- Clinicians should perform diagnostic HIV laboratory tests in full compliance with New York State HIV/AIDS Laws and Regulations. Additional information regarding testing procedures and regulations is available from the Wadsworth Center (518-474-2163). Report confirmed cases of HIV according to New York State Law (see NYSDOH Provider Reporting and Partner Services).

**HIV Screening and Diagnosis**

- Clinicians should use a 4th-generation (HIV-1/2 Ag/Ab combination) immunoassay to screen patients for HIV infections. (A2)

- Clinicians must perform diagnostic HIV laboratory tests in full compliance with New York State HIV/AIDS Laws and Regulations. Additional information regarding testing procedures and regulations is available from the Wadsworth Center (518-474-2163). Report confirmed cases of HIV according to New York State Law (see NYSDOH Provider Reporting and Partner Services).
1. Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody immunoassay [a] that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to test for established HIV-1 and HIV-2 infection and for acute HIV-1 infection, respectively. No further testing is required for specimens that are non-reactive on the initial immunoassay. However, if there is a possibility of very early infection leading to a non-reactive initial antigen/antibody immunoassay, such as when recent HIV exposure is suspected or reported, then conduct an HIV-1 nucleic acid test (NAT), or request a new specimen and repeat the algorithm according to CDC guidance (1,4,5,6).

2. Specimens with a reactive antigen/antibody 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 supplemental antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies [b], or HIV antibodies, untypable (undifferentiated).

3. Specimens that are reactive on the initial antigen/antibody immunoassay and non-reactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 NAT.
   - A reactive HIV-1 NAT result and non-reactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence of acute HIV-1 infection.
   - A negative HIV-1 NAT result and non-reactive or HIV-1 indeterminate antibody differentiation immunoassay result indicates an HIV-1 false-positive result on the initial immunoassay.
   - A negative HIV-1 NAT result and repeatedly HIV-2 indeterminate or HIV indeterminate antibody differentiation immunoassay result should be referred for testing with a different validated supplemental HIV-2 test (antibody test or NAT) or repeat the algorithm in 2 to 4 weeks, starting with an antigen/antibody immunoassay (3).

4. Laboratories should use this same testing algorithm, beginning with an antigen/antibody immunoassay on all serum or plasma specimens submitted for testing after a preliminary positive result from any rapid HIV test conducted in a CLIA-waived setting (7).

[a] The FDA-approved single-use rapid HIV-1/HIV-2 antigen/antibody immunoassay can be used as the initial assay in the laboratory HIV testing algorithm for serum or plasma. If any instrumented antigen/antibody test is available, it is preferred due to its superior sensitivity for detecting HIV during acute infection (1,2).

[b] This includes specimens reported as HIV-2 positive with HIV-1 cross-reactivity (3).

[c] Refer to last bullet, item 3 above.

2) Use of the Determine HIV 1/2 Ag/Ab Combo Test with Serum or Plasma in the Laboratory Algorithm for HIV Diagnosis https://stacks.cdc.gov/view/cdc/48472
3) Technical Update on HIV-1/2 Differentiation Assays https://stacks.cdc.gov/view/cdc/40790
4) Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm https://stacks.cdc.gov/view/cdc/45930
5) Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016 https://stacks.cdc.gov/view/cdc/38856
7) Web content: Clinical Laboratory Improvement Amendments https://wwwn.cdc.gov/clia/