CLINICAL GUIDELINES PROGRAM ¼-FOLDED GUIDE

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HIV TESTING

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE OCTOBER 2018

A NEW HIV DIAGNOSIS IS A CALL TO ACTION

- In support of the NYSDOH AIDS Institute's January 2018 call to action for patients newly diagnosed with HIV, this committee stresses the following:
  - Immediate linkage to care is essential for any person diagnosed with HIV.
  - For the person with HIV, antiretroviral therapy (ART) dramatically reduces HIV-related morbidity and mortality.
  - Viral suppression helps to prevent HIV transmission to sex partners of people with HIV and prevents perinatal transmission of HIV.
- The urgency of ART initiation is even greater if the newly diagnosed patient is pregnant, has acute HIV infection, is ≥50 years of age, or has advanced disease. For these patients, every effort should be made to initiate ART immediately, and ideally, on the same day as diagnosis.
- All clinical care settings should be prepared, either on-site or with a confirmed referral, to support patients in initiating ART as rapidly as possible after diagnosis.

ALL RECOMMENDATIONS P.1

HIV Screening and Diagnosis

- Clinicians should use a 4th-generation (HIV-1/2 Ag/Ab combination) immunoassay to screen patients for HIV infection. (A1)
- 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*).

KEY POINTS

- **Assess for PEP:** Patients presenting for testing for possible exposure to HIV should be assessed for PEP (see the NYSDOH AI guidelines on *PEP to Prevent HIV Infection*). Expert advice may be obtained from the Clinical Education Initiative (CEI) PEP Line at 866-637-2342.
- A reactive result on the initial screening test with inconclusive supplemental serologic testing may represent either a false or a true positive. In the setting of acute HIV infection, a nonreactive supplemental Ab test may be a false-negative, and further testing with an HIV RNA assay is indicated.
  - The clinician should contact the laboratory to determine the significance of the nondefinitive results and the supplemental testing that is indicated.
  - Determining the significance of nondefinitive results is of particular importance when testing pregnant individuals, newborn children, and patients with suspected acute HIV infection or HIV-2.
- The HIV-1 Western blot and HIV-1 indirect immunofluorescence assay (IFA) are no longer recommended for confirming a reactive screening test and are not part of the recommended testing algorithm.
- If the laboratory is unable or does not automatically reflex directly to the RNA test, clinicians should order an HIV-1 RNA test as soon as possible. However, if the person being tested is receiving antiretroviral agents for PEP, PrEP, or rapid ART start, a false-negative result may occur for the HIV-1 RNA test. This result should be interpreted in the context of the overall clinical situation, and re-testing should be performed accordingly (see Table 2 in full guideline).

← Use this code with your phone's QR code reader to go directly to a mobile-friendly version of this guideline.

This ¼-Folded Guide is a companion to the New York State Department of Health AIDS Institute guideline *HIV Testing*. The full guideline is available at hivguidelines.org.

ALL RECOMMENDATIONS *(continued from P.1)* **P.2**

HIV Screening and Diagnosis

- Clinicians should offer assistance with notifying partners or should refer patients to other sources for partner notification assistance: in NYS, see *NYSDOH Partner Services*, and in New York City, see *Contact Notification Assistance Program (CNAP)*.
- When immediate results are necessary, such as in the labor/delivery, newborn, or post-exposure settings, or when the person receiving testing is unlikely to return for a follow-up visit, clinicians should use an FDA-approved screening test that produces results within 60 minutes. (A2)
- Clinicians should not wait for serologic confirmation of HIV to initiate ART when pregnant individuals are diagnosed with acute HIV infection by HIV RNA testing. Initiation of ART is strongly recommended for pregnant individuals. (A2)
- Because all screening tests are subject to false-positive results, clinicians should consider all reactive screening test results preliminary; reactive specimens require further testing with appropriate tests to determine the final result. (A1)
- For all individuals who test negative and have recent or ongoing high-risk behavior, clinicians should discuss goal-oriented, harm-reduction strategies such as PrEP and the emergency availability of post-exposure prophylaxis (PEP). Clinicians should refer these patients as appropriate for counseling services and should offer repeat testing every 3 months, or sooner if acute HIV infection is suspected, for as long as high-risk behavior continues. (A3) See the NYSDOH AI guidelines *PEP to Prevent HIV Infection* and *PrEP to Prevent HIV Acquisition*.
- Clinicians should not delay initiation of ART pending results of repeat testing (see the NYSDOH AI guideline *When to Initiate ART, With Protocol for Rapid Initiation*).
- **NOTE:** Recommendations for management when acute HIV is suspected are available in the NYSDOH AI guideline *Diagnosis and Management of Acute HIV*.

ALL RECOMMENDATIONS *(continued from P.2)* **P.3**

Steps in the HIV Diagnostic Testing Algorithm

- Clinicians should begin diagnostic HIV testing of adults and children aged 2 years and older with an FDA-approved 4th-generation HIV-1/2 Ag/Ab immunoassay. (A1)
- The CDC/APHL HIV Diagnostic Testing Algorithm (see inside) is recommended for laboratories conducting primary diagnostic testing and confirmation of a reactive rapid screening test from serum or plasma. (A1)
- The NYSDOH strongly recommends that all New York State birth facilities use the pediatric HIV testing services at the Wadsworth Center.
  - For information about this service, which is free of charge for New York State clinicians caring for HIV-exposed infants, contact the Wadsworth Center at 518-474-2163.
  - Facilities that choose to use laboratories other than the Wadsworth Center should verify that testing is performed with an HIV nucleic acid test (NAT) that has been validated and approved for diagnosing HIV infection, including non-B subtypes of HIV-1.
- Clinicians should use an HIV NAT to detect HIV RNA or DNA and establish the diagnosis of infection in infants born to individuals with HIV-1. (A1) See the NYSDOH AI *NYS Good Practices in Managing Infant Perinatal HIV Exposure*.

