**FINAL AND PROPOSAL**

**FINAL AAP**

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**Title 10
MARYLAND DEPARTMENT OF HEALTH**

**Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)**

**10.18.02 HIV and CD4+ Investigations and Case Reporting**

Authority: Health-General Article, §§18-102, 18-103, 18-201.1, 18-202.1,
 18-205, and 18-207, Annotated Code of Maryland

**Notice of Final Action**

[20-045-F]

On April 28, 2020, the Secretary of Health adopted amendments to Regulations **.01—.03** and **.06—.09** under **COMAR 10.18.02 HIV and CD4+ Investigations and Case Reporting**. This action, which was proposed for adoption in 47:3 Md. R. 208—209 (January 31, 2020), has been adopted as proposed.

**Effective Date: May 18, 2020.**

ROBERT R. NEALL
Secretary of Health

**PROPOSAL**

**Maryland Register**

**Issue Date: January 31, 2020**

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**Subtitle 18 HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)**

**10.18.02 HIV and CD4+ Investigations and Case Reporting**

Authority: Health-General Article, §§18-102, 18-103, 18-201.1, 18-202.1,
18-205, and 18-207, Annotated Code of Maryland

**Notice of Proposed Action**

[20-045-P]

     The Secretary of Health proposes to amend Regulations **.01—.03** and **.06—.09** under **COMAR 10.18.02 HIV and CD4+ Investigations and Case Reporting**.

**Statement of Purpose**

The purpose of this action is to amend the chapter regarding HIV and CD4+ investigations and reporting. These changes are the result of a Regulatory Review and Evaluation Act (RREA) review of the chapter, in which the Department found that these regulations require:

(1) Clarifications about which tests shall be reported to the Department for HIV surveillance activities; and

(2) Updates to be consistent with technology developed since the adoption of the regulations in 2002.

**Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

**Estimate of Economic Impact**

The proposed action has no economic impact.

**Economic Impact on Small Businesses**

The proposed action has minimal or no economic impact on small businesses.

**Impact on Individuals with Disabilities**

The proposed action has no impact on individuals with disabilities.

**Opportunity for Public Comment**

Comments may be sent to Jake Whitaker, Acting Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through March 2, 2020. A public hearing has not been scheduled.

**.01 Scope.**

A. This chapter establishes the requirements for:

(1)—(2) (text unchanged)

**[**(3) Laboratory reporting of a test result for HIV infection or CD4+ count; and**]**

*(3) Laboratory reporting of a test result for:*

*(a) HIV detection;*

*(b) HIV viral load;*

*(c) CD4+ cell count or percentage; or*

*(d) HIV genotype sequence; and*

(4) Follow-up of:

(a)—(c) (text unchanged)

**[**(d) A laboratory’s report of HIV infection or CD4+ count.**]**

*(d) A laboratory’s report of a test result for:*

*(i) HIV detection;*

*(ii) HIV viral load;*

*(iii) CD4+ cell count or percentage; or*

*(iv) HIV genotype sequence infection or CD4+ count.*

B. Except as noted in §C **[**or D**]**of this regulation, this chapter applies to all instances of laboratory testing of specimens from a human body for **[**HIV infection or CD4+ count.**]***:*

*(1)  HIV detection;*

*(2) HIV viral load;*

*(3) CD4+ cell count or percentage; or*

*(4) HIV genotype sequence*.

C. This chapter does not apply if the specimen from a human body is:

**[**(1) Not tested for HIV infection or CD4+ count;**]**

*(1) Not tested for:*

*(a) HIV detection;*

*(b) HIV viral load;*

*(c) CD4+ cell count or percentage; or*

*(d) HIV genotype sequence;*

(2) Tested for HIV **[**infection**]***detection*solely for the purpose of determining the suitability of the source individual as a prospective donor of blood, semen, or tissue;

(3) (text unchanged)

(4) Tested for HIV **[**or CD4+ count**]***detection*as part of research conducted by an institution within Maryland under the following conditions:

(a)—(d) (text unchanged)

(5) Tested for HIV **[**or CD4+ count**]***detection*as part of research conducted under a research protocol approved by an institutional review board of an institution located outside of Maryland;

(6) (text unchanged)

(7) Tested for HIV **[**or CD4+ count**]** *detection* as part of a research project that has been approved under Regulation .02 of this chapter for an exemption.

**[**D. If the director of a medical laboratory has submitted one report of HIV infection from a patient as required under Regulation .06 of this chapter and another specimen from the same patient shows evidence of HIV infection, it is not necessary for the director to submit another report of HIV infection for the patient.**]**

**.02 Exemptions.**

A.—B. (text unchanged)

C. Approval.

(1) (text unchanged)

(2) If the application is complete and the research protocol meets the specified criteria, the Director shall grant an exemption from the requirements set forth in Regulation .06 of this chapter for any specimen tested for HIV **[**infection or CD4+ lymphocyte count**]** *detection*under the research project approved for exemption.

(3) (text unchanged)

D. Responsibilities of the Principal Investigator. If a research project is granted an exemption under §C of this regulation, the principal investigator of the research project shall send to each laboratory to which specimens collected under the research protocol will be sent to be tested for HIV **[**or CD4+ count**]***detection*a copy of the notification from the Director issued pursuant to §C(3)(a) of this regulation to verify that the project has been exempted from the reporting requirements of Regulation .06 of this chapter.

