HIV CLINICAL RESOURCE ¼-FOLDED GUIDE

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HIV TESTING

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE MAY 2022

NEW YORK STATE LAW

- Clinicians must perform diagnostic HIV laboratory tests in full compliance with NYS HIV/AIDS Laws and Regulations.
- Clinicians must report confirmed cases of HIV according to NYS law (see NYSDOH Provider Reporting and Partner Services).
- Additional information regarding testing procedures and regulations is available from the NYSDOH Wadsworth Center (518-474-2163).
- See full guideline for overview of NYS public health law HIV testing requirements (Box 1).

ALL RECOMMENDATIONS P.1

HIV Testing With the Standard 3-Step Algorithm

Step 1: HIV-1/2 Antigen/Antibody Immunoassay

- For initial HIV testing (aka "screening"), clinicians should use an HIV-1/2 Ag/Ab immunoassay (formerly known as the "4th-generation" test). (A2)
- For initial testing of newborns or individuals who are in labor, being evaluated for PEP, or unlikely to return for test results, clinicians should use an FDA-approved HIV screening test that provides results within 60 minutes (A2); otherwise, rapid tests are not recommended for step 1 of the standard HIV laboratory testing algorithm.
- Because all initial HIV tests are subject to false positive results, clinicians should consider all reactive initial test results preliminary and perform appropriate laboratory diagnostic testing to confirm a patient's HIV status. (A1)
- Clinicians should educate patients about the limitations of in-home testing and emphasize that a laboratory should repeat both nonreactive and reactive results of any in-home HIV testing. (A3)

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

Step 1: HIV-1/2 Antigen/Antibody Immunoassay *Continued*

- In the case of a nonreactive result, the clinician should discuss goal-oriented, harm-reduction strategies, including PrEP and emergency PEP, with any patient who reports recent or likely ongoing HIV risk exposures or refer the patient for prevention services. (A3)
- Clinicians should offer repeat HIV testing every 3 months, or sooner if acute HIV is suspected, for as long as an individual remains at high risk of HIV exposure. (A3)

Step 2: HIV-1/HIV-2 Antibody Differentiation Immunoassay

- Per the standard HIV laboratory testing algorithm, if a reactive result is obtained with an HIV-1/2 Ag/Ab immunoassay testing (step 1), clinicians should perform supplemental testing (step 2) with an FDA-approved HIV-1/HIV-2 Ab differentiation immunoassay. (A1)
- If the result of the HIV Ab differentiation immunoassay (step 2) is positive for HIV-1 or HIV-2 Abs, the clinician should provide or refer the patient for rapid ART initiation and transmission prevention counseling. (A1)
  - Refer to the NYSDOH AI guideline *Rapid ART Initiation*.
  - Note: If the HIV Ab differentiation assay result is positive but undifferentiated (i.e., reactive for both HIV-1 and HIV-2), repeat testing may determine if the patient has HIV-1 or HIV-2 infection.

Step 3: HIV-1 Nucleic Acid Testing *(qualitative or quantitative HIV RNA testing)*

- If the HIV-1/2 Ab differentiation immunoassay (step 2) result is nonreactive (negative), indeterminate (neither positive nor negative for HIV-1 or HIV-2), and the lab does not perform reflex testing, the clinician should immediately order HIV-1 RNA NAT (step 3) to detect the presence of HIV-1 RNA and confirm or exclude HIV-1 infection. (A*)
- If HIV-1 RNA is detected, the clinician should inform the patient of the acute HIV-1 diagnosis, recommend ART initiation, and prioritize counseling to prevent HIV transmission. (A1)

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

Step 3: HIV-1 Nucleic Acid Testing *(qualitative or quantitative HIV RNA testing)* *Continued*

- Clinicians should not wait for serologic confirmation of HIV to initiate ART when pregnant individuals are diagnosed with acute HIV infection by HIV-1 NAT; initiation of ART is strongly recommended for pregnant individuals. (A2)
  - See DHHS: *Recommendations for the Use of Antiretroviral Drugs in Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States.*
- To determine the HIV status of an infant born to an individual with HIV-1, clinicians should perform HIV-1 RNA NAT. (A1)

Diagnosis of HIV-2 Infection

- When HIV-2 antibodies are detected, clinicians should perform a clinical evaluation for HIV-2 infection that is similar in scope to the evaluation of patients with HIV-1. (A1)

