by the Centers for Disease Control and Prevention of the United States Public Health Services in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Review (MMWR) published on December 18, 1992 and in Volume 43 No. RR-17 of the MMWR published on September 30, 1994 and updated in Volume 48 No. RR-13 of the MMWR published on December 10, 1999.

"Audit" means the review of medical records to determine the type and dates of services related to HIV infection provided by a health care provider, responsible party, or institution, and to verify compliance with this subchapter.

"CD4 count" means a count of lymphocytes containing the CD4 epitope as determined by the results of lymphocyte phenotyping.

1. An absolute CD4 count means the number of lymphocytes containing the CD4 epitope per cubic millimeter.

2. A relative CD4 count means the number of such cells expressed as a percentage of total lymphocytes.

"Division" means the Division of HIV/AIDS Services located in the Department.

"Epidemiologic investigations" means the review of medical records to determine disease progression, co-morbidities of other diseases with HIV or AIDS, treatments prescribed, laboratory test results, and other characteristics of individuals diagnosed with HIV infection or AIDS.

"Human Immunodeficiency Virus" or "HIV" means the virus that causes AIDS and that meets the case definition of HIV specified by the Centers for Disease Control and Prevention of the United States Public Health Services in Volume 41 No. RR-17 of the Morbidity and Mortality Weekly Review (MMWR) published on December 18, 1992 and in Volume 43 No. RR-17 of the MMWR published on September 30, 1994 and updated in Volume 48 No. RR-13 of the MMWR published on December 10, 1999.

"Institution" means a hospital, sanitarium, nursing home, correctional facility, clinic, blood bank, insurance company or facility for HIV counseling and testing.

"Laboratory HIV results" means clinical laboratory results showing the presence of HIV or components of HIV, or laboratory results showing the presence of antibodies to HIV, or results from viral load laboratory tests.

"Perinatally exposed" means that a child is born to a woman who is known to be HIV infected at the time of delivery, either through HIV testing prior to or during her pregnancy, or diagnosed by a health care provider.

"Responsible party" means the individual having control or supervision over any institution, such as a chief administrator.

New Rule, R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).

Former N.J.A.C. 8:57-2.3, Reporting children perinatally exposed to HIV, recodified to N.J.A.C. 8:57-2.6.

8:57-2.4 Reporting HIV Infection for health care providers and responsible parties

(a) A health care provider or responsible party for an institution providing services to an individual found to be infected with HIV, or ordering a test resulting in the diagnosis of HIV, shall, within 24 hours of receipt of a laboratory report indicating such a condition, or within 24 hours of making a diagnosis of HIV infection, report in writing to the Department using the Adult HIV/AIDS Confidential Case Report Form, available at subchapter Appendix A.

(b) A health care provider or responsible party testing individuals as part of the New Jersey HIV Counseling and Testing System and using the New Jersey Public Health and Environmental Laboratories shall, within 24 hours of receipt of a laboratory report indicating such a condition, report in writing such condition directly to the Department using the HIV Test Form, available at subchapter Appendix D.

i. The health care provider or responsible party shall use the Instructions for HIV Reporting using the HIV Test Form, available at subchapter Appendix E.

(c) A health care provider or responsible party, may delegate this reporting activity to a member of the staff, but this delegation does not relieve the health care provider or responsible party of the ultimate reporting responsibility.

(d) A health care provider or responsible party who provides medical services to an individual found to be infected with HIV, or orders tests resulting in the diagnosis of HIV, shall make the names of the individuals infected with HIV along with their medical records available to the Department for audit or epidemiologic investigation.

The following annotations apply to former N.J.A.C. 8:57-2.2 prior to its recodification as N.J.A.C. 8:57-2.4 and 2.5 by R.2009 d.107:

Amended by R.1991 d.516, effective October 21, 1991.
See: 23 N.J.R. 2089(a), 23 N.J.R. 3138(b).
Reporting of HIV results with identifiers required.
Amended by R.1992 d.215, effective May 18, 1992.
See: 23 N.J.R. 3735(a), 24 N.J.R. 1891(b).
Clinical labs to report results indicative of HIV within five working days.
Amended by R.2003 d.412, effective October 20, 2003.
See: 34 N.J.R. 3945(a), 35 N.J.R. 4883(b).
In (b), inserted "or other entity requiring HIV testing as part of underwriting process" in the first sentence.

