· If the laboratory is unable or does not automatically reflex directly to the
  result, the clinician should contact the laboratory to determine the
  significance of nondefinitive results and the presence of other nonreactive
  results are inconclusive. (A2)
  - Reactions with inconclusive supplemental serologic testing may represent 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.
  - Clinicians 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.

Steps in the HIV Diagnostic Testing Algorithm

1. Exposure
2. Sensitivity
3. Specificity
4. Confirmation
5. Interpretation
6. Follow-up

See the NYSDOH AID guideline procedures on testing pregnant women.

ALL RECOMMENDATIONS (continued from P.2)

KEY POINTS

- Assess for PEP: Patients presenting for testing for possible exposure to
  HIV should be assessed for PEP (see the NYSDOH AID 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.

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).

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 250 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.

CLINICAL GUIDELINES PROGRAM ¼-FOLDED GUIDE VISIT HIVGUIDELINES.ORG TO LEARN MORE OR VIEW COMPLETE GUIDELINE

HIV TESTING

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE OCTOBER 2018

- 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 250 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
### Step 1. HIV-1/2 antigen/antibody immunoassay [a]

- (+) indicates reactive test result
- (-) indicates non-reactive test result

<table>
<thead>
<tr>
<th>HIV-1 (+)</th>
<th>HIV-2 (-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 antibodies detected</td>
<td>HIV-2 antibodies detected</td>
</tr>
</tbody>
</table>

### Step 2. HIV-1/ HIV-2 antibody differentiation immunoassay

- (+) indicates reactive test result
- (-) indicates non-reactive test result

<table>
<thead>
<tr>
<th>HIV-1 (+)</th>
<th>HIV-2 (+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 antibodies detected</td>
<td>HIV-2 antibodies detected</td>
</tr>
</tbody>
</table>

### Step 3. HIV-1 NAT

- (+) HIV-1 NAT (+)
  - Acute HIV-1 infection
  - HIV-1 antibodies detected
- (-) HIV-1 NAT (-)
  - Negative for HIV-1 [c]
  - HIV-1 antibodies not detected

---

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/