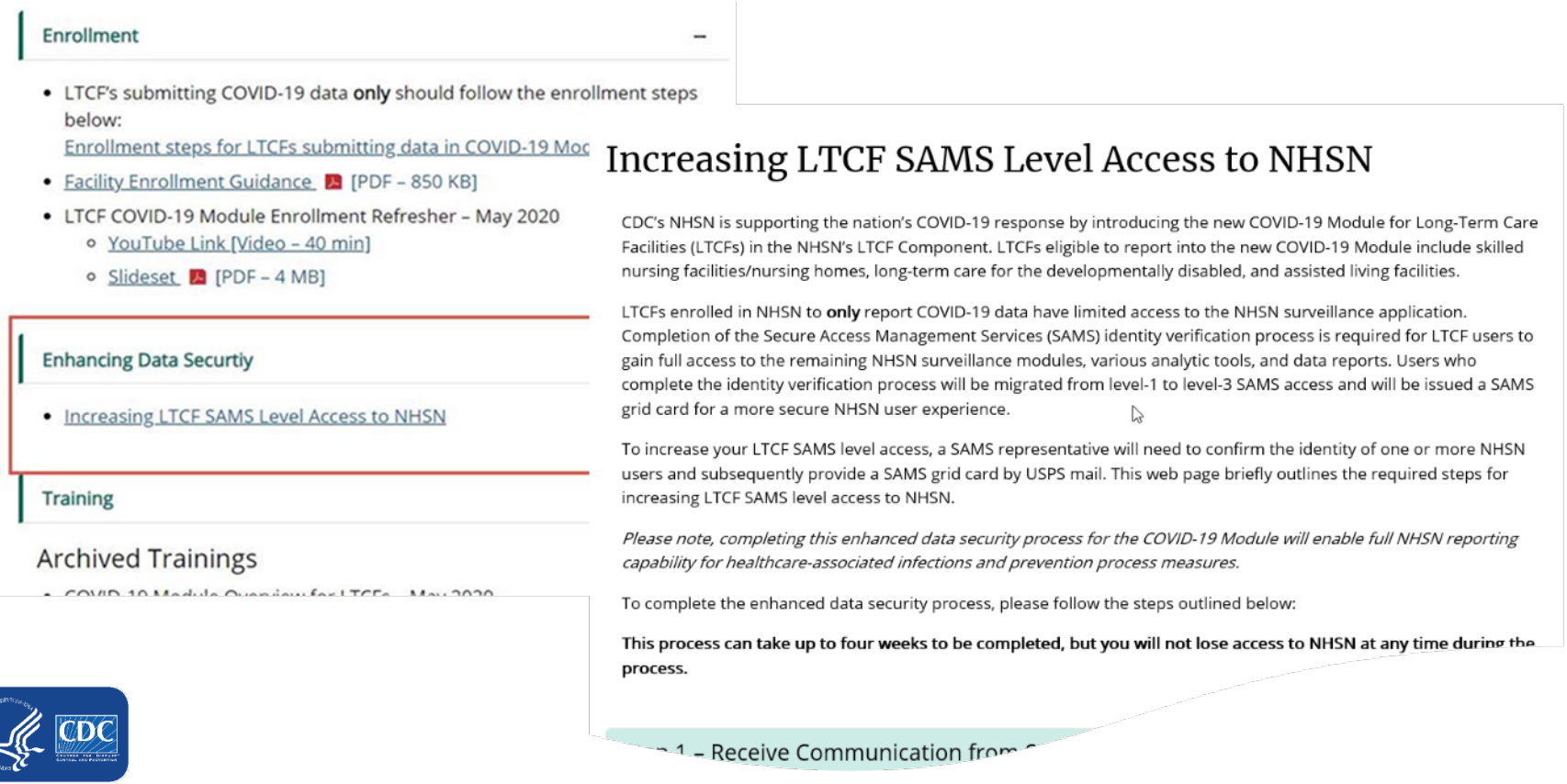
Visit NHSN LTCF COVID-19 Module Web-Page



https://www.cdc.gov/nhsn/ltc/covid19/index.html

Enhanced Data Security

https://www.cdc.gov/nhsn/ltc/covid19/index.html



Enrollment

- LTCF's submitting COVID-19 data **only** should follow the enrollment steps below:
  Enrollment steps for LTCFs submitting data in COVID-19 Mod
- Facility Enrollment Guidance [PDF – 850 KB]
- LTCF COVID-19 Module Enrollment Refresher – May 2020
  - YouTube Link [Video – 40 min]
  - Slideset [PDF – 4 MB]