The following annotation applies to N.J.A.C. 8:57-2.4 after its recodification from N.J.A.C. 8:57-2.2 by R.2009 d.107:

Recodified in part from N.J.A.C. 8:57-2.2 and amended by R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).
Section was "Reporting HIV Infection". Rewrote the section. Former N.J.A.C. 8:57-2.4, Reporting AIDS, recodified to N.J.A.C. 8:57-2.7 and N.J.A.C. 8:57-2.8.

Case Notes

Health care provider, who orders an HIV test for a patient, has a duty to take reasonable measures to notify that patient of the results of the

test. A health care provider who violates this duty becomes civilly liable to not only the patient but to all reasonably foreseeable individuals who contract the virus from the HIV positive patient. C.W. v. Cooper Health Sys., 388 N.J. Super. 42, 906 A.2d 440, 2006 N.J. Super. LEXIS 234 (App.Div. 2006).

8:57-2.5 Reporting HIV infection for clinical laboratories

(a) A clinical laboratory director shall, within five working days of completion of a quantitative HIV viral load test regardless of test result, or any other laboratory test, which has results indicative of infection with HIV, report in writing such results to the Department using one of the following two methods:

1. An electronic file in accordance with the Instructions for Electronic Submission of Laboratory Results Indicative of HIV Infection, available at subchapter Appendix G; or

2. The HIV/AIDS Laboratory Report Form (DHAS-43), available at subchapter Appendix B.

(b) The clinical laboratory director shall only report specimens sent to the clinical laboratory from a healthcare provider or institution located in New Jersey, or obtained from residents of New Jersey.

The following annotations apply to former N.J.A.C. 8:57-2.2 prior to its recodification as N.J.A.C. 8:57-2.4 and 2.5 by R.2009 d.107:

Amended by R.1991 d.516, effective October 21, 1991.
See: 23 N.J.R. 2089(a), 23 N.J.R. 3138(b).
Reporting of HIV results with identifiers required.
Amended by R.1992 d.215, effective May 18, 1992.
See: 23 N.J.R. 3735(a), 24 N.J.R. 1891(b).
Clinical labs to report results indicative of HIV within five working days.
Amended by R.2003 d.412, effective October 20, 2003.
See: 34 N.J.R. 3945(a), 35 N.J.R. 4883(b).
In (b), inserted "or other entity requiring HIV testing as part of underwriting process" in the first sentence.

The following annotation applies to N.J.A.C. 8:57-2.5 after its recodification from N.J.A.C. 8:57-2.2 by R.2009 d.107:

Recodified in part from N.J.A.C. 8:57-2.2 and amended by R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).
Section was "Reporting HIV Infection". Rewrote the section. Former N.J.A.C. 8:57-2.5, Testing procedures, recodified to N.J.A.C. 8:57-2.9.

8:57-2.6 Reporting children perinatally exposed to HIV

(a) A health care provider or responsible party for an institution providing care to a child known to be perinatally exposed to HIV, or ordering a test resulting in the diagnosis of perinatally exposed to HIV, shall, within 24 hours of receipt of a laboratory report indicating such a condition, report in writing such condition directly to the Department using the Pediatric HIV/AIDS Case Report Form (DHAS-45), available at subchapter Appendix C.

(b) The health care provider or responsible party of the institution may delegate this reporting activity to a member of the staff, but this delegation does not relieve the health care provider or responsible party of the ultimate reporting responsibility.

(c) A health care provider attending a child who was exposed perinatally to HIV or the responsible party at an institution in which any child is determined to have been perinatally exposed to HIV shall make the medical records of the mother and child available to the Department for audit or epidemiologic purposes.

Recodified from N.J.A.C. 8:57-2.3 and amended by R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).
Rewrote (a) and (b); and added (c). Former N.J.A.C. ***8:57-2.6, Exceptions*** to communicable disease classification of AIDS and HIV, repealed.

8:57-2.7 Reporting AIDS for health care providers and responsible parties

(a) A health care provider or responsible party for an institution providing services to an individual determined to be diagnosed with AIDS shall, within 24 hours of the time AIDS is diagnosed, report in writing such condition directly to the Department using the Adult HIV/AIDS Confidential Case Report Form (DHAS-44), available at subchapter Appendix A.

