

UPDATE: Guidance for Reporting Point of Care SARS-CoV-2 Test Results

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TO:	Health Alert Network
FROM:	Keara Klinepeter, Acting Secretary of Health
SUBJECT:	UPDATE: Guidance on Reporting Point of Care SARS-CoV-2 Test Results
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This transmission is a “Health Update” provides updated information regarding an incident or situation; unlikely to require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; **EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

- The U.S. Food and Drug Administration (FDA) has issued [Emergency Use Authorizations \(EUA\)](#) for a number of COVID-19 point of care (POC) tests for rapid detection of SARS-CoV-2.
- These POC tests may be used by both traditional healthcare providers (e.g., hospitals, outpatient providers) and by non-traditional settings who have appropriate Clinical Laboratory Improvement Amendments (CLIA) Certificate to conduct this testing.
- [HAN 633](#) outlines guidance for reporting results of SARS-CoV-2 test results to the Pennsylvania Department of Health (DOH).
- On April 4, 2022, the U.S. Department of Health & Human Services (HHS) updated its [reporting guidance](#) to indicate that CMS-certified long-term care facilities are not required but recommended to use the National Healthcare Safety Network (NHSN) to fulfill POC test reporting. Additional information regarding this process is detailed in this message.
- This message will provide additional guidance on mechanisms used for POC reporting.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) CERTIFICATE

Any entity utilizing Point-of-Care (POC) tests for COVID-19 must have a Pennsylvania laboratory permit and a Clinical Laboratory Improvement Amendments (CLIA) Certificate. If you already have a Pennsylvania laboratory permit and CLIA Certificate, you must also ensure that COVID-19 is listed in your test menu. Please see [Understanding Clinical Laboratory Regulation in Pennsylvania](#) for more information. If you have questions about laboratory permits or CLIA certification, please notify RA-DHPACLIA@pa.gov to assure laboratory compliance.

REPORTING

CMS-certified Long-Term Care Facilities

On October 15, 2020, the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) added a Point-of-Care (POC) Laboratory Reporting Tool within the NHSN Long-Term Care Facility COVID-19 Module. This capability offers Centers for Medicare & Medicaid Services (CMS)-certified long-term care (LTC) facilities to comply with COVID-19 data reporting recommendations.

On April 4, 2022, the U.S. Department of Health & Human Services (HHS) updated its reporting guidance to indicate that CMS-certified long-term care facilities are **recommended** to use NHSN to meet this reporting requirement. Specifically, the new [HHS guidance](#) states:

Centers for Medicare & Medicaid Services (CMS)-certified long-term care (LTC) facilities **may** submit point-of-care SARS-CoV-2 testing data, including antigen testing data, to CDC's National Healthcare Safety Network (NHSN). This CDC- and **CMS-preferred pathway** to submit data to CDC's NHSN applies only to CMS-certified LTC facilities. Test data submitted to NHSN will be reported to appropriate [state, tribal, local, or territorial (STLT)] health departments using standard electronic laboratory messages. Other types of LTC facilities may also report testing data in NHSN for self-tracking or to fulfill STLT reporting requirements, if any.

In order to utilize this tool to report POC test results to NHSN, (LTC) NHSN users will need to upgrade their NHSN Secure Access Management Service (SAMS) from Level 1 to Level 3. If current NHSN users need assistance in obtaining Level 3 access, please contact NHSN@cdc.gov and include in the subject line, "**Enhancing Data Security.**"

Forms, instructions, instructions to upload CSV (comma-separated value) files, and an instructional video on the NHSN POC test reporting module can be found at: <https://www.cdc.gov/nhsn/ltc/covid19/index.html>. Questions about the NHSN POC reporting tool can be sent to NHSN@cdc.gov and include in the subject line, "**POC test reporting.**"

NHSN will submit individual POC test results from the POC test reporting tool to Pennsylvania's National Electronic Disease Surveillance System (PA-NEDSS). This means facilities using the NHSN POC reporting module do not need to report POC test result data directly into PA-NEDSS. Only facilities with NHSN users who have been upgraded to SAMS level 3 access can stop reporting results to PA-NEDSS. Until NHSN access is granted and POC reporting begins, facilities must enter required POC COVID test results into PA-NEDSS as outlined in [HAN 633](#). Note that HAN 633 states that LTC facilities that perform testing on-site using rapid antigen tests or other POC devices should not report individual negative antigen or negative POC PCR test results, either directly to PA-NEDSS or through NHSN. All individual-level positive COVID test results must still be reported.

