pennsylvania
DEPARTMENT OF HEALTH

January 6, 2021

Providing Demographic Variables as Part of Laboratory Submission Forms

Frequently Asked Questions

Q: Does a clinical laboratory performing COVID-19 testing need to report COVID-19 test results with demographic variables to public health authorities?
A: Clinical laboratories are required to report to state and local public health authorities in accordance with 28 Pa. Code § 27.22, "Reporting of cases by clinical laboratories." Clinical laboratories are mandated to report the name, age, address, telephone number, and other information requested by the Pennsylvania Department of Health regarding the person from whom the specimen was obtained. See 28 Pa. Code § 27.22(c)(1), (8). Race and ethnicity are information requested by the Department. Modifying the laboratory information system and specimen submission forms to include these variables is strongly encouraged.

Additionally, 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 notify the Department of your intent to implement COVID-19 testing to ensure that COVID-19 is added to the list of tests that you are approved to perform.

Please see Understanding Clinical Laboratory Regulation in Pennsylvania for more information about requirements for laboraties in Pennsylvania. If you have questions about laboratory permits or CLIA certification, please notify RA-DHPACLIA@pa.gov.

Q: Does a health care provider performing COVID-19 testing need to report COVID-19 test results with demographic variables to public health authorities?
A: Providers should always include patient name, date of birth, address, telephone number, and race and ethnicity information when completing the laboratory submission/requisition form for patients. Laboratories are unable to report this information unless they receive it with submitted specimens.

Additionally, any entity utilizing Point-of-Care (POC) tests for COVID-19 must have a Pennsylvania laboratory permit and a CLIA Certificate. If you already have a Pennsylvania laboratory permit and CLIA Certificate, you must notify the Department of your intent to implement COVID-19 testing to ensure that COVID-19 is added to the list of tests that you are approved to perform.

Please see Understanding Clinical Laboratory Regulation in Pennsylvania for more information about requirements for laboraties in Pennsylvania. If you have questions about laboratory permits or CLIA certification, please notify RA-DHPACLIA@pa.gov.

Q: Why is it necessary for health care providers and laboratories to report these variables?
A: These variables are essential for a complete and timely public health response to patients with COVID-19 and other reportable diseases. This reporting is important to protect the public's health; for

example, comprehensive laboratory testing data can contribute to understanding disease incidence and trends, inform mitigation and control activities, and understand health disparities across the Commonwealth.

Q: How does the Pennsylvania Department of Health use these variables once reported?
A: The Department uses these demographic fields to assign cases to the correct jurisdiction and to timely initiate case investigations so that public health response can happen in the appropriate time frame. This information is also necessary to understand health disparities across the Commonwealth and to guide resource needs and allocation.

Q: What should a health care provider do if unable to capture all the requested information on laboratory submission/requisition forms?
A: A health care provider should always include patient name, date of birth, address, telephone number, and race and ethnicity information when completing the laboratory submission/requisition form for patients. If this information is not included on the laboratory submission/requisition form, the ordering facility should enter these demographic elements into PA-NEDSS as mandated under 28 Pa. Code §27.21(a). Health care providers performing POC tests are reminded to follow reporting guidance outlined in PA HAN 534. The PA-NEDSS Manual Test Reporting Instructions for COVID Tests and PA-NEDSS Manual Reporting FAQs can be found in PA HAN 534.

Clinical laboratories are required under 28 Pa. Code § 27.22(c) to report the name, age, address, and telephone number from whom the specimen was obtained. They are unable to comply with this requirement if they do not receive the information from the providers submitting specimens.

Q: What is the process for a health care provider and clinical laboratory to report these variables through electronic laboratory reporting (ELR)?
A: A clinical laboratory reporting via ELR should report race data in PID-10 and ethnicity data in PID-22 as per Health Level Seven (HL7) version 2.5.1 guidelines. A clinical laboratory using manual entry into PA-NEDSS should include this information in the appropriate short form sections.