Enhancing Data Securtiy

- Increasing LTCF SAMS Level Access to NHSN

Training

Archived Trainings

Increasing LTCF SAMS Level Access to NHSN

CDC's NHSN is supporting the nation's COVID-19 response by introducing the new COVID-19 Module for Long-Term Care Facilities (LTCFs) in the NHSN's LTCF Component. LTCFs eligible to report into the new COVID-19 Module include skilled nursing facilities/nursing homes, long-term care for the developmentally disabled, and assisted living facilities.

LTCFs enrolled in NHSN to **only** report COVID-19 data have limited access to the NHSN surveillance application. Completion of the Secure Access Management Services (SAMS) identity verification process is required for LTCF users to gain full access to the remaining NHSN surveillance modules, various analytic tools, and data reports. Users who complete the identity verification process will be migrated from level-1 to level-3 SAMS access and will be issued a SAMS grid card for a more secure NHSN user experience.

To increase your LTCF SAMS level access, a SAMS representative will need to confirm the identity of one or more NHSN users and subsequently provide a SAMS grid card by USPS mail. This web page briefly outlines the required steps for increasing LTCF SAMS level access to NHSN.

Please note, completing this enhanced data security process for the COVID-19 Module will enable full NHSN reporting capability for healthcare-associated infections and prevention process measures.

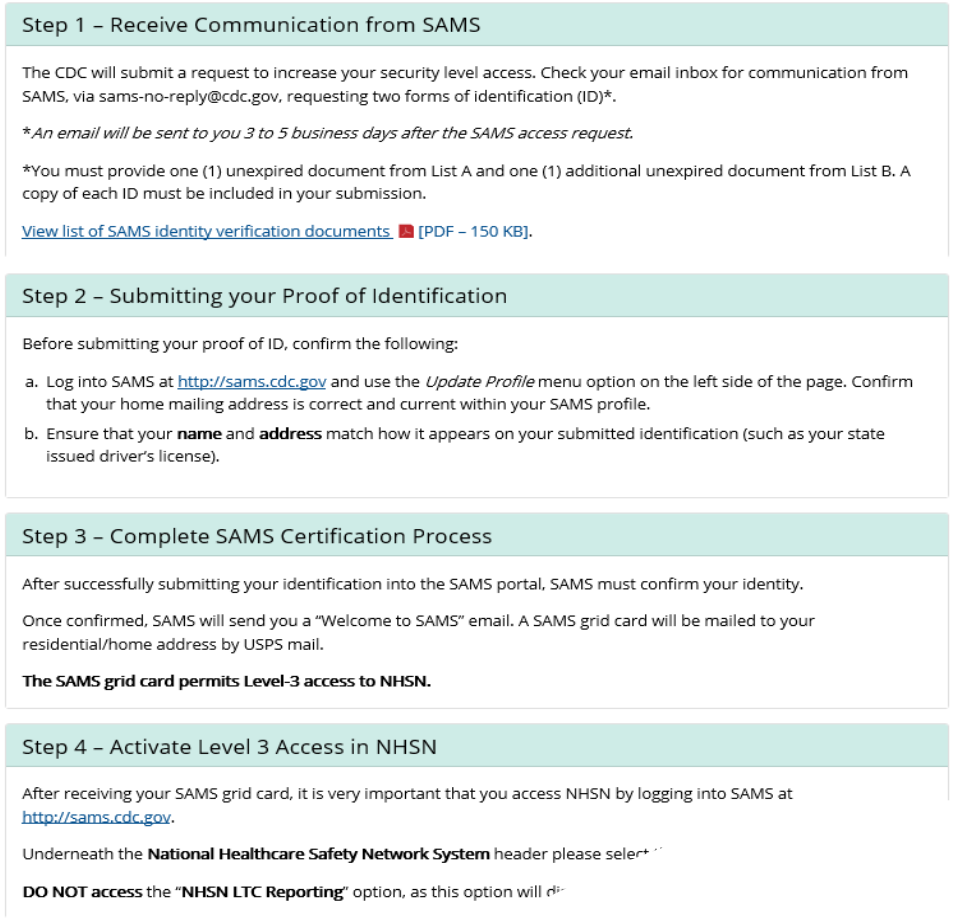
To complete the enhanced data security process, please follow the steps outlined below:

This process can take up to four weeks to be completed, but you will not lose access to NHSN at any time during the process.

