Legacy LabAlert

March 2017

An Important Update from Legacy Laboratory Services

Updates to HIV Antibody Testing

Legacy Laboratory Services has adopted an enhanced automated method for HIV confirmatory testing, (Geenius ™ HIV 1/2 Supplemental Immunochromatographic Assay) as of February 21, 2017. The HIV Screen naming convention has changed to **HIV 1/2 Antibody and P24 Antigen Screen with Reflex (HIV SCN DIFF)** from HIV Combined Ab/Ag with Reflex (HIV 4).

Legacy Laboratory Services continues to follow the recommended CDC algorithm for HIV Screening (refer to Figure 1). All HIV screens are performed by the 4th generation Siemens Centaur HIV Combo Chemiluminescent Immunoassay. "Non-reactive" screens will be reported out immediately. "Reactive" screening tests will be reflexed to a confirmatory test that differentiates between HIV-1 and HIV-2 antibodies. The result will be turned out as either "Reactive", "Non-reactive", or "Inconclusive" for each HIV antibody. **To assist healthcare providers with completing the CDC algorithm, Laboratory Staff will contact providers on all "Inconclusive" results, to recommend they submit an additional order and a new specimen for HIV NAAT testing.**

The **HIV Differentiation and Confirmation Assay (HIV DIFF)** is available for those clients who perform their own 4th generation screen in-house and would like to send Legacy the confirmatory test only. HIV DIFF replaces the old HIVCONF assay. Specimen requirements are listed in Table 1.

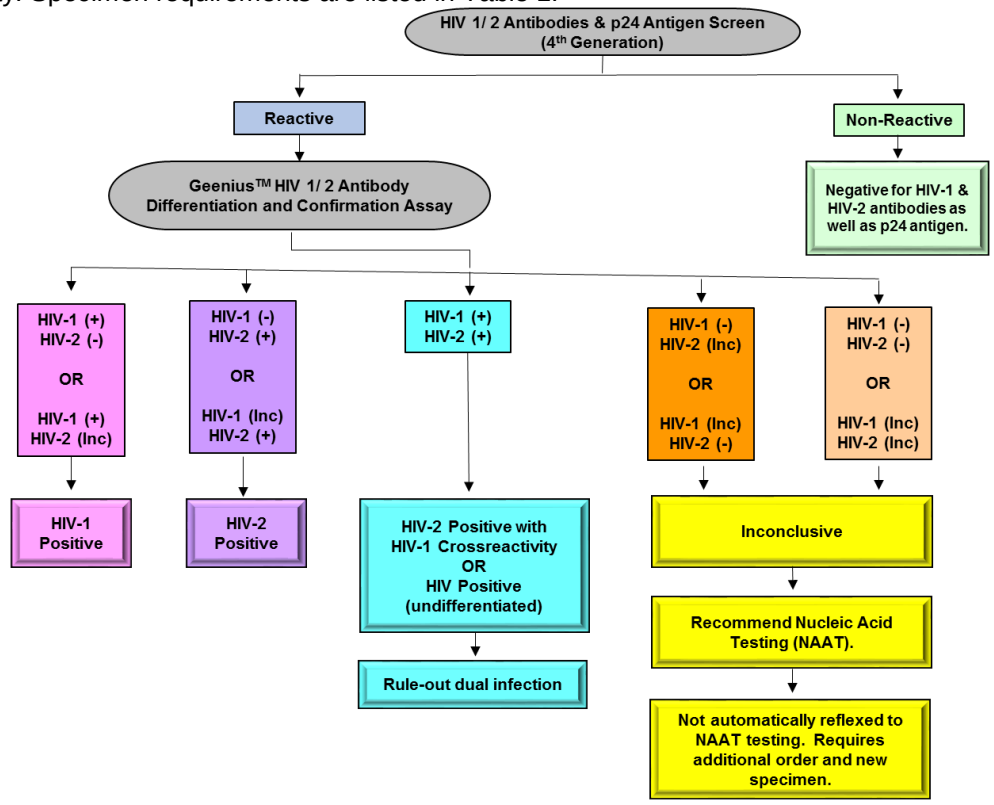

Figure 1: CDC HIV Algorithm – HIV Screen is reflexed to the differentiation assay. If HIV antibody cannot be typed as 1 or 2, then additional nucleic acid testing may be necessary.

Table 1: Specimen Requirements for HIV Testing

Name		HIV 1/2 Antibody and P24 Antigen Screen with Reflex	HIV 1/2 Differentiation and Confirmation Assay
Mnemonic		HIV SCN DIFF	HIV DIFF
Replaces		HIV 4	HIVCONF
Includes		**Screen:** HIV 1/ 2 Antibody and p24 Ag by CIA **Possible confirmation, if indicated:** • HIV 1/ 2 Differentiation • HIV NAAT	**Confirmation:** HIV 1/ 2 Differentiation **Possible confirmation, if indicated:** • HIV NAAT
Guidelines		The performance of the assay has not been established for the population of neonates. A disclaimer will accompany the results.	Legacy Laboratory Services performs this as a reflex for HIV Confirmation and Differentiation. The test is reflexed only from a fourth generation HIV Screening protocol.
Collect		Serum, one 5.0 mL gold (SST) or 7.0 mL red top tube	Serum, one 5.0 mL gold (SST) or 7.0 mL red top tube
Handling		Allow serum to clot completely at room temperature (minimum: 30 minutes). Centrifuge and separate from cells within 24 hours of collection.	Allow serum to clot completely at room temperature (minimum: 30 minutes). Centrifuge and separate from cells within 24 hours of collection.
Preferred Volume		1.5 mL Serum	1.0 mL Serum
Minimum Volume		0.5 mL Serum (*1.2 mL minimum whole blood draw*)	0.1 mL Serum (*0.6 mL minimum whole blood draw*)
Transport		Refrigerated (2-8 ºC)	Refrigerated (2-8 ºC)
Rejection Criteria		Cord blood, body fluids other than serum, neonatal specimens, cadaver specimens, heat inactivated specimens, and/or microbial contamination	Cord blood, body fluids other than serum, neonatal specimens, cadaver specimens, heat inactivated specimens, and/or microbial contamination
Stability	**Room Temperature (18-26°C)**	24 hours	24 hours
	Refrigerated (2-8°C)	48 hours	48 hours
	Frozen (< -20°C)	8 months	8 months
Method		**Screen:** Chemiluminescent Immunoassay **Possible confirmation, if indicated:** • Immunochromatographic Assay • Nucleic Acid Amplification Test	**Confirmation:** Immunochromatographic Assay **Possible confirmation, if indicated:** • Nucleic Acid Amplification Test
Reference Range		Interpretation provided.	Interpretation provided.
Comments		Reactive HIV screening results are automatically reflexed to HIV 1/ 2 Differentiation and Confirmation Assay. For non-reactive and inconclusive results, additional follow-up with HIV-1 NAAT testing is strongly recommended.	For non-reactive and inconclusive results, additional follow-up with HIV-1 NAAT testing is strongly recommended.
CPT Codes		HIV 1/2 Ab & p24 Ag Screen: 87389 Confirmation, if indicated: 86701-59 HIV NAAT, if indicated: 86702-59	Confirmation: 86701-59 HIV NAAT, if indicated: 86702-59

Reference: Quick reference guide for: Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. [stacks.cdc.gov/view/cdc/23447]. Published 6/27/2014.

For additional information, please contact your account representative, client services or consult our website:
Legacy Laboratory Client Services: 503-413-1234, 877-270-5566, www.legacyhealth.org\labservices