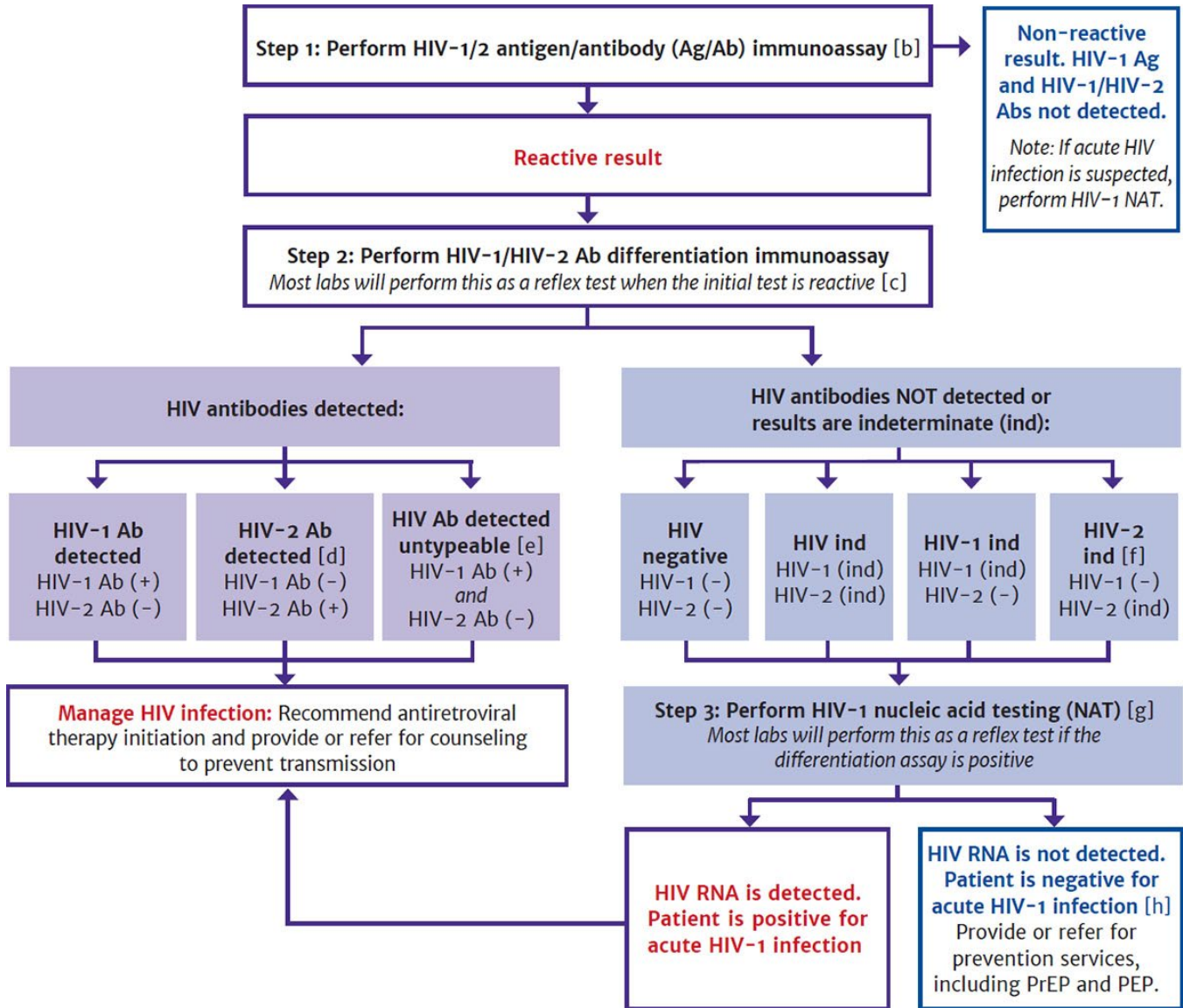




## HIV Testing

May 2022

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.

**Figure 2: HIV Laboratory Testing Algorithm [a]**

- 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 Ab 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.