HIV IMMUNOASSAYS AVAILABLE IN NYS

See appendix in full guideline for information on FDA-approved HIV screening and diagnostic tests available for use in NYS, including:

- Clinical Laboratory Improvement Amendments (CLIA)-waived point-of-care HIV screening tests
- Rapid HIV screening tests
- Laboratory HIV screening tests
- Home-based tests
- Alternative HIV tests (oral and urine specimens)
- HIV tests that are not recommended

KEY POINTS

HIV-1/2 Antigen/Antibody Immunoassay (Step 1)

- Become familiar with the laboratory's internal testing algorithm and results-reporting policies. Many labs will reflex additional screening steps (such as HIV Ab differentiation immunoassay and HIV RNA) on the original sample without supplemental orders. Other labs may require additional samples or supplemental orders to complete all steps in the algorithm.
- When possible, collect blood by venipuncture for laboratory submission.
- Consult the specimen collection and handling instructions provided by the laboratory to ensure the specimen will be suitable for all tests in the algorithm.
- NYSDOH strongly recommends that all NYS birth facilities use the pediatric HIV testing services at the Wadsworth Center, which is free of charge for NYS clinicians providing care for HIV-exposed infants. For information about this service, contact the Wadsworth Center at 518-486-9605.

HIV-1/HIV-2 Antibody Differentiation Immunoassay (Step 2)

- If the Geenius HIV 1/2 Supplemental Assay interpretation is nonreactive or indeterminate for any HIV type (HIV-1, HIV-2, or untypable HIV), test the specimens for HIV-1 RNA, even if the result is HIV-2 indeterminate.
- Nonspecific reactivity could cause an HIV-2 indeterminate result to occur in some cases.
- If HIV-1 RNA is not detected and the Geenius Reader interpretation is HIV-2 indeterminate or HIV indeterminate, an HIV-2 NAT may be warranted.

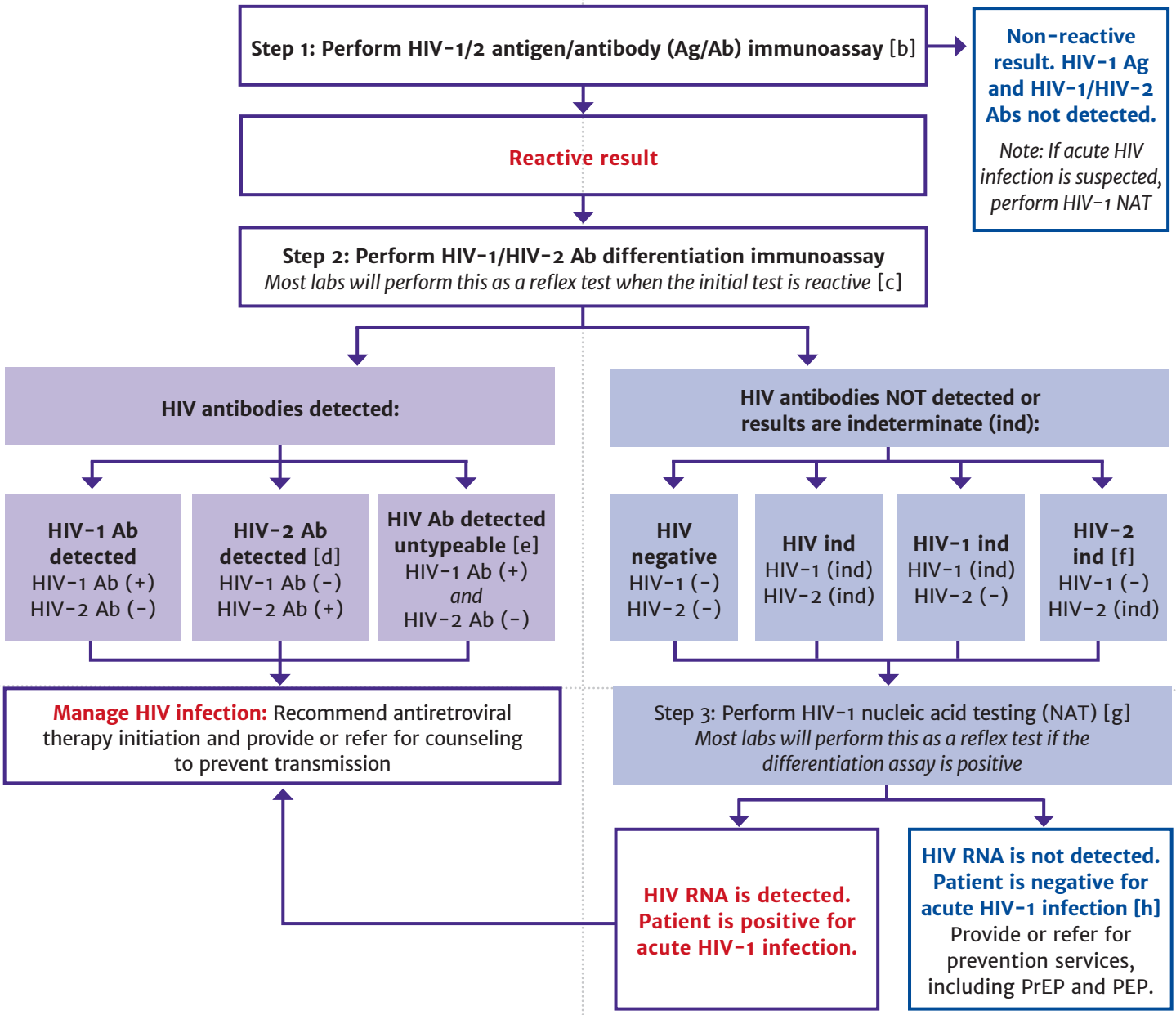
HIV-1 RNA Nucleic Acid Testing (Step 3)

