



Department of Health

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Dear Colleague:

This letter and the enclosed resource materials have been prepared to help medical providers report newly diagnosed cases of HIV infection and AIDS to the New York State Department of Health (NYSDOH) using the DOH-4189 Medical Provider HIV/AIDS and Partner/Contact Report Form (PRF). Completion of the PRF within 14 days of diagnosis is required by Public Health Law, Article 21, Title III, Section 2130.

The PRF is now able to be completed electronically using the Provider Portal on the NYSDOH Health Commerce System at <https://commerce.health.ny.gov>.

The confidential PRF is an important source of data required by Centers for Disease Control and Prevention (CDC) to confirm the eligibility of cases for HIV incidence and case surveillance.

- The PRF also serves as a mechanism for you to notify the NYSDOH and the New York City Department of Health and Mental Hygiene (NYCDOH) that your patient needs linkage to Health Department Partner Services.
- The information submitted by you on the PRF is crucial in determining the allocation of federal and state funds, identifying trends in HIV transmission, facilitating access to health, social and prevention services, and targeting and evaluating prevention interventions.
- The PRF is a mechanism for you to document your referral of the newly diagnosed patient for linkage to HIV medical care as required by Public Health Law.
- Lastly, the important testing history variables (Section II) are used to estimate HIV incidence and to determine acute or early infection.

Additionally, the Provider Portal can be used to submit inquiries for your patients with diagnosed HIV infection who are thought to be in need of assistance with linkage to or retention in HIV medical care.

For information regarding accessing the Provider Portal or for paper copies of the PRF, please call 518-474-4284.

Sincerely,

Bridget J. Anderson, PhD
Director
Bureau of HIV/AIDS Epidemiology

HIV/AIDS Reporting at a Glance

Five Things to Know About HIV/AIDS Reporting in New York State

One. What is Reportable?

NYS Public Health Law (PHL) Article 21 (**Chapter 163 of the Laws of 1998**) requires the reporting of persons with HIV as well as AIDS to the NYSDOH. The law also requires that reports contain the names of sexual or needle-sharing partners known to the medical provider or whom the infected person wishes to have notified. The **Medical Provider Report Form (PRF) (DOH-4189)**, must be completed within 14 days of diagnosis for persons with the following diagnoses or with known sex or needle-sharing partners:

1. **Initial/New HIV diagnosis** - First report of HIV positive test results.
2. **Previously diagnosed HIV (non-AIDS)** - Applies to a medical provider who is seeing the patient for the first time.
3. **Initial/New diagnosis of AIDS** - Including <200 CD4 cells/ μ L or an opportunistic infection (AIDS-defining illness).
4. **Previously diagnosed AIDS** - Applies to a medical provider who is seeing the patient for the first time.
5. **Known sex or needle-sharing partners of persons with diagnosed HIV infection.**

Two. What Do Laboratories Report?

Laboratories and blood and tissue banks conducting HIV-related testing for NYS residents and/or for NYS providers (regardless of patient residence) are required to electronically report to NYSDOH results of any laboratory test, tests or series of tests approved for the diagnosis of HIV or for the periodic monitoring of HIV.

1. All reactive/repeatedly reactive initial **HIV immunoassay** results AND all results (e.g. positive, negative, indeterminate) from all **supplemental HIV immunoassays** (HIV-1/2 antibody differentiation assay, HIV-1 Western blot, HIV-2 Western blot or HIV-1 Immunofluorescent assay);
2. All **HIV nucleic acid** (RNA or DNA) detection tests (qualitative and quantitative), including tests on individual specimens for confirmation of nucleic acid-based testing (NAT) screening results;
3. All **CD4 lymphocyte** counts and percentages, unless known to be ordered for a condition other than HIV;
4. **HIV genotypic resistance testing** via the electronic submission of the protease, reverse transcriptase and integrase nucleotide sequence; and,
5. Positive **HIV detection** tests (culture, P24 antigen).

Three. How Do Providers Report?

Medical providers must complete the **NYS PRF (DOH-4189)** for all reportable cases. Information regarding electronic reporting or paper forms are available from the NYSDOH **518-474-4284**; clinicians located in NYC should call **212-442-3388**. *In order to protect patient confidentiality, faxing of reports is not permitted.*

Four. What Guidance is Available for Notifying Partners of HIV-infected Persons?

NYS Public Health Law requires that medical providers talk with HIV-diagnosed individuals about their options for informing their sexual and needle-sharing partners that they may have been exposed to HIV. The **NYSDOH Partner Services program** provides assistance to HIV-positive individuals and to medical providers who would like help notifying partners. **Call your local Health Department or NYSDOH Regional Contacts for Partner Services for STD/HIV for assistance.**

Five. What About HIPAA and Confidentiality?