Steps for Increasing LTCF SAMS Level Access to NHSN

https://www.cdc.gov/nhsn/ltc/covid19/sams-access.html

For questions about getting started or if you experience problems during enrollment, please contact the NHSN user support nhsn@cdc.gov
Include "Enhancing Data Security" in the subject line



Step 1 – Receive Communication from SAMS

The CDC will submit a request to increase your security level access. Check your email inbox for communication from SAMS, via sams-no-reply@cdc.gov, requesting two forms of identification (ID)*.

**An email will be sent to you 3 to 5 business days after the SAMS access request.*

*You must provide one (1) unexpired document from List A and one (1) additional unexpired document from List B. A copy of each ID must be included in your submission.

View list of SAMS identity verification documents [PDF – 150 KB].

Step 2 – Submitting your Proof of Identification

Before submitting your proof of ID, confirm the following:

a. Log into SAMS at http://sams.cdc.gov and use the *Update Profile* menu option on the left side of the page. Confirm that your home mailing address is correct and current within your SAMS profile.
b. Ensure that your **name** and **address** match how it appears on your submitted identification (such as your state issued driver's license).

Step 3 – Complete SAMS Certification Process

After successfully submitting your identification into the SAMS portal, SAMS must confirm your identity.

Once confirmed, SAMS will send you a "Welcome to SAMS" email. A SAMS grid card will be mailed to your residential/home address by USPS mail.

The SAMS grid card permits Level-3 access to NHSN.

Step 4 – Activate Level 3 Access in NHSN

After receiving your SAMS grid card, it is very important that you access NHSN by logging into SAMS at http://sams.cdc.gov.

Underneath the **National Healthcare Safety Network System** header please select

DO NOT access the "**NHSN LTC Reporting**" option, as this option will

Congratulations,

Responses to Common Questions

	MOLECULAR TEST	ANTIGEN TEST	ANTIBODY TEST
Also known as...	Diagnostic test, viral test, molecular test, nucleic acid amplification test (NAAT), RT-PCR test, LAMP test	Rapid diagnostic test (Some molecular tests are also rapid tests.)	Serological test, serology, blood test, serology test
How the sample is taken...	Nasal or throat swab (most tests) Saliva (a few tests)	Nasal or throat swab	Finger stick or blood draw
How long it takes to get results...	Same day (some locations) or up to a week	One hour or less	Same day (many locations) or 1-3 days
Is another test needed...	This test is typically highly accurate and usually does not need to be repeated.	Positive results are usually highly accurate but negative results may need to be confirmed with a molecular test.	Sometimes a second antibody test is needed for accurate results.
What it shows...	Diagnoses active coronavirus infection	Diagnoses active coronavirus infection	Shows if you've been infected by coronavirus in the past
What it can't do...	Show if you ever had COVID-19 or were infected with the coronavirus in the past	Definitively rule out active coronavirus infection. Antigen tests are more likely to miss an active coronavirus infection compared to molecular tests. Your health care provider may order a molecular test if your antigen test shows a negative result but you have symptoms of COVID-19.	Diagnose active coronavirus infection at the time of the test or show that you do not have COVID-19

https://www.fda.gov/media/140161/download

FDA Emergency Approval

Coronavirus (COVID-19) Update: FDA Authorizes First Antigen Test to Help in the Rapid Detection of the Virus that Causes COVID-19 in Patients

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For Immediate Release: May 09, 2020

Statement From: Commissioner of Food and Drugs - Food and Drug Administration
Stephen M. Hahn M.D.
Director - CDRH Offices: Office of the Center Director
Dr. Jeffrey E. Shuren MD, JD

Español

The U.S. Food and Drug Administration has issued the first emergency use authorization (EUA) for a COVID-19 antigen test, a new category of tests for use in the ongoing pandemic. These diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. The EUA was issued late Friday to Quidel Corporation for the Sofia 2 SARS Antigen FIA. This test is authorized for use in high and moderate complexity laboratories certified by Clinical Laboratory Improvement Amendments (CLIA), as well as for point-of-care testing by facilities operating under a CLIA Certificate of Waiver.