(b) The health care provider or responsible party may delegate this reporting activity to a member of the staff, but this delegation does not relieve the health care provider or responsible party of the ultimate reporting responsibility.

(c) A health care provider or responsible party shall complete the required report established at (a) above regardless of whether the patient previously had been reported as having HIV infection.

(d) The report of AIDS will be deemed to also be a report of HIV infection.

(e) A health care provider attending an individual found to be diagnosed with AIDS or the health care provider or responsible party at any institution shall make the names of the individuals diagnosed with AIDS along with their medical records available to the Department for audit or epidemiologic purposes.

Recodified in part from N.J.A.C. 8:57-2.4 and amended by R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).
Section was "Reporting AIDS". Rewrote the section; and recodified former (c) as N.J.A.C. 8:57-2.8. Former N.J.A.C. 8:57-2.7, Access to information, recodified to N.J.A.C. 8:57-2.11.

8:57-2.8 Reporting AIDS for Clinical Laboratories

(a) A clinical laboratory director shall, within five working days of completion of a CD4 count, which has absolute or relative results below a level specified by the Centers for Disease Control and Prevention as criteria for defining AIDS, report such results to the Department using one of the following methods:

1. An electronic file in accordance with the Instructions for Electronic Submission of Laboratory Results indicative of HIV infection, available in subchapter Appendix G; or

2. The HIV/AIDS Laboratory Report Form (DHAS-43), available in subchapter Appendix B.

(b) The clinical laboratory director shall only report specimens sent to the clinical laboratory from a health care provider or institution located in New Jersey, or obtained from residents of New Jersey.

Recodified in part from N.J.A.C. 8:57-2.4 and amended by R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).
Section was "Reporting AIDS". Recodified former (a) and (b) as N.J.A.C. 8:57-2.7; recodified former (c) as (a); rewrote (a); and added (b). Former N.J.A.C. 8:57-2.8, Failure to comply with reporting requirements, recodified to N.J.A.C. 8:57-2.12.

8:57-2.9 Testing procedures

(a) No health care provider or responsible party may direct a person to be tested for HIV, a component of HIV, or antibodies to HIV, unless the name and address of the person whose specimen is being tested is known and recorded by the health care provider or responsible party and provided to the testing laboratory, except that the Commissioner may designate facilities, which are permitted to test for antibodies to HIV without obtaining the name and address of the person being tested.

1. The Department does not require a health care provider or responsible party to report the name or address of any individual that requests testing at a facility designated by the Commissioner to test for HIV anonymously.

Recodified from N.J.A.C. 8:57-2.5 and amended by R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).
Inserted designation (a); substituted "health care provider or responsible party" for the first occurrence of "physician or institution" and "health care provider or responsible party and provided to the testing laboratory" for the second occurrence of "physician or institution"; deleted ", Department of Health and Senior Services" following "Commissioner"; inserted a comma following "facilities"; deleted the last sentence; and added (a)1.

8:57-2.10 Specimen submissions

(a) A health care provider, responsible party or clinical laboratory director shall, within one week of completion of a confirmatory diagnostic test indicative of HIV infection, send the residual specimen of such test to the State's Public Health and Environmental Laboratories (PHEL), except as noted in (b) below.

1. The specimen must contain identifying information so that the Department can link the specimen to the identifying information contained in the reports required at N.J.A.C. 8:57-2.5 and 2.8.

2. The specimen shall be sent in accordance with the Instructions for Submission of Positive HIV Diagnostic Specimens, available at subchapter Appendix F.

(b) A health care provider or responsible party shall not send a specimen to the PHEL if they obtained the specimen from an individual without identifying information at a facility designated by the Commissioner to test for HIV anonymously.

New Rule, R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).

8:57-2.11 Access to information

(a) The forms submitted to the Department pursuant to this subchapter contain demographic and medical information related to the Department's investigations and epidemiologic studies of HIV and AIDS and shall not be considered "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq. and shall be deemed:

1. "Information relating to medical . . . history, diagnosis, treatment, or evaluation" within the meaning of Executive Order 26, §4(b)1 (McGreevey, August 13, 2002);

2. "Records concerning morbidity, mortality and reportable diseases of named individuals required to be made, maintained or kept by any State or local governmental agency" within the meaning of Executive Order 9, §2(c) (Hughes, September 30, 1963); and/or

3. Information "for use in the field of forensic pathology or for use in medical or scientific education or research" pursuant to N.J.S.A. 47:1A-1.1.