Under the federal HIPAA Privacy Rule, public health authorities have the right to collect or receive information "for the purpose of preventing or controlling disease" and in the "conduct of public health surveillance..." without further authorization. *This exception to HIPAA regulations authorizes medical providers to report HIV/AIDS cases to the NYSDOH without obtaining patient permission.*

Local Health Department and NYSDOH Regional Contacts for Health Department Partner Services for HIV and STD

The Partner Services Program provides an immediate link between health care providers, persons diagnosed with HIV, *Chlamydia*, gonorrhea or syphilis, and their sexual and/or needle-sharing partners. Partner Services can serve as a medical provider's proxy in identifying partners, conducting domestic violence screening and the notification plan, and will assist in completing the PRF (DOH-4189). Partner Services staff work with patients to develop a plan to notify their partners. Based on the patient's needs, staff can notify potentially exposed partners anonymously, as well as help patients who want to tell their partners on their own.

Local Health Department	Telephone Number
Albany County	518-447-4516
Dutchess County	845-486-3452
Erie County	716-858-7683
Monroe County	585-753-5391
Nassau County	516-227-9439
Onondaga County	315-435-3240
Orange County	845-568-5333
Rockland County	845-364-2992
Schenectady County	518-386-2824
Suffolk County	631-854-0364
Westchester County	914-813-5115

Regional Office and Counties within Region	Telephone Number
Buffalo Regional Office <i>Allegany, Cattaraugus, Chautauqua, Erie, Genesee, Niagara, Orleans, Wyoming</i>	716-847-4511 or 1-800-962-5064
Capital District Regional Office <i>Clinton, Columbia, Delaware, Essex, Franklin, Fulton, Greene, Hamilton, Montgomery, Otsego, Rensselaer, Saratoga, Schoharie, Warren, Washington</i>	518-402-7411 or 1-800-962-5065
Central New York Regional Office <i>Broome, Cayuga, Chenango, Cortland, Herkimer, Jefferson, Lewis, Madison, Oneida, Oswego, St. Lawrence, Tioga, Tompkins</i>	315-477-8166 or 1-800-562-9423
Metropolitan Area Regional Office <i>Putnam, Sullivan, Ulster</i>	914-654-7187 or 1-800-828-0064
New York City CNAP <i>Bronx, Kings, New York, Queens, Richmond</i>	212-693-1419
Rochester Regional Office <i>Chemung, Livingston, Ontario, Schuyler, Seneca, Steuben, Wayne, Yates</i>	585-423-8095 or 1-800-962-5063

For more information on Partner Services, visit www.health.ny.gov/diseases/communicable/std/partner_services

Additional Resources

HIV Testing Toolkit: Resources to Support Routine HIV Testing for Adults and Teens: This toolkit was developed for primary care providers and contains all of the resources needed to meet New York State clinical guidelines and legal requirements for offering voluntary, routine HIV testing as a part of health care to all patients aged 13-64.

http://www.health.ny.gov/diseases/aids/providers/testing/docs/testing_toolkit.pdf

Clinician Focused Interim Guidelines for Laboratories on the use of a new Diagnostic Testing Algorithm for HIV Infection: <http://www.health.ny.gov/diseases/aids/providers/testing/algorithm.htm>

NYS Department of Health HIV/AIDS Hotline: 1-800-541-AIDS

<http://www.health.ny.gov/diseases/aids/index.htm>

HIV Training for Providers: <http://www.health.ny.gov/diseases/aids/providers/training/index.htm>

CDC/APHL Laboratory Testing for the Diagnosis of HIV Infection Updated Recommendations

<http://www.cdc.gov/hiv/pdf/hivtestingalgorithmrecommendation-final.pdf>

NYSDOH Partner Services: http://www.health.ny.gov/diseases/communicable/std/partner_services

NYC HIV Care Status Report and Provider Call Line: Eligible NYC providers with patients who have been out-of-care for at least 12 months can use the NYCDOHMH's HIV Care Status Reports System (CSR) to obtain NYC current care status. Information from the CSR may be useful to your follow-up efforts. Eligible NYC providers may also call the NYC DOHMH Provider Call Line at 212-442-3388 to obtain information that may help link or retain patients in care.

<http://www1.nyc.gov/site/doh/health/health-topics/aids-hiv-care-status-reports-system.page>

FDA-Approved HIV Medicines <https://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines>

HIV Clinical Resource: <http://www.hivguidelines.org>

NYS HIV Laws and Regulations:

<http://www.health.ny.gov/diseases/aids/providers/regulations/index.htm>

HIV Statistics in New York State: <http://www.health.ny.gov/diseases/aids/general/statistics/index.htm>

Required HIV Related Consent and Authorization Forms:

<http://www.health.ny.gov/diseases/aids/providers/forms/informedconsent.htm>

HIV/AIDS Provider Portal Quick Start Guide

New York State Department of Health

Purpose of the HIV/AIDS Provider Portal

- The HIV/AIDS Provider Portal is an electronic system which enables clinicians to meet their Public Health reporting requirements electronically and to request information about their patients thought to be out of care.

