CPAL
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HIV Ag/Ab Combo Assay

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Effective Date:
March 1, 2011

NOTE: The current HIV 1/2 Plus O Antibody Screen assay (Test Code 3400010) will be discontinued after March 15, 2011.

Reference Range:
Non Reactive

Summary:
Effective March 1, 2011, CPAL will be offering a new **HIV Ag/Ab Combo Assay (Test Code: 3400700)**. This assay will be performed on the Abbott Architect testing platform. The Architect HIV Ag/Ab Combo uses anti-HIV p24 antibodies as reagents to detect HIV-1 p24 antigen, thereby decreasing the window period and improving early detection of HIV infection. The ARCHITECT HIV Ag/Ab Combo assay is a chemiluminescent microparticle immunoassay (CMIA) for the simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV-1 group M and group O) and/or type 2 (HIV-2) in human serum and plasma (EDTA and heparin). The ARCHITECT HIV Ag/Ab Combo assay is intended to be used as an aid in the diagnosis of HIV-1/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/HIV-2 infection in pediatric subjects (i.e., children as young as two years of age) and in pregnant women.

An ARCHITECT HIV Ag/Ab Combo reactive result does not distinguish between the detection of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody.

Specimens:

Serum or plasma specimens may be used in the test. The following specimen and tube types have all been evaluated and found to be acceptable:

A. ***GLASS collection tube***: serum, tri-potassium (k3) EDTA, disodium (Na2) EDTA.
B. **Plastic collection tube:** serum with or without separator, lithium heparin with gel separator, sodium heparin, and plasma w/ dipotassium EDTA (with or without gel separator).

Handling and Storage:

Samples may be stored at 22°C (Room Temp) for no longer than 3 days. If the assay will not be completed within 3 days, refrigerate the sample at 2-8°C. If the assay will not be completed within 7 days, remove the sample from the clot or separator and freeze at -20°C. Avoid more than 5 freeze/thaw cycles.

Results: Initially reactive specimens will be retested in duplicate. If both retest results are nonreactive; the specimen is considered negative for HIV Ag/Ab. If one or both retest results are reactive, the specimen is considered repeatedly reactive for the presence of HIV Ag/Ab and will be sent out for HIV-1 Western Blot testing. If the HIV-1 blot is negative, subsequent HIV-2 antibody testing will be ordered.

Limitations of the Procedure:

1. The interpretation of specimens with a final result of reactive by the ARCHITECT HIV Ag/Ab Combo assay and indeterminate by supplemental testing is not definitive; further clarification may be obtained by testing another specimen taken at least 1 month later.
2. The ARCHITECT HIV Ag/Ab Combo assay result and supplemental assay results should be interpreted in conjunction with the patient's clinical presentation, history, and other laboratory results. If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
3. An individual who has antibodies to HIV is presumed to be infected with the virus; however, an individual who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation, and possibly additional testing to determine whether a diagnosis of HIV infection is accurate.
4. A test result that is nonreactive does not exclude the possibility of exposure to or infection with HIV-1 and/or HIV-2. Nonreactive results in this assay for individuals with prior exposure to HIV-1 and/or HIV-2 may be due to antigen and antibody levels that are below the limit of detection of this assay.
5. The performance of this assay has not been established for individuals younger than 2 years of age. Nearly all infants born to HIV-infected mothers passively acquire maternal antibody and, in some cases, will test antibody positive until age 18 months regardless of whether they

are infected. Definitive diagnosis of HIV infection in early infancy requires other assays, including HIV nucleic acid tests and viral culture.

6. Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed results when tested with assay kits (such as ARCHITECT HIV Ag/Ab Combo) that employ mouse monoclonal antibodies. ARCHITECT HIV Ag/Ab Combo reagents contain a component that reduces the effect of HAMA reactive specimens.
7. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous results may be observed. Additional information may be required for diagnosis.