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Recommendations for Accurate Diagnosis of HIV Infection

Key Points

1. HIV screening and testing technology continues to improve, which may present challenges with interpretation and reporting of results. DPHS has become aware of several recent cases in which clinicians' interpreted testing and informed patients incorrectly.
2. Healthcare providers and laboratories should review and follow the Centers for Disease Control and Prevention's (CDC) *Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens* and *Reporting Results from the HIV Diagnostic Testing Algorithm to Persons Ordering HIV tests and Public Health Authorities*.
3. All new HIV diagnoses (including positive preliminary results) must be reported to the NH Division of Public Health Services at 1-800-852-3345 Ext. 4496 or (603) 271-4496 within 72 hours of diagnosis or suspicion of diagnosis.

Background Information

CDC estimates that there are 1.2 million people in the United States living with HIV, including 156,300 people who do not know they are infected. Each year, nearly 45,000 people are diagnosed with HIV and 30% of new HIV infections are transmitted by people who are living with undiagnosed HIV. HIV testing is recommended for:

- All adults and adolescents from ages 13 to 64 at least once in their lifetime
- All women when a pregnancy is confirmed
- Annually for persons who have sex without a condom or share drug equipment
- Annually for sexually active men who have sex with men

HIV screening and testing technology continues to improve, which may present challenges with interpretation and reporting of results. Current HIV assays which are approved by the Food and Drug Administration (FDA) allow detection of HIV sooner after infection than previous assays which is useful because HIV transmission from persons with acute infection is much more likely than from persons with established infection; and starting antiretroviral treatment (ART) early in the course of HIV infection has clinical benefits and can reduce the risk of transmission.

DPHS has become aware of several recent cases in which clinicians interpreted testing and informed patients incorrectly. In one such example, a patient reported a history of sharing injection drug equipment and was tested for HIV. The clinician received a laboratory report that read "Repeatedly Reactive" for the HIV 1/2 Ag/Ab and "Negative" by HIV 1/2 Ab Differentiation. Subsequently, the

clinician received a report that HIV-1 was not detected by the Nucleic Acid Amplification Test. However, the provider informed the patient that he had HIV based on the first test.

There are now three types of HIV diagnostic tests: HIV 1/2 antigen/antibody combination immunoassay (often referred to as the 4th Generation HIV test), HIV1/2 differentiation and HIV-1 NAT, as indicated in the testing algorithm.

Test	Purpose of the Test
HIV-1/2 antigen/antibody combination immunoassay (often referred to as the 4th Generation test)	These tests detect acute and chronic HIV infection. It can take 2 to 6 weeks after initial infection to identify HIV infection using these tests. This is a screening test and positive specimens must be confirmed by other tests. No further testing is required for specimens that are nonreactive on the initial immunoassay.
HIV-1/HIV-2 antibody differentiation immunoassay	HIV-1/HIV-2 differentiation assays are used following a positive HIV-1/2 antigen/antibody combination immunoassay in order to distinguish between HIV-1 and HIV-2.
HIV-1 Nucleic Acid Amplification Test	These tests identify infection with HIV-1 within 7 to 28 days of the initial HIV infection.

Recommendations

- Implement CDC recommendations for HIV testing of adults, adolescents and pregnant women. **http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm**
- Review and follow the Centers for Disease Control's (CDC) *Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens* (Attachment A) and *Reporting Results from the HIV Diagnostic Testing Algorithm to Persons Ordering HIV tests and Public Health Authorities* (Attachment B).

  http://www.cdc.gov/hiv/pdf/guidelines_testing_recommendedlabtestingalgorithm.pdf
- Report all positive HIV diagnostic testing results (including positive preliminary results) to the NH Division of Public Health Services at 1-800-852-3345 Ext. 4496 or (603) 271-4496 within 72 hours of diagnosis or suspicion of diagnosis.

For Additional Information

For any questions regarding the contents of this message, please contact NH DHHS, DPHS, Bureau of Infectious Disease Control at 603-271-4496 (after hours 603-271-5300).