(b) As provided by N.J.S.A. 26:4-2 and 26:5C-5 through 14, the information reported to the Department shall not be subject to public inspection, but shall be subject to access only by the Department for public health purposes.

(c) The Department may release data in summary format without identifying information in the form of reports and epidemiologic profiles.

Recodified from N.J.A.C. 8:57-2.7 and amended by R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).
Added (a) and (c); recodified the former undesignated text as (b); and in (b), deleted "of Health and Senior Services" following the second occurrence of "Department".

8:57-2.12 Failure to comply with reporting requirements

(a) The Department shall provide written notification to health care providers that fail to fulfill the reporting requirements of this subchapter.

1. Health care providers failing to meet these reporting requirements, despite warning, shall be subject to fines, as allowed by N.J.S.A. 26:4-129 and 1.30.

2. Health care providers shall be subject to other actions, including notification of the Board of Medical Examiners of the Department of Law and Public Safety,

and appropriate hospital medical directors or administrators.

(b) The Department shall provide written notification to the responsible party for an institution, who fails to fulfill the reporting obligations of this subchapter.

1. A responsible party failing to meet these reporting requirements, despite warning, shall be subject to a fine, as allowed by N.J.S.A. 26:4-129 and 1.30.

2. The responsible party shall be subject to other actions, including notification of the Department's Health Facilities Evaluation and Licensing Division, other appropriate licensing review organizations, and other appropriate agencies.

(c) The Department shall provide written notification to clinical laboratory directors that fail to fulfill the aforementioned reporting obligations.

1. Clinical laboratory directors failing to meet these requirements, despite warning, shall be subject to fines as allowed by N.J.S.A. 26:4-129 and 1.30.

2. The clinical laboratory director shall be subject to other actions, including notification of the Department's Clinical Laboratory Improvement Service.

Recodified from N.J.A.C. 8:57-2.8 and amended by R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).
Rewrote the section.

Column Starts	Column Ends	Field Length	Field Description	Required Field	Coding Information
601	635	35	Laboratory Street Address #1		
636	670	35	Laboratory Street Address #2		
671	705	35	Laboratory City		
706	707	2	Laboratory State		
708	717	10	Laboratory Zip Code		
718	767	50	Laboratory Contact Person	Yes	
768	768	1	Specimen Sent to Reference Lab	Yes	1=Yes, 2=No
769	793	25	Test Code #1	Yes	* See Below
794	818	25	Test Manufacturer #1	Yes	
819	827	9	Test Result #1	Yes	Pos, Neg, High, Low, Detected, Undetected
828	837	10	Test Value #1	Yes	Quantity if applicable
838	845	8	Date Specimen Collected #1	Yes	YYYYMMDD
846	853	8	Date Specimen Tested #1	Yes	YYYYMMDD
854	863	10	Type of Specimen #1	Yes	Blood, Saliva, Urine, Other, Unknown
864	888	25	Test Code #2	Yes, if done	* See Below
889	913	25	Test Manufacturer #2	Yes, if done	
914	922	9	Test Result #2	Yes, if done	Pos, Neg, High, Low, Detected, Undetected
923	932	10	Test Value #2	Yes, if done	Quantity if applicable
933	940	8	Date Specimen Collected #2	Yes, if done	YYYYMMDD
941	948	8	Date Specimen Tested #2	Yes, if done	YYYYMMDD
949	958	10	Type of Specimen #2	Yes, if done	Blood, Saliva, Urine, Other, Unknown
959	983	25	Test Code #3	Yes, if done	* See Below
984	1008	25	Test Manufacturer #3	Yes, if done	
1009	1017	9	Test Result #3	Yes, if done	Pos, Neg, High, Low, Detected, Undetected
1018	1027	10	Test Value #3	Yes, if done	Quantity if applicable
1028	1035	8	Date Specimen Collected #3	Yes, if done	YYYYMMDD
1036	1043	8	Date Specimen Tested #3	Yes, if done	YYYYMMDD
1044	1053	10	Type of Specimen #3	Yes, if done	Blood, Saliva, Urine, Other, Unknown
1054	1078	25	Test Code #4	Yes, if done	* See Below
1079	1103	25	Test Manufacturer #4	Yes, if done	
1104	1112	9	Test Result #4	Yes, if done	Pos, Neg, High, Low, Detected, Undetected
1113	1122	10	Test Value #4	Yes, if done	Quantity if applicable
1123	1130	8	Date Specimen Collected #4	Yes, if done	YYYYMMDD
1131	1138	8	Date Specimen Tested #4	Yes, if done	YYYYMMDD
1139	1148	10	Type of Specimen #4	Yes, if done	Blood, Saliva, Urine, Other, Unknown
1149	1173	25	Test Code #5	Yes, if done	* See Below
1174	1198	25	Test Manufacturer #5	Yes, if done	
1199	1207	9	Test Result #5	Yes, if done	Pos, Neg, High, Low, Detected, Undetected
1208	1217	10	Test Value #5	Yes, if done	Quantity if applicable
1218	1225	8	Date Specimen Collected #5	Yes, if done	YYYYMMDD
1226	1233	8	Date Specimen Tested #5	Yes, if done	YYYYMMDD