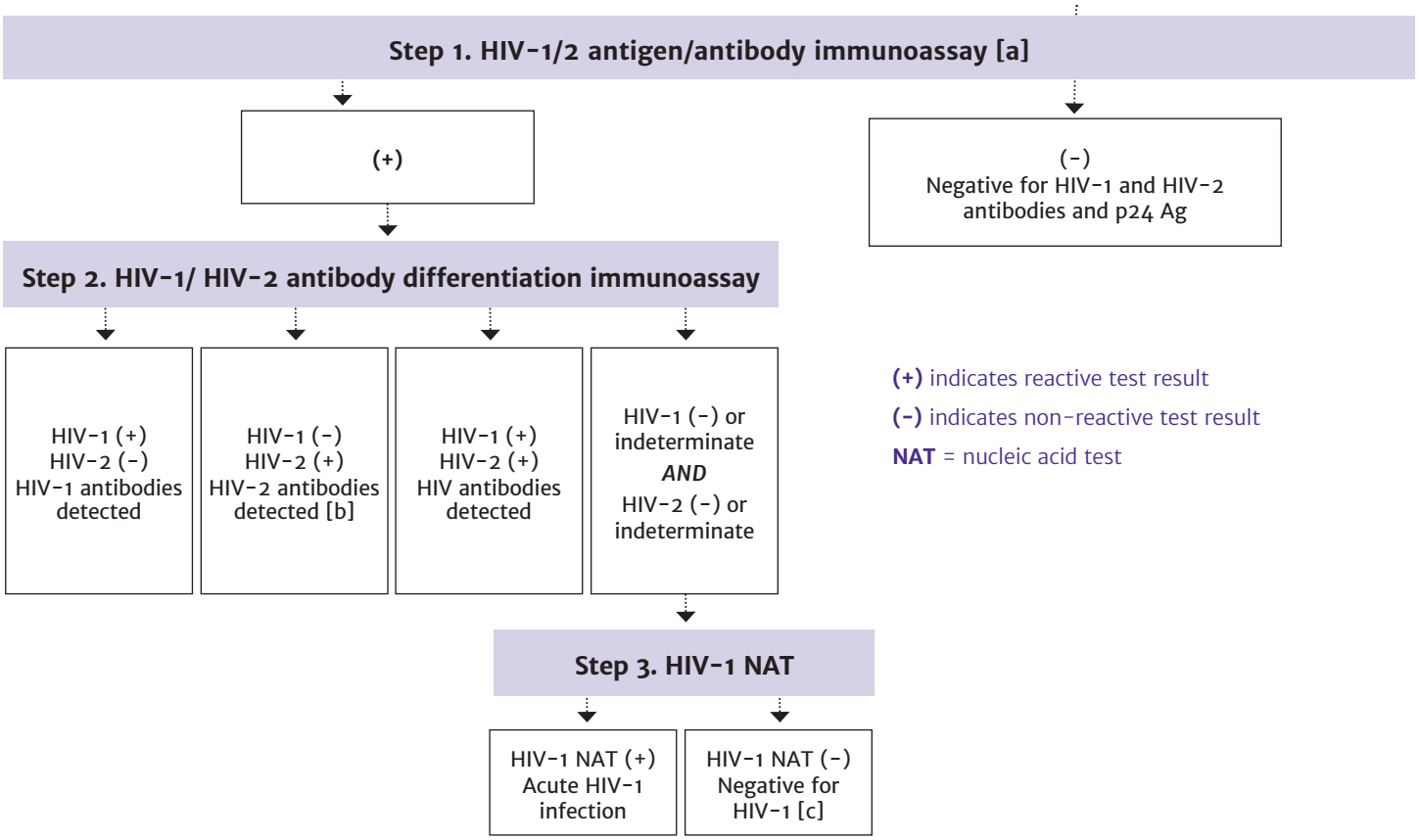
HIV-2 RNA Tests for Diagnostic Use

- Individuals who screen reactive with an HIV-1/2 or HIV-1/2 Ag/Ab immunoassay and are positive for HIV-2 Abs on an FDA-approved supplemental HIV-1/2 Ab-differentiation assay are considered positive for HIV-2 Abs; clinicians should perform a clinical evaluation for HIV-2 infection. (A1)
- Clinicians caring for patients with HIV-2 infection should contact the Wadsworth Center's Bloodborne Viruses Laboratory at 518-474-2163 for guidance on HIV-2 viral load monitoring.

Home-Based Tests

- Clinicians should educate patients about the limitations of in-home testing and emphasize that both nonreactive and reactive results of any in-home HIV testing should be repeated by a laboratory.

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens [CDC. Updated January 2018]



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).

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[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.

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1) Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations https://stacks.cdc.gov/view/cdc/23447
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
6) Web content: How Soon Can Clinicians Rule Out Infection? https://www.cdc.gov/hiv/testing/clinical/index.html
7) Web content: Clinical Laboratory Improvement Amendments https://wwwn.cdc.gov/clia/