Requirements for the HIV/AIDS Provider Portal

- A New York State Department of Health (NYSDOH) Health Commerce System (HCS) Medical Professionals account is required. You likely are already using the HCS for electronic prescribing, to order official prescription pads, subscribe to public health alerts through the Health Alert Network, and access other health information exchange applications that focus on preparedness, planning, communications, response and recovery.
- To access the HCS, please visit: <https://commerce.health.ny.gov/>
 - If you already have an HCS account, ensure that your password is up to date and your NYS medical license is associated with your HCS profile.
 - If you do not have an HCS account, apply for one by calling the Commerce Accounts Management Unit at 1-866-529-1890, option1 (M-F 8am-4:45 pm) or online at <https://apps.health.ny.gov/pub/top.html>
- HIV/AIDS Provider Portal access is limited to NYS licensed MD, DO, DDS, NP, PA and midwife clinicians with a valid medical license number associated with their HCS profile. Once you establish your account, you are able to designate the HIV/AIDS Provider Portal usage to a delegate.
- **System Requirements:** Due to application and data security requirements, you must have Mozilla Firefox Internet Browser (<https://www.mozilla.org/en-US/firefox/new/>) and an updated Windows operating system (versions 7, 8, 9, or 10).

How to Access the HIV/AIDS Provider Portal

- Login to the HCS at <https://commerce.health.ny.gov/>
- Select “Refresh My Applications List” on left side “My Applications” List
- Select **HIV/AIDS Provider Portal**
OR
- Select “My Content” at the top of the page
- Scroll down and select “All Applications”
- Scroll over and select “H”
- Select **HIV/AIDS Provider Portal**

HIV/AIDS Provider Portal Account Set Up

- Account set up is a simple one-time process that requires the following information:
 1. Your National Provider Identification (NPI)
 2. Your email address
 3. Your practice or facility address
 4. The name and HCS user ID of your desired account administrator
 5. The name and HCS user ID of your desired data entry operators

HIV/AIDS Provider Portal Quick Start Guide New York State Department of Health

- Only you, the licensed Medical Provider, can add an administrator to the account. This step enables you to delegate HIV/AIDS Provider Portal usage. The licensed Medical Provider must enter the desired administrator's HCS user ID and grant this person the administrator role. Once completed, the administrator has the same permissions in the system as the provider. Anyone with assigned roles in the HIV/AIDS Provider Portal must have a valid HCS User ID.
 - Once an administrator has been associated with the account, the provider may 'Skip Setup' and delegate the remaining set up to the Administrator.
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Using the HIV/AIDS Provider Portal for Electronic Submission of the DOH-4189 Medical Provider HIV/AIDS and Partner/Contact Report Form (PRF)

- Clicking on the '**ePRF Data Entry**' link from the home page will direct you to the electronic version of the PRF (ePRF) for data entry.
- The ePRF will open once the user selects the Address and Document Source.

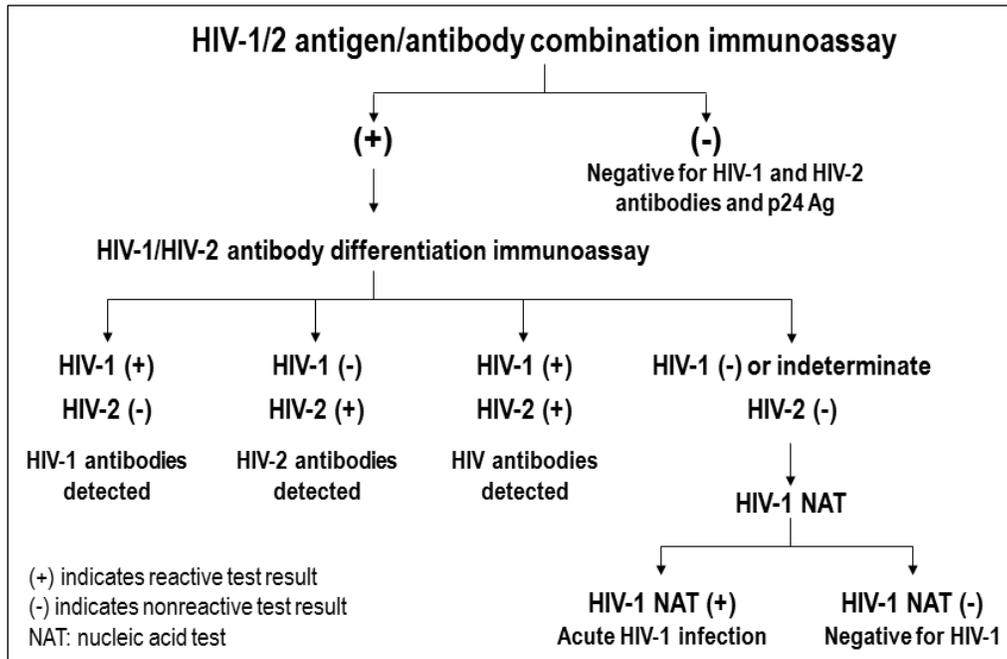
Using the HIV/AIDS Provider Portal for Submission of Out of Care (OOC) or Diagnosed Not Linked to Care Patient Lists