E. Scope of Exemption.

(1) (text unchanged)

(2) A principal investigator, laboratory director, or other individual is not required to report **[**positive**]** HIV *detection*test results**[**, CD4+ counts less than 200 per cubic millimeter, or both,**]** if the test is done as part of the research project and the individual tested:

(a)—(b) (text unchanged)

**.03 Definitions.**

A. (text unchanged)

B. Terms Defined.

(1)—(4) (text unchanged)

(5) “Clinical material” means:

(a)—(b) (text unchanged)

(c) If neither **[**§B(6)(a) or (b)**]** *§B(5)(a) nor §B(5)(b)*of this regulation is available, material from an individual already held by the medical laboratory, in the following order of preference:

(i)—(iii) (text unchanged)

(6)—(18) (text unchanged)

**.06 Responsibilities of Laboratory Directors.**

A. Except as provided in Regulations .01C and .02 of this chapter, the director of a medical laboratory shall:

(1) Submit a report to the health officer for the jurisdiction where the laboratory is located, within 48 hours after an examination of a specimen from a human body shows one of the following:

**[**(a) A positive result on a test designed to confirm in a sample the presence of HIV infection in accordance with Health-General Article, §18-207(b)(1), Annotated Code of Maryland;

(b) A test result showing a level of HIV viral load in an individual not known to be HIV negative; or

(c) A CD4+ count in an individual not known to be HIV negative;**]**

*(a) A result on a test designed to detect in a sample the presence of HIV in accordance with Health-General Article, §18-207(b)(1), Annotated Code of Maryland, including negative results;*

*(b) A quantitative or qualitative HIV viral load test result, including undetectable;*

*(c) A CD4+ cell test result, count, or percentage in an individual not known to be HIV negative; or*

*(d) An HIV genotype sequence test result;*

(2) (text unchanged)

(3) Include all of the following information in the report required under §A(1) of this regulation:

(a)—(b) (text unchanged)

**[**(c) Type and result of laboratory test, that is, HIV infection, HIV viral load, or CD4+ count;**]**

*(c) Type and result of laboratory test, that is, HIV detection, HIV viral load, CD4+ cell count or percentage, or HIV genotype sequence;*

(d)—(g) (text unchanged)

(4) (text unchanged)

B.—D. (text unchanged)

**.07 Out-of-State Laboratories.**

An out-of-State laboratory that holds a permit to operate issued by Maryland and performs HIV **[**or CD4+**]** *detection, HIV viral load, CD4+ cell count or percentage, or HIV genotype sequence*tests shall submit the report required under Regulation .06 of this chapter to the Secretary.

**.08 Responsibility of Health Officer.**

A. This regulation establishes requirements for follow-up by the health officer of a report of HIV or AIDS or newborn HIV exposure or laboratory report of HIV **[**infection or CD4+ count**]** *detection, HIV viral load, CD4+* *cell*count *or percentage, or HIV genotype sequence*.

B. This regulation does not supplant or otherwise modify the:

(1)—(2) (text unchanged)

(3) Laboratory director’s obligation to report a test result of HIV **[**infection or CD4+ count**]** *detection, HIV viral load,* *CD4+* *cell count* *or percentage, or HIV genotype sequence*under Health-General Article, §18-205, Annotated Code of Maryland, and Regulation .06 of this chapter.

C. Upon receipt of a report from a physician pursuant to Regulation .04 of this chapter, a clinical or infection control practitioner pursuant to Regulation .05 of this chapter, **[**or a laboratory director pursuant to Regulation .06 of this chapter,**]** the health officer shall:

(1) (text unchanged)

(2) Complete the case investigation if the patient has HIV or AIDS or is a newborn HIV exposure and the case of HIV or the case of AIDS or the newborn HIV exposure has not been reported previously; *and*

(3) Submit the HIV/AIDS case report as set forth in Health-General Article, 18-207, Annotated Code of Maryland, to the Department if the case of HIV or the case of AIDS or the newborn HIV exposure has not been reported previously**[**; and

(4) Take action as specified in COMAR 10.18.04**]**.

*D. Upon receipt of a test result report from a laboratory director pursuant to Regulation .06 of this chapter, the health officer shall:*

*(1) Determine whether the report matches to a case of HIV, a case of AIDS, or a newborn HIV exposure that has been reported previously, and submit the report to the Department if the report matches;*

*(2) Complete a case investigation if the report indicates the patient has HIV or AIDS or is a newborn HIV exposure and the case of HIV or the case of AIDS or the newborn HIV exposure has not been reported previously;*

*(3) Submit the case report, as set forth in Health-General Article, §18-207, Annotated Code of Maryland, to the Department if the case of HIV or the case of AIDS or the newborn HIV exposure has not been reported previously; and*

*(4) Retain a nonmatching report for up to 4 years, rematching the report, not less than annually, to test result reports and to cases of HIV or cases of AIDS or newborn HIV exposures that had not been reported previously, to identify new matches, and submit the report to the Department if the report matches.*

**[**D.**]** *E.*(text unchanged)

**.09 Record Maintenance and Confidentiality.**

A. (text unchanged)

B. Except for a designated anonymous HIV test site, a person that ordered the laboratory examination shall make available to the health officer or the Secretary the information necessary to compile an HIV/AIDS case report, according to Regulations .04 and .05 of this chapter, upon receipt of one of the following:

(1) A **[**positive result on a test designed to confirm**]** *result on a test designed to* *detect*in a sample the presence of HIV **[**infection**]** in accordance with Health-General Article, §18-207(b)(1), Annotated Code of Maryland*, including negative results*;

(2) **[**The report that an**]***A qualitative or quantitative*HIV viral load test **[**was performed on an individual not known to be HIV negative; or**]***result, including undetectable;*

(3) ACD4+ *cell test result,*count*, or percentage* **[**on**]** *in*an individual not known to be HIV negative**[**.**]***; or*

*(4) An HIV genotype sequence test result.*

C. (text unchanged)

ROBERT R. NEALL
Secretary of Health