

**PENNSYLVANIA DEPARTMENT OF HEALTH**

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**Reporting of all CD4 T-lymphocyte, Viral Load, and Genotyping Test Results Associated with HIV Infection are now Mandatory in Pennsylvania**

<b>DATE:</b>	<b>December 8, 2020</b>
<b>TO:</b>	Health Alert Network
<b>FROM:</b>	Rachel Levine, MD, Secretary of Health
<b>SUBJECT:</b>	<b>Reporting of All CD4 T-lymphocyte, Viral Load, and Genotyping Test Results Associated with HIV Infection are now Mandatory in Pennsylvania</b>
<b>DISTRIBUTION:</b>	Statewide
<b>LOCATION:</b>	Statewide
<b>STREET ADDRESS:</b>	n/a
<b>COUNTY:</b>	n/a
<b>MUNICIPALITY:</b>	n/a
<b>ZIP CODE:</b>	n/a

**This transmission is a “Health Advisory” provides important information for a specific incident or situation; may not require immediate action.**

**HOSPITALS:** PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, 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**

On October 31, 2020, an amendment to the Pennsylvania HIV reporting regulations was published in the Pennsylvania Bulletin to mandate the reporting of all CD4 T-lymphocyte, viral load, genotyping test results that are associated with HIV infection to the Pennsylvania Department of Health (Department). **This amendment is effective immediately.**

HIV infections continue to be a major public health crisis. Since 1981, more than 62,600 residents of Pa. have been diagnosed with HIV disease. Approximately 27,000 of these persons have died, and an estimated 36,000 are currently living with the disease. The estimated number of persons living with HIV has increased each year on average by approximately 1,000 persons. CDC also reports that one in seven people living with HIV does not know their HIV status.

The Department added HIV infection to the list of reportable diseases and conditions in the Commonwealth in 2002. As part of those reporting requirements, the Department required the reporting of CD4 T-lymphocyte test results with a count of less than 200 cells/ $\mu$ L or a CD4 T-lymphocyte percentage of less than 14% of total lymphocytes as well as detectable viral load test results. The incomplete reporting of key laboratory markers of HIV infection, such as CD4 t-lymphocyte, viral load, and genotyping test, has hampered the Department’s ability to adequately measure the effectiveness of HIV prevention and care activities. To address this concern, the Department has amended these regulations to require the reporting of **all** CD4 T-lymphocyte, viral load, and genotyping test results relating to HIV infection. This regulatory amendment will help to ensure persons living with HIV are engaged in medical care and virally suppressed, facilitate the

monitoring of the HIV epidemic, and bring HIV reporting in the Commonwealth in line with national standards.

### **Reporting:**

- Health care practitioners and laboratories are required to report any test results associated with HIV infection (as described below) to the Department through the Pennsylvania National Electronic Disease Surveillance System (PA-NEDSS) online application at: <https://www.nedss.state.pa.us>.
- The report shall be made within **5 workdays** of obtaining the test results.

### **Reporting by clinical laboratories:**

A person in charge of a clinical laboratory shall report:

1. CD4 T-lymphocyte counts and percentages.
2. Positive test results of any test approved by the FDA to establish the presence of HIV, including a serologic, virologic, nucleic acid (DNA or RNA) or any other type of test the FDA approves to establish the presence of HIV.
3. HIV viral load test results, including detectable and undetectable viral load results, and HIV genotyping results.

The above shall be reported to the Department's electronic disease surveillance system within 5 workdays of obtaining the test results.

The report shall include the following information:

- (i) The individual's name and the address, city, county, and zip code of the individual's residence.
- (ii) The patient identifying number assigned to the individual by the physician or at the facility requesting the laboratory test.

### **Reporting by health care practitioners, hospitals, and other persons or entities:**

A health care practitioner, hospital, person providing HIV services or person in charge of an entity providing HIV services, who makes a diagnosis of AIDS or who receives HIV test results, CD4 T-lymphocyte counts and percentages, HIV viral load test results, including detectable and undetectable results, or HIV genotyping test results shall report the case through the PA-NEDSS within 5 workdays of the diagnosis of AIDS or the receipt of the results of the test.

### **Testing for HIV:**

With these newly established amendments for reporting of testing results, the Department would like to take the opportunity to remind clinicians of current HIV testing recommendations.

- CDC recommends that individuals between the ages of 13 and 64 be tested for HIV at least once as part of routine health care and those with risk factors get tested more frequently. A general rule for those with risk factors is to get tested at least annually.

- CDC has issued specific guidance for HIV screening for gay, bisexual and other men who have sex with men (MSM). CDC recommends that clinicians screen asymptomatic sexually active MSM at least annually. Clinicians should consider the benefits of more frequent screening (e.g. once every 3 or 6 months) for individual MSM at increased risk for HIV Infection.
- Additional information regarding HIV testing can be found at the following link:  
<https://www.cdc.gov/hiv/clinicians/screening/clinical-settings.html>

Questions or comments about the amended regulations can be directed to the Pennsylvania Department of Health HIV Surveillance & Epidemiology Program at 717-787-3350. Information about the full amendment can be obtained at the following link:

<https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol50/50-44/1487.html>.

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 December 8, 2020 but may be modified in the future.
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