Entities utilizing external commercial laboratories should continue to ensure that these laboratories report those test results on their behalf to PA-NEDSS. If it is determined that a laboratory is not reporting results, it is the facility's responsibility to ensure these test results are entered into PA-NEDSS.

All other reporters

[HAN 633](#) outlines guidance for reporting requirements for SARS-CoV-2 test results to the Pennsylvania Department of Health (DOH). A summary of information from this HAN is below.

- Nucleic Acid Amplification Test (NAAT) (e.g., RT-PCR, TMA, etc.) test performed in a lab setting need to be reported regardless of result (i.e., positive, negative, inconclusive, indeterminate).
- Antibody tests (e.g., AB, IgM, IgG, IgA) regardless of results no longer need to be reported.
- Only positive results from antigen tests (e.g., rapid test, lateral flow test, etc.) need to be reported.
- Only positive results from any point-of-care (POC) test, i.e., any COVID-19 diagnostic test performed on-site at a CLIA-waived facility, such as a nursing home need to be reported. This includes POC PCR tests (Abbott ID NOW).

NHSN

Some other non-CMS-certified LTC facilities have access to and report other COVID data to NHSN. These facilities can also report POC test results via NHSN to PA-NEDSS. As described above, NHSN users in these facilities will need to acquire SAMS Level 3 access through CDC to report POC COVID test results. Facilities wishing to use this mechanism can follow the same instructions provided [above](#).

PA-NEDSS

All other reporters who are not reporting via NHSN must request a PA-NEDSS account if they do not already have one to begin the reporting process. This can be done by completing a [Prime Contact Information Form](#) and sending this form to PA-NEDSS@pa.gov. Once access has been established with PA-NEDSS, a facility can opt to report in one of the following ways.

- Once access has been established with PA-NEDSS, reporters MUST enter individual patient test results into PA-NEDSS manually. Instructions for reporting POC test results and an accompanying FAQ to assist reporters with this entry can be found at the following:
 - [PA-NEDSS Manual Test Reporting Instructions for Point of Care \(POC\) Tests](#)
 - [Reporting FAQs](#)
- A reporter can request the option to upload all results in a CSV file created from an Excel file format template. In order to report through this method, a PA-NEDSS user must request access to the Excel template by sending an email to RA-DHNEEDSS@pa.gov. It should be noted that this process to report via CSV requires the reporter to complete a test message review process before permission is granted to upload to production PA-NEDSS. It should also be noted that the review process can take some time. **All reporters MUST manually enter data into PA-NEDSS until they are formally approved to begin submitting CSV files.**

If an individual is tested on multiple platforms (e.g., antigen and PCR), results from both platforms must be recorded in PA-NEDSS. For example, if a positive antigen test is followed by

a positive PCR, both results must be recorded in PA-NEDSS. This information is applicable to NHSN and PA-NEDSS users.

As a reminder, entities utilizing external commercial laboratories for testing should continue to ensure that these laboratories report those test results on their behalf to PA-NEDSS. If it is determined that a laboratory is not reporting results, it is the facility's responsibility to ensure these test results are entered into PA-NEDSS.

Additional information about the use of antigen tests and factors that should be considered in the interpretation of their results can be found in [HAN-605](#).

If you have questions about this guidance, please call your local health department or **1-877-PA-HEALTH (1-877-724-3258)**.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of April 12, 2022 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.