HIV AG/AB COMBO SCREEN
HIV-1, HIV-2 CONFIRMATION

Effective December 16, 2014, the clinical laboratory will switch methodologies for the HIV screening test and for the HIV confirmation test. The screening test will switch from the Siemens ADVIA Centaur 3rd generation HIV1/2 antibody assay to the Abbott ARCHITECT i1000 4th generation assay that includes the P24 antigen, as well as antibodies to HIV-1 and HIV-2. The new confirmation test, the BioRad Multispot HIV-1/HIV-2, detects and distinguishes between HIV-1 and HIV-2 antibodies and will replace the former Western Blot confirmation that detected only HIV-1 antibodies. Samples repeatedly reactive by the screening test will automatically reflex to the confirmation test. (The confirmation test is not orderable as a stand-alone test in the EMR.)

Sample Requirements: Collect - SST (gold top) or plain red top serum or EDTA plasma, 4 mL

Patient Preparation: None

Storage/Transport: Deliver at room temperature to the laboratory for processing. If sample cannot be delivered to the laboratory within 8 hours of collection, centrifuge sample and transport separated serum or plasma refrigerated at 2-8°C.

Stability: Separated serum/plasma: Room temperature for 48 hrs; refrigerated 2-8°C for 7 days, or frozen at -20°C for longer storage.

Minimum Volume: 0.5 mL serum/plasma

Unacceptable Conditions: samples other than serum or EDTA plasma; samples not held at correct temperature; and grossly hemolyzed samples.

Reference Interval: Nonreactive

Interpretive Information:
This Abbott ARCHITECT 4th generation screening assay detects 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, but does not distinguish between the presence of HIV-1 p-24 antigen, HIV-1 antibody, and HIV-2 antibody. The BioRad Multispot HIV-1/HIV-2 confirmation assay will distinguish between HIV-1 and HIV-2 antibodies, but doesn’t detect antigen. As with all immunoassays, the Architect HIV Ag/Ab Combo screening assay may yield nonspecific reactions due to other causes. The screening and confirmation 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 such as HIV-1 Viral Load is suggested to confirm the result.
**Vaccine.** 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.

The performance of the Abbott ARCHITECT 4th generation screening 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 or viral culture.

The lab continues to offer the Ora-Quick Rapid HIV screening test used for Needlestick panels; also the lab continues to offer HIV-1 Viral load testing. There have been no changes in methodologies for these two assays.

**Routine Testing:**
- HIV Ag/Ab Combo Screen – Daily, Mon-Fri, dayshift in Special Chemistry at the STC lab site.
- HIV-1, HIV-2 Confirmation test – Results will be available within 72 hours.

If you have questions or need additional information, please contact Laboratory Client Services at (916) 734-7373 or email pathologyclientservices@ucdmc.ucdavis.edu.