- If the person being tested is taking antiretroviral agents as PEP, PrEP, or for rapid ART initiation, a false negative result for the HIV-1 RNA test may occur.

← 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*. Full guideline is available at hivguidelines.org.

FIGURE 2: HIV Laboratory Testing Algorithm [a]



Abbreviations: Ab, antibody; Ag, antigen; APHL, Association of Public Health Laboratories; CDC, Centers for Disease Control and Prevention; ind, indeterminate; FDA, U.S. Food and Drug Administration; NAT, nucleic acid test; NYSDOH, New York State Department of Health; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis.

Notes:

a. Adapted from CDC *2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens* and *APHL Suggested reporting language for the HIV laboratory diagnostic testing algorithm*.

b. APHL and CDC continue to recommend that laboratories use an FDA-approved instrumented HIV-1/HIV-2 Ag/Ab immunoassay as the initial assay in the laboratory HIV testing algorithm for serum or plasma due to their superior sensitivity for detecting acute HIV infection. However, the FDA-approved single-use rapid HIV-1/HIV-2 Ag/Ab immunoassay may be used as the initial assay in the laboratory HIV testing algorithm for serum or plasma if an instrumented assay is not available.

c. Become familiar with the laboratory's internal testing algorithm and results-reporting policies. Many labs will reflex additional screening steps (such as HIV Ab differentiation immunoassay and HIV RNA) on the original sample without supplemental orders. Other labs may require additional samples or supplemental orders to complete all steps in the algorithm.

d. This includes specimens reported as HIV-2 positive with HIV-1 cross-reactivity.

e. Further testing may be performed to determine type.

f. Per the Geenius package insert, specimens with this final assay interpretation should be retested with a new cartridge. If the final assay interpretation is again HIV-2 indeterminate, it should be reported as such and followed with an HIV-1 NAT.

g. Most laboratories reflex directly to an HIV-1 RNA test without requiring an additional test order or new specimen, either by performing the test in-house or referring the specimen to another laboratory. If the laboratory is unable to or does not automatically reflex directly to the RNA test, clinicians should order an HIV-1 RNA test as soon as possible. To reflex directly to an HIV-1 RNA test, a test kit approved by either the FDA or NYSDOH to aid in diagnosing HIV-1 infection is required. If HIV-1 RNA is detected, acute HIV-1 is present, and clinicians should proceed with clinical evaluation. If no HIV-1 RNA is detected, the initial immunoassay result is presumed false positive.

h. 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) if available. Alternatively, redraw and repeat algorithm in 2 to 4 weeks to assess HIV-2 infection.