



STATE OF NEW YORK  
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H., Dr. P.H.  
*Commissioner*

Dennis P. Whalen  
*Executive Deputy Commissioner*

August 1, 2003

Dear Laboratory Director:

This mailing is to bring your attention to pending **adoption** of an amendment to 10 NYCRR Subpart 58-8: **Human Immunodeficiency Virus Testing** (copy enclosed). The regulation becomes **effective August 13, 2003** upon Notice of Adoption published in the State Register. The new rule:

- eliminates the requirement for duplicate runs for diagnostic testing and allows use of the test manufacturer's algorithm across all applications of HIV testing. An algorithm with a single HIV antibody test as an initial step should be familiar to most laboratories because of its predicate application in HIV screening of insurance applicants; newborns in a labor and delivery setting; blood and organ donors; and persons with occupational exposure. NOTE: Regulated parties may, but are not required to, incorporate the testing algorithm change into their HIV testing procedures.
- deletes unnecessary and confusing distinctions arising from terminology such as "prognostic" and "other-than-diagnostic testing," and consolidates all testing for purposes of patient medical management under a single definition of "diagnostic testing," consistent with 10 NYCRR Section 63.4 reporting requirements for HIV tests;
- clarifies that the prohibition against using words such as "HIV" or "human immunodeficiency virus" in a bill, claim or invoice was never intended to apply where the recipient is a third-party payor, hospital or other entity with established confidentiality protocols;
- eliminates record-keeping and administrative requisites that do not directly contribute to testing quality. For example, the requirement that a laboratory submit its HIV testing standard operating procedure manual for Department approval has been eliminated; and
- modifies terminology for molecular testing technologies, i.e., viral load assays.

NOTE: The regulation retains the requirement for confirmatory testing of reactive specimens. It also continues to provide for release of preliminary (screen only) test results.

If you have questions concerning the new regulation, please feel free to contact Betty Kusel, Director, Regulatory Affairs Program, by e-mail to [kusel@wadsworth.org](mailto:kusel@wadsworth.org), or by telephone at 518- 485-5369.

Pursuant to the authority vested in the Commissioner of Health by Section 576 of the Public Health Law, Part 58 of 10NYCRR is amended, and is **effective August 13, 2003**, the date of publication of a Notice of Adoption in the New York State Register, as follows:

**SUBPART 58-8**  
**Human Immunodeficiency Virus (HIV) Testing**

**Sec.**

**58-8.1 Definitions**

**58-8.2 HIV testing and record keeping requirements**

**58-8.3 Confidentiality**

**58-8.4 HIV result reporting requirements**

**Section 58-8.1 Definitions.** For the purposes of this Subpart, unless the context indicates otherwise, the terms below shall have the following meanings:

- (a) Department means the New York State Department of Health.
- (b) Donor means a human being, living or dead, who is the source or potential source of a body, organ, tissue or fluid for transfusion, transplantation, transfer, artificial insemination or implantation.
- (c) FDA means the Food and Drug Administration of the United States Department of Health and Human Services.
- (d) HIV antibody screening means the performance of tests to detect HIV antibodies, which tests are not sufficiently specific to ensure definitive evidence of HIV infection.
- (e) HIV identification testing means the performance of tests to detect or characterize HIV or HIV viral components, including, but not limited to, HIV protein and HIV nucleic acid. HIV identification testing shall also include cultivation of the infectious virus.
- (f) HIV confirmatory testing means the performance of one or more supplemental tests to substantiate or refute results of HIV testing procedures that are not sufficiently specific to ensure definitive evidence of HIV infection.
- (g) HIV diagnostic testing means the performance of HIV tests for purposes of diagnosing, assessing or monitoring HIV infection in persons who may have been exposed to HIV, are at risk of exposure to HIV, or are known to be HIV-infected, but shall not include testing of donors. HIV testing of individuals in conjunction with an application for insurance shall be considered HIV diagnostic testing whenever test results are communicated to the applicant or his/her medical provider by the insurance company's medical director or a consulting physician or a physician under the medical director's supervision.
- (h) Preliminary finding of HIV infection means results of antibody screening that have been neither substantiated nor refuted by HIV confirmatory testing.

**58-8.2 HIV testing and record keeping requirements.** In addition to other applicable requirements in this Part, and Parts 52 and 63 of this Title, clinical laboratories, blood banks and tissue banks with a New York State clinical laboratory permit to perform HIV testing shall meet the following requirements:

(a) Specimens for testing patients, donors and insurance applicants shall be only of the type approved by the FDA or acceptable to the department for use with the particular method or test kit.

(b) All tests shall employ reagents, methods, techniques and procedures approved by the FDA or acceptable to the department in conformance with generally accepted laboratory principles.

(c) If the test result is to be communicated to the test subject or other person legally authorized to receive the result, results for specimens found reactive in accordance with the test manufacturer's interpretation of HIV antibody screening test results shall be confirmed with HIV confirmatory testing.

(d) Confirmatory testing shall be performed as soon as practicable in all cases when notification of a preliminary finding of HIV infection is made.

(e) A standard operating procedure manual (SOPM) shall be developed and maintained current, and shall include, in addition to documentation required elsewhere in this Part and Part 52 of this Title, algorithms for use of each HIV test method or test kit, and policies and processes for accepting specimens, reporting results, and ensuring compliance with confidentiality requirements and, as applicable, reporting requirements of Article 21, Title III and Article 27-F of the Public Health Law and New York State Insurance Law section 2611(c).

**58-8.3 Confidentiality.** Each clinical laboratory, blood bank, tissue bank or organ procurement organization performing, or causing the performance or receiving the results of HIV testing shall establish and implement procedures for confidentiality, disclosure and re-disclosure consistent with applicable federal and state law and regulations, including Article 27-F of the Public Health Law and New York State Insurance Law section 2611(c). No bill, claim for reimbursement or invoice issued by a clinical laboratory, blood or tissue bank or its agent shall disclose the nature of the service rendered to a named individual by using the acronym HIV, or the words human immunodeficiency virus or similar identifying words, unless disclosure is authorized by law and the intended recipient of the bill, claim or invoice is an entity subject to New York State or federal confidentiality, disclosure and re-disclosure requirements.

**58-8.4 HIV result reporting requirements.**

(a) No clinical laboratory shall notify a physician or other person legally authorized to receive the result that an HIV test is positive solely on the basis of HIV antibody screening, except that a clinical laboratory may report a preliminary finding of HIV infection pursuant to the written request of a physician or other person legally authorized to receive the test results. Results for specimens found non-reactive by HIV antibody screening may be reported to the physician who ordered the testing or other person legally authorized to receive the result.

(b) For HIV diagnostic testing, a report of preliminary finding of HIV infection shall prominently and clearly state that the finding is preliminary, that results of confirmatory testing will follow, and that such confirmatory results must be considered in making a diagnosis related to HIV infection.

(c) No blood, tissue or organ donor, or consenting next of kin shall be notified that an HIV test result is positive solely on the basis of HIV antibody screening.