To change your contact information in the NH Health Alert Network, contact Thom Flynn at 603-271-7499 or email thomas.flynn@dhhs.nh.gov.

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From:	Elizabeth A. Talbot, MD – Deputy State Epidemiologist
Originating Agency:	NH Department of Health and Human Services, Division of Public Health Services

Attachments: Attachment A - Recommended Laboratory HIV Testing Algorithm
Attachment B - Reporting results from the HIV diagnostic testing algorithm

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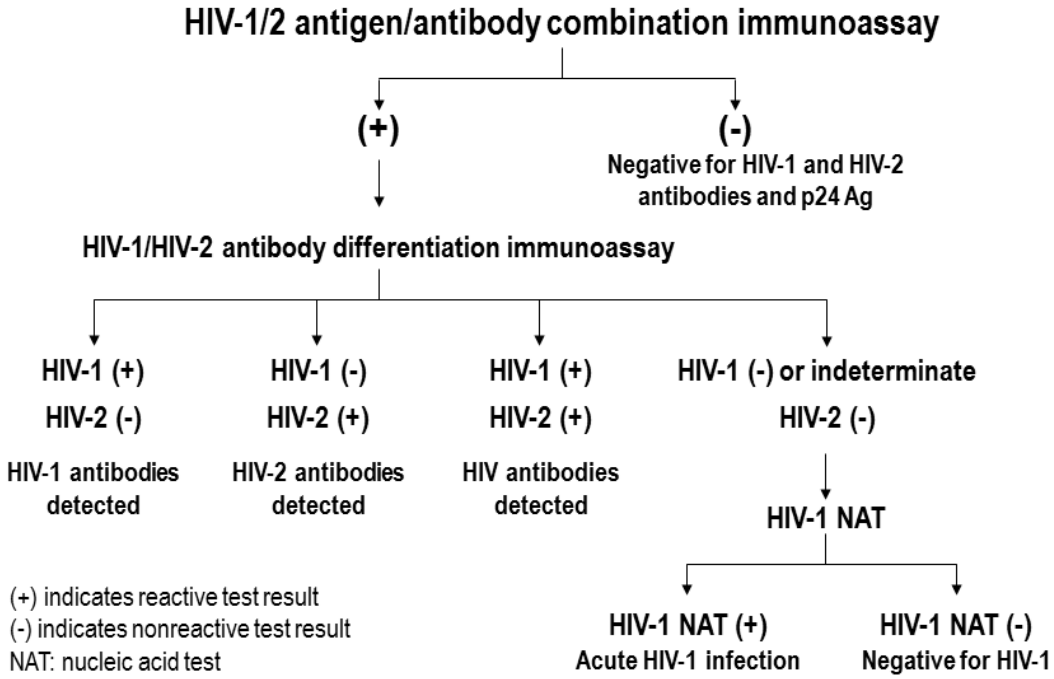
Attachment A

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



1. 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 screen for established infection with HIV-1 or HIV-2 and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial immunoassay.
2. 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.
3. 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.
4. 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) results from any rapid HIV test.
5.

**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.*

• A reactive HIV-1 NAT result and nonreactive HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence for acute HIV-1 infection.

http://www.cdc.gov/hiv/pdf/HIVtestingAlgorithmRecommendation-Final.pdf

Attachment B

Reporting results from the HIV diagnostic testing algorithm to persons ordering HIV tests and public health authorities[1]

Test performed	Test results	Final interpretation for provider report	Test results to be reported to public
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,	Reporting this test result is not required.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation	1. Reactive 2. HIV-1 reactive and HIV-2	Positive for HIV-1 antibodies. Laboratory evidence consistent with established HIV-1	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combo immunoassay 2. HIV-1/HIV-2 antibody differentiation	1. Reactive 2. HIV-1 nonreactive and HIV-2	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	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. 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	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	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	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)