



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, HIV Western Blot testing lacks seroconversion sensitivity when compared to the newer range of assays now available and published, approved new HIV testing algorithm guidelines do not utilize HIV Western Blot testing; and

WHEREAS, CD4 and viral load data can be used to identify cases, classify stage of disease at diagnosis, and monitor disease progression; and

WHEREAS, CD4 and viral load data can also be used to evaluate HIV testing and prevention efforts, determine entry into care and retention in care, measure viral load suppression, and assess unmet healthcare needs; and

WHEREAS, the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) used for HIV incidence surveillance has important public health implications for evaluating HIV intervention and prevention programs for effectiveness, for targeting prevention efforts associated with ongoing transmission, and for allocating resources to populations in greatest need of prevention efforts; and

WHEREAS, HIV drug resistance limits treatment options and reporting of genotypic resistance can monitor the prevalence of resistance.

NOW, THEREFORE, the Board of Health hereby amends the *Regulations Governing the Control of Communicable and Non-communicable 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. ~~Although HIV infection~~ **is a clinical condition defined by the federal Centers for Disease Control and Prevention (CDC). Certain laboratory test results or exposures indicators must be reported when they are definitively diagnosed because they indicate definite HIV infection cases or might indicate be probable HIV cases that need to be confirmed by follow-up health-department investigations. Both healthcare providers and laboratories must report HIV cases.** These conditions include the following:

(A) Reportable results

1. By healthcare providers:

Positive results of all tests used 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:

- **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 to establish the presence of HIV]**

if the patient is determined to be HIV positive by the algorithm or tests, including preliminary test results if no supplemental/confirmatory test was performed.

2. By Laboratories:

A positive result of any test ~~approved by the FDA~~ to establish the presence of HIV, including:

- **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 ~~serologic, virologic,~~ 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 ~~the FDA approves~~ 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; If an HIV genotype is performed, the fasta files (standard text-based format) containing the nucleotide sequence data, including the protease and reverse transcriptase regions shall be reported;

~~(B) A All CD4 T-lymphocyte test results with a count of less than 350 cells/ μ L or a CD4 T-lymphocyte percentage of less than 25% of total lymphocytes; or~~

~~(C) A perinatal exposure of a newborn to HIV.~~

(C) 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.

(D) A perinatal exposure of a newborn to HIV.

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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.

(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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