



CITY OF PHILADELPHIA
DEPARTMENT OF PUBLIC HEALTH

PASSED:

BOARD OF HEALTH: _____

LAW DEPARTMENT: _____

RECORDS DEPARTMENT: _____

**AMENDMENTS TO REGULATIONS
GOVERNING THE CONTROL OF COMMUNICABLE
AND NONCOMMUNICABLE DISEASES AND CONDITIONS**

WHEREAS, Section 6-201 of the Health Code of Philadelphia authorizes the Board of Health to establish lists of reportable diseases and conditions, and

WHEREAS, Section 6-202 of the Health Code requires health care providers and laboratories identifying these reportable diseases and conditions designated by the Board, to report the occurrence of such diseases and conditions to the Department;

WHEREAS, The Philadelphia Board of Health has adopted *Regulations Governing the Control of Communicable and Non-communicable Diseases and Conditions* (“Regulations”);

WHEREAS, The Regulations contain a listing of such diseases and the methods of reporting the occurrence thereof in Sections 2, 3 and 10 of said Regulations; and

WHEREAS, The Philadelphia Department of Public Health is the local reporting authority for the City of Philadelphia; and

WHEREAS, HIV testing technology is rapidly evolving; and

WHEREAS, HIV drug resistance testing now includes integrase inhibitor testing; and

WHEREAS, HIV can be transmitted perinatally from mother to infant and clinical interventions during pregnancy are critical to minimize transmission risk; and

WHEREAS, The highly infectious phase of acute HIV contributes disproportionately to HIV transmission; and

WHEREAS, Access to medical records is essential to investigations of reported HIV test results that indicate that the presence of HIV infection is confirmed, probable, or possible (indeterminate);

NOW, THEREFORE, the Board of Health hereby amends the *Regulations Governing the Control of Communicable and Noncommunicable Diseases and Conditions* to read as follows (additions in **Bold** and deletions in ~~Strikethrough~~):

REGULATIONS GOVERNING THE CONTROL OF COMMUNICABLE
AND NONCOMMUNICABLE DISEASES AND CONDITIONS

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2. REPORTABLE DISEASES AND CONDITIONS

The Board declares the following diseases, unusual outbreaks of illness, noncommunicable diseases and conditions, poisonings and occupational diseases to be reportable:

(a) Diseases

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() Human Immunodeficiency Virus (HIV) Infection and certain conditions indicative of HIV, as detailed below. HIV infection is a clinical condition defined by the federal Centers for Disease Control and Prevention (CDC) **for the purpose of reporting it to public health agencies, such as the Philadelphia Department of Public Health (PDPH). For PDPH to monitor this important public health problem, certain laboratory test results or exposures** must be reported because they indicate definite HIV infection ~~eases, or indicate~~ probable HIV ~~eases~~ **infection, or possible HIV infection (an uncertain diagnostic HIV status)** that needs to be confirmed by follow-up health-department investigations. Both healthcare providers and laboratories must report HIV ~~test results~~ **eases. This includes non-clinical testing venues or “points of care” (POC), where CLIA-waived rapid testing may be performed. (“CLIA” refers to the Clinical Laboratory Improvement Amendments to federal regulatory standards for all clinical laboratory testing performed on humans in the United States, except for clinical trials and basic research). Healthcare providers and laboratories must**

also report perinatal exposures to HIV among children, and pregnancies among HIV-infected women. These reporting requirements apply to HIV tests for Philadelphia residents (regardless of where the laboratory or healthcare provider was located) and to persons whose HIV tests were ordered by a Philadelphia-based healthcare provider (regardless of where the patient resided or the laboratory was located). These conditions include the following:

(A) Reportable results (by healthcare providers and laboratories unless otherwise indicated)

1. By healthcare providers:

1. ~~Positive~~All results (including negative [nonreactive] and indeterminate results, as well as positive [reactive] results) of all tests used to diagnose or screen for HIV infection as part of an HIV testing algorithm that is approved by the CDC, the Association of Public Health Laboratories, the Clinical and Laboratory Standards Institute, or the Food and Drug Administration to establish the presence of HIV [including:

if the patient is determined to have either:

- Confirmed HIV infection (with a positive final test result of the diagnostic) ~~be HIV positive by the algorithm or tests, including~~
- Or
- Probable or possible HIV infection (an uncertain diagnostic status with a positive preliminary test results ~~if~~ but no result from a supplemental/confirmatory test that is needed to confirm the diagnosis was performed or a with a negative supplemental antibody test result that requires additional testing with a nucleic acid test [viral load or qualitative] to resolve the contradiction between prior positive and negative antibody test results). These reportable test results do not include those from which the patient was determined not to have HIV infection (with either a negative initial test result or a negative final test result that does not require additional testing for further confirmation of the absence of HIV infection).

