PENNSYLVANIA DEPARTMENT OF HEALTH
2020 – PAHAN – 534-10-30-UPD

This document has been archived. Please refer to PA-HAN-633 for updated information on the topic.

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

DATE:	10/30/2020
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	**UPDATE: Guidance on Reporting Point of Care SARS-CoV-2 Test Results**
DISTRIBUTION:	Statewide
LOCATION:	n/a
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MUNICIPALITY:	n/a
ZIP CODE:	n/a

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 CLIA Certificate to conduct this testing.
- All entities conducting these POC tests are required to report these results, including positive, negative, and inconclusive/indeterminate, to public health authorities through PA-NEDSS.
- On October 19, 2020, HHS updated its reporting guidance to indicate that CMS-certified long-term care facilities are required to use National Healthcare Safety Network (NHSN) to fulfill POC test reporting. Additional information regarding this process are detailed in this message.
- Several mechanisms have been established for facilities not required to report via NHSN which will ensure reporters are compliant in providing the results of POC tests. Information regarding these reporting mechanisms are detailed in the message below.

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 added capability enables Centers for Medicare & Medicaid Services (CMS)-certified long-term care facilities to meet the Department of Health and Human Services' (HHS) requirement to report SARS-CoV-2 point-of-care antigen test data and other on-site COVID-19 laboratory testing data reporting requirements.

On October 19, 2020, HHS updated its reporting guidance to indicate that CMS-certified long-term care facilities are required to use NHSN to meet this reporting requirement. Specifically, the HHS guidance states that:

> *"CMS-certified long-term care facilities shall submit point-of-care SARS-CoV-2 testing data, including antigen testing data, to CDC's National Healthcare Safety Network (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 long-term care facilities may voluntarily report testing data in NHSN for self-tracking or to fulfill state or local reporting requirements, if any."*

In order to utilize the new tool to fulfill reporting requirements, long-term care facilities will need to upgrade their NHSN Secure Access Management Service (SAMS) from Level 1 to Level 3. Facilities have likely already been contacted by CDC to complete this enrollment but if facilities need assistance in obtaining Level 3 access, please contact NHSN@cdc.gov and include in the subject line, **"Enhancing Data Security."**

Information including upcoming training on the NHSN 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 reported POC test result data from facilities to 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 who have been upgraded to SAMS level 3 access and are currently reporting data into NHSN can stop reporting results to PA-NEDSS. Until NHSN access is granted and POC reporting begins, facilities must enter test results into PA-NEDSS.

It should be noted that if facilities are performing other types of tests (e.g., PCR) in-house, these individual test results should not be reported into NHSN and must be submitted to PA-NEDSS as outlined below. 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

All entities conducting testing to identify SARS-CoV-2, the virus that causes COVID-19, are required to report positive, inconclusive/indeterminate, and negative results to PA-NEDSS within 24 hours of test completion. PA-NEDSS is a secure, web-based system used in Pennsylvania for disease reporting and surveillance. There are a number of mechanisms that have been established to ensure reporters can be compliant in providing the results of POC tests. These mechanisms are outlined below.

NHSN

Some long-term care facilities are not required to report POC test results into NHSN as described above but have access and report other information via NHSN. These facilities can also report POC tests via NHSN to fulfill reporting requirements into PA-NEDSS. As described above, facilities will need to acquire SAMS Level 3 access through CDC in order to report POC testing. Facilities wishing to use this mechanism to fulfill their reporting requirements 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 point of care 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 (comma-separated value) 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-DHNEDSS@pa.gov. It should be noted that this process to report via CSV requires the facility 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 regardless of the result. For example, if a positive antigen test is followed by a negative PCR, both results must be recorded in PA-NEDSS. 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-532.

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 October 30, 2020 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.