HIV LABORATORY DIAGNOSTIC TESTING ALGORITHM

Public Health
IOWA HHS

The HIV Laboratory Diagnostic Testing Algorithm[1] should be used for testing serum or plasma to diagnose persons with HIV and for the confirmation of rapid HIV test results, starting from Step 1 of the algorithm, also commonly referred to as the screening test. CDC maintains lists of FDA-approved assays that can be used for Step 1 (the HIV-1/2 Antigen/Antibody [Ag/Ab] Immunoassay).[11] The algorithm recommends initial testing with an HIV-1/2 antigen/antibody immunoassay (IA) which, if reactive, is followed by supplemental testing. Recent updates from CDC allow for the Alere Determine HIV-1/2 Ag/Ab Rapid Test to be used in this first step for serum/plasma, though instrumented antigen/antibody immunoassays are preferred.5 Specimens that are reactive in Step 1 will undergo supplemental testing in Step 2 with an HIV-1/HIV-2 antibody differentiation assay. The only such assay currently FDA-approved and manufactured is the Geenius HIV-1/2 Supplemental Assay. Specimens with a Final Assay Interpretation of HIV antibody negative or indeterminate by the HIV-1/HIV-2 antibody differentiation assay require further testing in Step 3. Specimens with HIV-2 antibodies detected, including those with a Final Assay Interpretation of HIV-2 Positive and HIV-2 Positive with HIV-1 cross reactivity, do not require further testing. Step 3 is the HIV-1 NAT, of which there is currently only one FDA-approved test in this category. CDC maintains lists of FDA approved assays for supplemental testing including HIV-1/HIV-2 antibody differentiation immunoassays and HIV-1 NATs.[12]

Figure 2: Laboratory Testing Algorithm in Serum/Plasma
(modified from 2014 algorithm figure and CDC Quick Reference Guide)

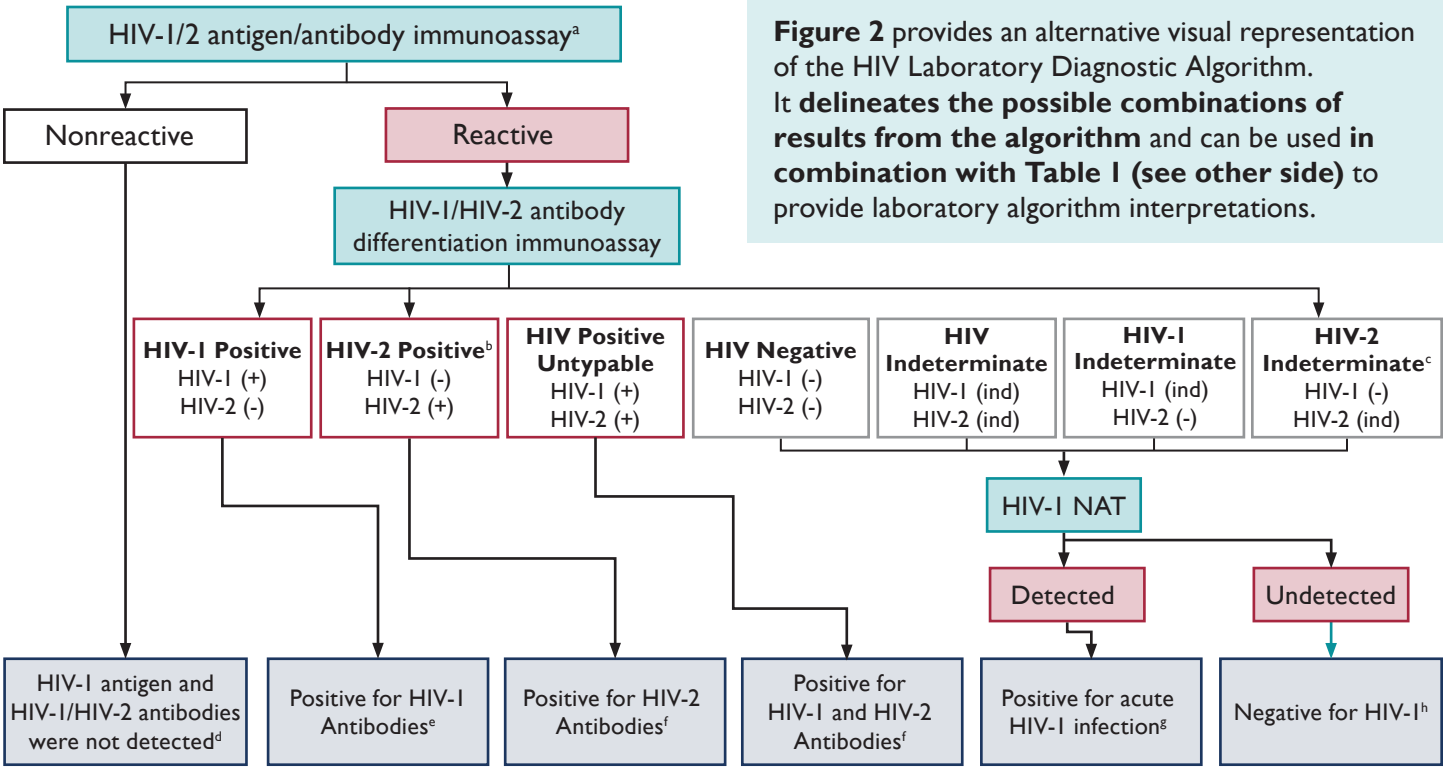

Figure 2 provides an alternative visual representation of the HIV Laboratory Diagnostic Algorithm. It **delineates the possible combinations of results from the algorithm** and can be used **in combination with Table 1 (see other side)** to provide laboratory algorithm interpretations.

a. APHL and CDC continue to recommend that laboratories use and FDA-approved instrumented HIV-1/HIV-2 antigen/antibody immunoassays as the initial assay 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 antigen/antibody immunoassay may be used as the initial assay the initial assay in the laboratory HIV testing algorithm for serum or plasma if an instrumental assay is not available. **b.** This includes specimens reported as HIV-2 positive with HIV-1 cross reactivity. **c.** 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. d. If recent HIV exposure is suspected or reported, conduct HIV-1 NAT or request a new specimen and repeat the algorithm according to CDC guidance. **e.** Link patient to HIV medical care and provide appropriate prevention counseling. **f.** Link patient to HIV medical care and provide appropriate prevention counseling. Provider may consider additional testing. **g.** Link patient to HIV medical care and provide appropriate prevention counseling immediately to expedite prevention practices. 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 2-4 weeks to assess HIV-2 infection.

Updated April 2023