Louisiana Office of Public Health Laboratories	
Test Name	Human Immunodeficiency Virus (HIV)
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	87389, (reflex) Geenius HIV 1/2 Supplemental 86701
Synonyms	HIV, HIV-1/2, Anti-HIV 1/2 O, HIV Combo, 4th Gen HIV, Geenius.
Brief Description of Test	**HIV 1/2 Ag/Ab Combo** Simultaneous qualitative detection of Human Immunodeficiency Virus (HIV) p24 antigen and antibodies to HIV Type 1 (HIV-1 Groups M and O) and HIV Type 2 (HIV-2) on the EVOLIS™. It is intended as an aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in pediatric subjects (i.e., children as young as 2 years of age). Results cannot be used to distinguish between the presence of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody in a sample. **Geenius HIV 1/2** The Geenius™ HIV 1/2 Supplemental Assay is intended for use as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. It is intended for use as an additional, more specific test to confirm the presence of antibodies to HIV-1 and HIV-2 for specimens found to be repeatedly reactive by diagnostic screening procedures. The assay may also be used to confirm the presence of antibodies to HIV-1 and/or HIV-2 in pediatric patients (i.e., children as young as 2 years of age). **HIV-1 RNA** The HIV-1 RNA assay is no longer being offered. A new specimen will be requested and will be outsourced to a reference laboratory.
Possible Results	**HIV 1/2 Ag/Ab Combo** Nonreactive Reactive **HIV 1/2 Geenius** HIV Antibody Negative HIV-1 Indeterminate

	HIV-2 Indeterminate HIV Indeterminate HIV-1 Positive HIV-2 Positive HIV-2 Positive with HIV-1 cross-reactivity HIV Positive Untypable
Reference Range	Nonreactive or Negative
Specimen Type	Serum
Specimen Container(s):	Blood Serum Collection Tube or Screw-cap aliquot tube
Minimum volume accepted:	Request 1mL 275 µL serum for HIV Combo (does not allow for repeat testing) 5 µL serum for Geenius
Collection Instructions	Specimen Container – Serum Separator Tubes (SST) or Screw Cap Aliquot Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique. Complete a STD-HIV Lab Form to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, test requested, and submitter's name, address, and contact number. Two unique identifiers **MUST** be recorded on the tube **AND** the Lab form. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	2-8°C for 7 days
Causes for Rejection	• Unspun • Short Draw/Overfill • Hemolyzed • Received outside acceptable transport conditions • Incorrect source • Expired collection tubes
Limitations of the Procedure	**HIV 1/2 Ag/Ab Combo** The GS HIV Combo Ag/Ab EIA detects circulating antibodies to HIV-1(Groups M and O) and HIV-2, and it also detects HIV-1 p24 antigen. Thus, it is useful in evaluating patients with signs or symptoms of AIDS, and in establishing prior infection with HIV-1 or HIV-2. Clinical studies continue to clarify and refine the interpretation and medical significance of the presence of antibodies

	to HIV-1 or HIV-2. Repeatedly reactive specimens must be investigated by additional, more specific, or supplemental tests. Recommendations for appropriate use of such additional tests may be issued periodically by the United States Public Health Service. For individuals who are confirmed positive for HIV antigen or antibodies, appropriate counseling and medical evaluation should be offered. Both confirmation of the test results on a freshly drawn sample and counseling should be considered an important part of testing for HIV antigen and antibody to HIV-1 and HIV-2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically. Testing alone cannot be used to diagnose AIDS, even if the recommended investigation of repeatedly reactive specimens suggests a high probability that HIV antigen or antibody to HIV-1 or HIV-2 is present. A negative test result at any point in the investigation of individual subjects does not preclude the possibility of exposure to or infection with HIV-1 and/or HIV-2. Negative results can occur if the quantity of markers present in the sample is too low for the detection limits of the assay, or if the marker which is detected is not present during the stage of disease in which a sample is collected. The performance of this assay has not been established for individuals younger than 2 years of age. It is generally recognized that detection of HIV antibody in infants born to seropositive mothers is not adequate to diagnose HIV infection in the infant, since maternal IgG frequently persists for as long as 18 months after birth. Nearly all infants born to HIV-infected mothers passively acquire maternal antibody. Supplemental assays designed specifically for neonatal specimens may be helpful in resolving such cases, including HIV nucleic acid tests or viral culture. **Geenius** False negative result may occur in individuals infected with HIV-1 and/or HIV-2 who are receiving highly active antiretroviral therapy (HAART). A negative or indeterminate result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to a recent exposure may take several months to reach detectable levels. It is recommended that testing be repeated on a specimen freshly drawn after 2-4 weeks. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus; however, a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. It is recommend that testing be repeated on a specimen freshly drawn after 2-4 weeks.

	An “Indeterminate” interpretation does not exclude the possibility of early seroconversion of the test subject or a cross-reaction with other retroviruses. The homology between HIV-1 and HIV-2 viruses can lead to cross reactivity between anti-HIV-1 and anti-HIV-2 antibodies. It is recommended that testing be repeated on a specimen freshly drawn after 2-4 weeks. Samples that meet the HIV-1 Positive criteria may, in some rare cases, show cross reactivity on one of the HIV-2 envelope bands. In most of the cases, this profile that confirms an HIV-1 infection does not exclude the rare possibility of a secondary HIV-2 seroconversion (co-infection). Samples which meet the HIV-2 Positive criteria can show cross reactivity on one or more HIV-1 bands. In most cases, an HIV-1 Indeterminate profile associated with an HIV-2 Positive profile is a true HIV-2 only infection. However it does not exclude the possibility of a secondary HIV-1 seroconversion (co-infection). Samples that meet both HIV-1 and HIV-2 Positive criteria, but are reactive with only one detected envelope band (gp160 or gp41), are generally HIV-2 positive samples which show HIV-1 cross reactivity. This represents 54% of the cases in the clinical study of 200 samples characterized as HIV-2 only infections. Such profiles do not exclude the rare possibility of HIV-1 and HIV-2 co-infection. Samples with reactivity to all 4 envelope bands (all of the HIV-1 envelope and HIV-2 envelope bands) have all been HIV-2 positive samples with HIV-1 reactivity that cannot be differentiated (HIV Untypable or Undifferentiated). Such samples represent 6% of the cases in the clinical study of 200 samples that have been characterized as positive for HIV-2 only. Such profiles do not exclude the possibility of HIV-1 and HIV-2 co- infection, which are rare. Only one (1) plasma sample of the total 1,043 samples for 299 patients with known HIV-1 infections was found to be HIV Untypable or Undifferentiated.
Interfering Substances	Extensive hemolysis may affect test performance. The potential interfering substances at the levels tested below did not produce a change in clinical interpretation: Hemolyzed: 500 mg/dL of hemoglobin Lipemic: 1000 mg/dL of triglycerides Icteric: 20 mg/dL of bilirubin Proteinemic: 12 g/dL of protein
References	GS HIV Combo Ag/Ab EIA Package Insert Geenius HIV 1/2 Supplemental Assay Instructions for Use Geenius™ Reader and Software User Manual EVOLIS™ Operator Manual

Additional Information	If HIV Antigen and Antibody, 4th Generation Screen is Repeatedly Reactive, HIV-1/2 Antibody Differentiation will be reflexed.
Release Date	10/18/2019
Warning: If you have printed a copy of this information please be advised that the Louisiana Office of Public Health Laboratories website and methods are updated on a regular basis. Please check the on-line version of this document to ensure you are relying on the most recent release.	