Column Starts	Column Ends	Field Length	Field Description	Required Field	Coding Information
1234	1243	10	Type of Specimen #5	Yes, if done	Blood, Saliva, Urine, Other, Unknown

*** Examples of Test Codes:**

HIV Antibodies:	HIV-1 EIA, HIV-1/2 EIA, HIV-2 EIA, HIV-1 Western Blot, HIV-2 Western Blot, HIV-1 IFA, Rapid #1, Rapid #2, Other
HIV Detection:	HIV-1 Proviral DNA, HIV-1RN-PCR (Qualitative), P24 Antigen, HIV-1 Culture, HIV-2 Culture, Other
HIV Viral Loads:	RNA RT-PCR (Standard), RN RT-PCR (Ultra sensitive), bDNA, RNA NASBA, RNA Other
Immunologic:	CD4 Absolute, CD4 Percent

3. Other Formats

Other formats may be accepted on a case-by-case basis with the approval of Epidemiologic Services. Questions regarding data standards may addressed by contacting Epidemiologic Services at (609) 984-5940 or PO Box 363, Trenton, NJ 08625-0363
Phone: (609) 984-5940

C. Mode of Electronic Transmission

The Department will work with individual laboratories to establish Secure File Transfer Protocol (SFTP) connections to transmit data. Other technologies such as Virtual Private Networks may be considered.

The Secure File Transfer Protocol is a program that uses the secure shell (SSH) program to transfer files. Unlike standard file transfer protocol, it encrypts both commands and data, thus preventing passwords and sensitive information from being transmitted in the clear over the network.
The Virtual Private Network is a network that is constructed by using the internet to connect nodes (Department and Laboratory Server). This will allow the data to be encrypted as well as ensure that only authorized users access the secure network.
All electronic interfaces shall be tested by the Department's laboratory staff prior to being sent to the production system. The test phase shall only be initiated once the laboratories have provided evidence that they have completed a list of diseases that they will be reporting along with the required LOINC and SNOMED tables.
During the first phase of testing, the laboratories can provide test data files to the Office of Information Technology Services to process into our test environment. Upon approval, the second phase of testing can be initialized by the laboratories to allow for the production and processing of data into the Department's test environment. Laboratories will provide hard copies of all test results (as they appear at the physicians' offices) to Epidemiologic Services. During this testing phase quality assurance will be conducted to verify the accuracy of the electronic data transmission. Upon completion of phase II testing, data will be put into production. However, hard copies may still be requested by Epidemiologic Services for a few months. Hard copy results can be discontinued if agreement is obtained by Epidemiologic Services and the specific Laboratory.

D. Contact Information

Division of HIV/AIDS Services
Epidemiologic Services
PO Box 363
Trenton, NJ 08625-0363
Phone: (609) 984-5940

E. References

http://www.h17org
http://www.cdc.gov/phin/phin_news.html#h17

New Rule, R.2009 d.107, effective April 6, 2009.
See: 40 N.J.R. 1962(a), 41 N.J.R. 1419(a).