- Clicking the '**OOC/Diagnosed Not Linked to Care/SNP**' link from the home page will direct you to the OOC and Diagnosed Not Linked to Care submission page.
 - Only the Medical Provider and his/her Administrator will have access to the out of care/diagnosed not linked to care page.
 - To submit an inquiry, select the downloaded template "ooc.xlsx" and enter the patient data in the file.
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Help Guide

- A comprehensive '**HELP GUIDE**' is located on the top right side of the HIV/AIDS Provider Portal page. It contains detailed instructions regarding setting-up the account, adding users, explains the roles of users and the functionality of each role, illustrates walkthroughs for tasks such as completing and submitting an ePRF, completing and submitting an OOC inquiry, and much more.
- For assistance with the HIV/AIDS Provider Portal, please contact the NYSDOH Bureau of HIV/AIDS Epidemiology at 518-474-4284.

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



- Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody combination immunoassay* that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to test for established HIV-1 or HIV-2 infection and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial immunoassay.
- Specimens with a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody combination immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, undifferentiated.
- Specimens that are reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT).
 - A reactive HIV-1 NAT result and nonreactive HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence for acute HIV-1 infection.
 - A reactive HIV-1 NAT result and indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates the presence of HIV-1 infection confirmed by HIV-1 NAT.
 - A negative HIV-1 NAT result and nonreactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates a false-positive result on the initial immunoassay.
- Laboratories should use this same testing algorithm, beginning with an antigen/antibody combination immunoassay, with serum or plasma specimens submitted for testing after a reactive (preliminary positive) result from any rapid HIV test.

* *Exception: As of April 2014, data are insufficient to recommend use of the FDA-approved single-use rapid HIV-1/HIV-2 antigen/antibody combination immunoassay as the initial assay in the algorithm.*

Reporting results from the HIV diagnostic testing algorithm to persons ordering HIV tests and public health authorities

Test performed	Test results	Final interpretation for provider report	Test results to be reported to public health authorities
1. HIV-1/2 Ag/Ab combination immunoassay	1. Nonreactive	Negative for HIV-1 antigen and HIV-1/HIV-2 antibodies. No laboratory evidence of HIV infection. If acute HIV infection is suspected, consider testing for HIV-1 RNA.	Reporting this test result is not required.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 reactive and HIV-2 nonreactive	Positive for HIV-1 antibodies. Laboratory evidence consistent with established HIV-1 infection is present.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combo immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 nonreactive and HIV-2 reactive	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive or indeterminate 3. RNA not detected	HIV antibodies were not confirmed and HIV-1 RNA was not detected. No laboratory evidence of HIV-1 infection. Follow-up testing for HIV-2 should be performed if clinically indicated.	Reporting this test result is not required.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive 3. RNA detected	Positive for HIV-1. Laboratory evidence consistent with acute HIV-1 infection is present.	Report test results 1, 2, and 3.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Indeterminate 3. RNA detected	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection confirmed by HIV-1 RNA.	Report test results 1, 2, and 3.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 and HIV-2 reactive	Positive for HIV antibodies. Laboratory evidence of HIV infection is present. HIV antibodies could not be differentiated as HIV-1 or HIV-2. Additional testing for HIV-1 RNA or HIV-2 RNA should be performed if clinically indicated.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. Nonreactive or indeterminate	HIV-1 antibodies were not confirmed and HIV-1 RNA testing was not performed. Testing of this specimen is incomplete. Follow-up testing for HIV antibodies and HIV-1 RNA is recommended as soon as possible.	Report test results 1 and 2.

Abbreviations: Ag/Ab, antigen/antibody; RNA, ribonucleic acid.

Adapted from *Interim Guidelines for Laboratories on the Use of a New Diagnostic Testing Algorithm for Human Immunodeficiency Virus (HIV) Infection*. New York State Department of Health (http://www.health.ny.gov/diseases/aids/providers/regulations/testing/docs/guidelines_diagnostic_testing.pdf).