Diagnostic testing is one of the pillars of our nation's response to COVID-19 and the FDA continues to take actions to help make these critical products available, including by issuing EUAs. During this pandemic, there have been two types of tests for which the FDA

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Issued Emergency Use Authorization for Point of Care Antigen Test

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For Immediate Release: July 06, 2020

The U.S. Food and Drug Administration issued an Emergency Use Authorization (EUA) for a COVID-19 antigen diagnostic test, the BD (Becton Dickinson) Veritor System for Rapid Detection of SARS-CoV-2. This is the second antigen test the FDA has authorized for the detection of SARS-CoV-2 antigens. This test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for high, moderate, or waived complexity testing, meaning it can be used in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Emergency use of this test is limited to authorized laboratories using the BD Veritor Plus Analyzer Instrument.

Presumptive Test Results

Question: How should presumptive test results be considered for NHSN COVID-19 reporting? Should a facility include a newly positive COVID-19 presumptive test result in the NHSN "*Confirmed*" count?

Response: YES. A resident/healthcare worker with a newly positive COVID-19 test result must be included in the COVID-19 "*Confirmed*"

Justification

- Test sensitivity can vary between testing platforms and other factors, such as presence or absence of symptoms, recent exposure, prevalence in community, timing between antigen and PCR testing. Antigen tests have lower sensitivity compared to molecular (increased risk for false negative results), but comparable specificity to identify individuals with COVID-19 infection

https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/08/05/
https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

Reinfection

Question

- Are reinfections in residents and staff reportable in NHSN?

Response

- YES. Individuals with recurrent symptoms after the first 3 months (>90 days) who test positive for COVID-19 should be considered newly positive and included in the "*Confirmed*" COVID-19 count.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html

Personal Protective Equipment Availability (PPE)

Question

- If my facility is continuing to operate at contingency or crisis capacity standards despite having enough PPE to move higher up on the optimization hierarchy, how do we respond to following question, "*does your facility have enough of each supply for one week?*"

Response

- Responses to be based on the availability of PPE and how long the supplies would last if the facility were operating at a conventional level.

Justification

- NHSN data about PPE and supplies are leveraged to evaluate supply needs and to direct resources where needed to return to operating at conventional capacity.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html

Reporting Total Deaths and COVID-19 Deaths

Question

- How long after a resident is discharged or transferred to another facility do I report a death?

Response

- If a resident is discharged from the reporting facility COVID-19 free and is documented as “non-expected” to return, surveillance stops at discharge
- If a resident is transferred to another facility with COVID-19, a subsequent death must be counted
- If a resident is transferred to another facility with “expected return,” a subsequent death must be counted

Resources: 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**
  - https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-ifc-cms-3401-ifc-additional-policy-and-regulatory-revisions-response-covid-19

- **Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by (CLIA) of 1988 Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency**
  - https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-ifc-cms-3401-ifc-updating-requirements-reporting-sars-cov-2-test-results-clia

- **Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/ Nursing Homes**
  - https://www.cms.gov/files/document/covid-faqs-snf-testing.pdf

Resources: CMS

- **COVID-19 Nursing Home Search Data**
  - https://www.medicare.gov/NursingHomeCompare/search.html
- **CMS Policy & Memos to States and Regions**
  - https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions
- **CMS-CDC Fundamentals of COVID-19 Prevention for Nursing Home Management (training opportunities)**
  - https://qioprogram.org/cms-cdc-fundamentals-covid-19-prevention-nursing-home-management
- **FDA -Coronavirus Testing Basics**
  - https://www.fda.gov/media/140161/download

Resources

- **Coronavirus Disease 2019 (COVID-19) 2020 Interim Case Definition, Approved August 5, 2020**
  - https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/08/05/

- **Considerations for Interpreting Antigen Test Results in Nursing Homes**
  - https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf

- **Interim Guidance for Rapid Antigen Testing for SARS-CoV-2**
  - https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html