



Screening and Diagnostic Testing

Test Name	Test Code	Specimen Requirements	Clinical Use Summary
HIV-1/2 Ag/Ab 4th Generation w/reflexes	3682	4 mL refrigerated serum from an SST (2 mL min).	Screen for and confirm HIV-1/HIV-2 infection, including acute infection; differentiate HIV-1 from HIV-2 infection. Repeatedly reactive screening results are reflexed to the supplemental HIV-1/2 antibody differentiation test at an additional charge; negative and indeterminate HIV-1/2 antibody differentiation results are reflexed to the HIV-1 Qualitative RNA, TMA test at an additional charge.
HIV 1/2 Antibody Differentiation, w/reflex HIV-1, Qualitative TMA (Supplemental assay)	906419	2 mL refrigerated serum from an SST or RT (1 mL min).	Intended to be used for the exclusion or confirmation of an HIV infection, after the initial screen is positive, as well as aid in discriminating between HIV-1 or HIV-2. If HIV 1/2 Antibody Differentiation is negative or indeterminate, HIV-1, Qualitative TMA will be performed at an additional charge.

Monitoring - Viral Load Testing

Test Name	Test Code	Specimen Requirements	Clinical Use Summary
HIV-1 Quantitative Real-Time PCR	902581	6 mL frozen EDTA plasma (3 mL minimum) collected in two EDTA lavender-top tubes. Centrifuge within 24 hours of collection and transfer plasma to a screw cap polypropylene vial prior to freezing.	Viral load test with linear range of 20 - 10,000,000 copies/mL (1.30 - 7.00 LogCopies/mL). Used to monitor drug therapy and disease progression.
HIV-1 DNA PCR, Qualitative	3753	3 mL refrigerated whole blood from a lavender-top (EDTA) tube (1 mL minimum). Do not freeze.	Diagnostic test with analytical sensitivity to 10 copies/mL; Used to detect the integrated (proviral) form of HIV-1 DNA.
HIV-1 Quantitative w/reflex to HIV-1 Genotype	904561	6 mL frozen EDTA plasma (3 mL minimum) collected in two EDTA lavender-top tubes. Centrifuge within 24 hours of collection and transfer plasma to a screw cap polypropylene vial prior to freezing.	Provides a direct assessment of viremia and should be used in conjunction with CD4+T-cell counts. Useful in patients to assess prognosis, monitor progression of HIV-1 infection, determine when to initiate therapy, and monitor effectiveness of antiretroviral therapy. Reflexes to genotype if ≥400 copies/mL (2.6 LogCopies/mL).





Monitoring - Flow Cytometry Testing

Test Name	Test Code	Specimen Requirements	Clinical Use Summary				
CD4, Absolute & Percent (includes WBC)	801133	4 mL room temperature lavender-top (EDTA) tube (1 mL minimum). Affix "Room Temperature" label to specimen bag. Specimen must reach the laboratory within 18 hours of collection.	Determine immune status of patients with HIV infection; Monitor anti-retroviral and immunosuppressive therapy; Used for differential diagnosis of congenital and acquired immune deficiencies.				
CD4/CD8 Panel (CD3; CD4; CD8 & CD4/8 Ratio; WBC & Absolute Counts)	205927	4 mL room temperature lavender-top (EDTA) tube (1 mL minimum). Affix "Room Temperature" label to specimen bag. Specimen must reach the laboratory within 18 hours of collection.	Determine immune status of patients with HIV infection; Monitor anti-retroviral and immunosuppressive therapy; Used for differential diagnosis of congenital and acquired immune deficiencies.				
Resistance Testing	Resistance Testing and Drug Selection						
HIV-1 Genotype	11888	3 mL frozen EDTA plasma from an LT or PPT white-top tube* (1 mL min). Centrifuge within 24 hours of collection and transfer plasma to a plastic vial.	Intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment.				
HIV-1 Genotyping, Pr & RT, DNA Sequencing	906139	4 mL frozen EDTA plasma from an LT or PPT white-top tube* (1 mL min). Centrifuge within six hours of collection and transfer plasma to a plastic vial.	Detects drug resistant associated mutations present in the patient's HIV viral genome, sequencing a total of 400 codons including both protease (Pr) and reverse transcriptase (RT) coding regions. Requires a viral load of at least 2000 copies/mL.				
HLA-B*5701 Typing	902652	5 mL room temperature whole blood collected in a lavender-top tube (3 mL min).	Used to determine Abacavir ("ABC") hypersensitivity reaction ("HSR") to determine patient eligibility for Epzicom and other ABC containing products. In Abacavir-naive patients, HLA-B*5701 genotyping may be useful for risk stratification.				
HIV-1 Coreceptor Tropism, Ultradeep Sequencing	906729	2 mL frozen EDTA plasma from an LT or PPT white-top tube* (0.6 mL min). Centrifuge within 24 hours of collection and transfer plasma to a plastic vial.	Detects the presence of HIV-1 envelope V3 loop variants associated with CXCR4 (X4) coreceptor utilization. The use of CCR5 coreceptor antagonists to treat HIV-1 is not recommended for patients harboring X4-tropic virus. [HIV-1 Coreceptor Tropism results of 'Not Detected' reflex to Ultradeep Sequencing at an additional charge]				
HIV-1 Integrase Genotype	904506	2 mL frozen EDTA plasma from an LT or PPT white-top tube* (0.6 mL min). Centrifuge within 24 hours of collection and transfer plasma to a plastic vial.	Amplifies and sequences the HIV-1 integrase gene and reports mutations at positions associated with integrase inhibitor drug resistance.				

Tests on this chart may change periodically.

*Frozen PPT white-top tubes are NOT acceptable.