The types of tests to which this regulation pertains include the following:

- serologic tests (antibody tests of any type, regardless of whether used as a preliminary/screening test or a supplemental/confirmatory test) and
- virologic tests (antigen tests or nucleic acid tests [NAT or nucleic acid amplification tests, including DNA or RNA qualitative or quantitative tests, such as viral loads, including those with undetectable results]) or
- any other type of test (e.g., **combination antigen/antibody tests**) used to **diagnose or screen for** ~~establish the presence of~~ HIV infection

2. Positive (reactive) results of all tests for HIV infection, including detectable viral loads, and negative (non-reactive) or indeterminate results of all tests for HIV infection within 180 days of (before, after, or on the same date as) the patient’s first positive HIV test result (excluding known false-positive results) shall be reported. The test dates refer to the dates of specimen collection. These include tests used alone or as part of an HIV testing algorithm (including initial or preliminary tests in the algorithm) approved by the Food and Drug Administration or validated according to CLIA regulations. The negative/indeterminate test results are needed to recognize infections that are early or acute (when transmission to others is more likely, and intervention is more urgent).

- ~~• serologic tests (antibody tests of any type, regardless of whether used as a preliminary/screening test or a supplemental/confirmatory test) and~~
- ~~• any other type of test to establish the presence of HIV,~~

~~used alone or as part of an HIV testing algorithm (including preliminary results) that is approved by the CDC, the Association of Public Health Laboratories, the Clinical and Laboratory Standards Institute, or the Food and Drug Administration;~~

3. Virologic tests (antigen tests or nucleic acid tests [NAT or nucleic acid amplification tests, including DNA or RNA qualitative or quantitative tests, such as viral loads, including those with negative or undetectable results]);

4. (Laboratory only) If an HIV genotype is performed, the ~~fasta~~ **FASTA or FASTQ** files (standard text-based format) containing the nucleotide sequence data, including the protease and reverse transcriptase regions **and, if available, the integrase region**, shall be reported;

5. All CD4 T-lymphocyte test results;

6. (Laboratory Only) Each laboratory that reports a confirmed positive HIV test result in persons 13 years of age or older must also report an HIV recency test result, if available. Special requirements for the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS):-

~~1. Each laboratory that reports a confirmed positive HIV test in persons 13 years of age and older must also report a STARHS test result.~~

~~2. In lieu of producing this test result, each laboratory that reports a confirmed positive HIV test must submit a sample for additional testing using STARHS. The laboratory is permitted to send the remaining blood specimen or an aliquot of at least 0.5 ml if available to the Philadelphia Department of Health, in a manner, timeframe, and to a location as specified by the AIDS Activities Coordinating Office.~~

~~3. Nationally based laboratories with an existing contract to ship specimens directly to a STARHS laboratory designated by CDC will not be required to send a specimen to the Philadelphia Department of Public Health.~~

~~4. Exemptions for submission of specimens for STARHS testing may be requested from the Philadelphia Health Commissioner's Office.~~

7. A perinatal exposure of a newborn to HIV:

- a. Birth of an infant to a woman with HIV infection (even if the infant is not known to have HIV infection)**
- b. Pregnancy in a woman with HIV infection (including pregnancies prior to birth).**

(B) Timing of Reporting

All test results and HIV case reports shall be reported to the PDPH within 5 business days of receipt of the results with two exceptions:

- 1. Confirmed or suspected acute HIV infections shall be reported within 1 business day by telephone to the PDPH;**
- 2. Pregnancy in an HIV infected woman and all perinatal exposures shall be reported within 1 business day by telephone to the PDPH.**

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10. REGULATIONS PERTAINING TO THE CONTROL OF THE INFECTED INDIVIDUALS, CONTACTS, AND ENVIRONMENT FOR EACH REPORTABLE DISEASE

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() Human Immunodeficiency Virus (HIV) Infection

(1) Reporting. Report HIV, as defined in subsection 2 of these Regulations, to the Philadelphia Department of Public Health, AIDS Activities Coordinating Office, using the standard HIV/AIDS confidential case report form CDC 50.42A (or current version) for adult cases and CDC 50.42B (or current version) for pediatric cases and perinatal exposures. **The PDPH will have access to and may review the patient medical records of physicians, hospitals, persons providing HIV services and persons in charge of entities providing HIV services, who make diagnoses of HIV, or who receive or provide any HIV test results. Access and review will enable the PDPH to conduct case investigations, to determine whether under-reporting is occurring, to investigate reporting delays and to investigate other reporting problems.**

(2) Isolation. Observe standard precautions for bloodborne pathogens.

(3) Concurrent disinfection. Environments contaminated with blood or infectious body fluids shall be disinfected.

(4) Terminal disinfection. Terminal disinfection shall consist of thorough cleaning.

(5) Quarantine. No quarantine is required.

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