TABLE 1: GUIDANCE FOR REPORTING RESULTS FROM THE HIV LABORATORY DIAGNOSTIC TESTING ALGORITHM FOR SERUM AND PLASMA

Guidance for Reporting Results from the HIV Laboratory Diagnostic Testing Algorithm for Serum and Plasma Specimens

Test Outcomes	Test Sequence			Laboratory Algorithm Interpretation[d]	Interpretation for Provider Use[e]	Further Actions[f]
	Step 1	Step 2	Step 3			
	HIV-1/HIV-2 Ag/Ab IA[b]	HIV-1/HIV-2 Antibody Differentiation IA[c]	HIV-1 NAT			
	Nonreactive	n/a	n/a	HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection.	HIV negative	If recent HIV exposure is suspected or reported, conduct HIV-1 NAT or request a new specimen and repeat the algorithm according to CDC Guidelines.[g]
	Reactive	HIV-1 Positive	n/a	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present.	HIV-1 Positive	Link patient to HIV medical care and provide appropriate prevention counseling.[h]
	Reactive	HIV-2 Positive	n/a	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	HIV-2 Positive	Link patient to HIV medical care and provide appropriate prevention counseling.[h]
	Reactive	HIV-2 Positive with HIV-1 Cross reactivity	n/a	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	HIV-2 Positive. This result is distinct from HIV positive untypable (undifferentiated).	Link patient to HIV medical care and provide appropriate prevention counseling.[h]
	Reactive	HIV Positive untypable (undifferentiated)	n/a	Positive for HIV-1 and HIV-2 antibodies. Laboratory evidence of HIV-1 and/or HIV-2 infection is present.	HIV Positive	Link patient to HIV medical care & provide appropriate prevention counseling.[h] Provider may consider additional testing for HIV-1 RNA **or** DNA and HIV-2 RNA **or** DNA to verify or rule out HIV-1/HIV-2 dual infection. Request additional specimen if original specimen volume is insufficient.
	Reactive	HIV-1 indeterminate or, HIV-2 indeterminate[i] or, HIV indeterminate	Detected	Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.	Acute HIV-1 Positive	Link patient to HIV medical care and provide appropriate prevention counseling immediately[h] to expedite prevention practices.
	Reactive	HIV-1 indeterminate	Not detected	HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.	HIV Negative	If recent HIV exposure is suspected or reported, request a new specimen and repeat the algorithm according to CDC guidance.[g]
	Reactive	HIV-2 indeterminate[i]	Not detected	HIV antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive.	HIV-1 Negative, HIV-2 inconclusive	Refer sample 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.
	Reactive	HIV Indeterminate	Not detected	HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected. HIV-2 inconclusive.	HIV-1 Negative, HIV-2 inconclusive	Refer sample 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.
	Reactive	HIV Antibody Negative	Detected	Positive for HIV-1. Laboratory evidence of HIV-1 infection consistent with an acute HIV-1 infection.	Acute HIV-1 Positive	Link patient to HIV medical care and provide appropriate prevention counseling immediately[h] to expedite prevention practices.
	Reactive	HIV Antibody Negative	Not detected	HIV antibodies were not confirmed and HIV-1 RNA was not detected.	HIV Negative	If recent HIV exposure is suspected or reported, request a new specimen and repeat the algorithm according to CDC guidance.[g]
	Reactive	HIV Antibody Negative or Indeterminate	Invalid or not performed	Inconclusive	Inconclusive	Request an additional specimen and repeat the algorithm. Ensure HIV-1 NAT is performed, if indicated by results of HIV-1/HIV-2 Ag/Ab IA and HIV-1/HIV-2 Ab differentiation IA.

For more information or any questions, please contact: STI Program, Bureau of HIV, STI, and Hepatitis, Iowa HHS | **Phone:** 515-281-3031 | **Fax:** 515-725-1278

a. The tests outlined in this table are not FDA approved for oral fluid or dried blood spots. **b.** The need for repeating screening immunoassay (IA) on an initial reactive test is assay dependent, refer to product package insert. **c.** This column contains the Final Assay Interpretation per the Geeniuspackage insert, the only FDA approved test for this step. We recommend excluding the individual HIV-1 and HIV-2 results on the laboratory report. If they are used the Geenius Final Assay Interpretation should also be included. d. This column contains suggested language to be used for the laboratory report and it can be directly used for reporting from LIMS systems. **e.** This column contains simplified language of the previous column, "Laboratory Algorithm Interpretation," and is included here for healthcare providers or other non-laboratorians that may also use this table as a reference document. This does not need to be included on the laboratory report. **f.** Comments under "Further Action" can be included as language in the laboratory report or can be used as guidance for laboratorians to discuss test results with healthcare providers or health department staff. **g.** Please refer to the Centers for Disease Control and Prevention Laboratory Guidance. Available at: https://www.cdc.gov/hiv/testing/laboratorytests.html, https://stacks.cdc.gov/view/cdc/38856 and https://www.cdc.gov/hiv/testing/clinical/index.html **h.** Please refer to the Centers for Disease Control and Prevention HIV Guidelines and Recommendations to find the most appropriate information by age and risk group for the patient in question. Available at: http://www.cdc.gov/hiv/guidelines **i.** Follow Geenius package insert and refer to the CDC Technical Update. Available at: https://stacks.cdc.gov/view/cdc/40790. *Updated June 2023*