

Laboratory Testing

Laboratory Testing for Initial Assessment and Monitoring of HIV-Infected Patients on Antiretroviral Therapy (Last updated July 14, 2016; last reviewed July 14, 2016)

A number of laboratory tests are important for initial evaluation of HIV-infected patients upon entry into care, and before and after initiation or modification of antiretroviral therapy (ART) to assess the virologic and immunologic efficacy of ART and to monitor for laboratory abnormalities that may be associated with antiretroviral (ARV) drugs. [Table 3](#) outlines the Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel)'s recommendations on the frequency of testing. As noted in the table, some tests may be repeated more frequently if clinically indicated.

Two surrogate markers are routinely used to monitor HIV-infected patients: CD4 T lymphocyte cell count to assess immune function and plasma HIV RNA (viral load) to assess level of HIV viremia. Resistance testing should be used to guide selection of an ARV regimen. A viral tropism assay should be performed before initiation of a CCR5 antagonist or at the time of virologic failure that occurs while a patient is receiving a CCR5 antagonist. HLA-B*5701 testing should be performed before initiation of abacavir. Patients should be screened for hepatitis B and hepatitis C virus infection before initiating ART, as treatment of these coinfections may affect the choice of ART. The rationale for and utility of these laboratory tests are discussed in the corresponding sections of the guidelines.

Table 3. Laboratory Testing Schedule for Monitoring HIV-Infected Patients Before and After Initiation of Antiretroviral Therapy^a (page 1 of 2)

Laboratory Test	Timepoint/Frequency of Testing								
	Entry into Care	ART Initiation ^b or Modification	2 to 8 Weeks After ART Initiation or Modification	Every 3 to 6 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated	If ART Initiation is Delayed ^c
HIV Serology	√ If HIV diagnosis has not been confirmed								
CD4 Count	√	√		√ During first 2 years of ART or if viremia develops while patient on ART or CD4 count <300 cells/mm ³		√ <u>After 2 years on ART with Consistently Suppressed Viral Load:</u> CD4 Count 300–500 cells/mm ³ : • Every 12 months CD4 Count >500 cells/mm ³ : • CD4 monitoring is optional	√	√	√ Every 3-6 months
HIV Viral Load	√	√	√ ^d	√ ^e	√ ^e		√	√	Repeat testing is optional
Resistance Testing	√	√ ^f					√	√	√ ^f
HLA-B*5701 Testing		√ If considering ABC							
Tropism Testing		√ If considering a CCR5 antagonist					√ If considering a CCR5 antagonist or for failure of CCR5 antagonist-based regimen	√	

Table 3. Laboratory Testing Schedule for Monitoring HIV-Infected Patients Before and After Initiation of Antiretroviral Therapy^a (page 2 of 2)

Laboratory Test	Timepoint/Frequency of Testing								
	Entry into Care	ART Initiation ^b or Modification	2 to 8 Weeks After ART Initiation or Modification	Every 3 to 6 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated	If ART Initiation is Delayed ^c
Hepatitis B Serology ^{g,h}	√	√ May repeat if patient is nonimmune and not chronically infected with HBV ^h				√ May repeat if patient is nonimmune and not chronically infected with HBV ^h		√	
Hepatitis C Antibody Test (if positive, confirm with HCV RNA test)	√	√ May repeat for at-risk patients if negative result at baseline				√ May repeat for at-risk patients if negative result at baseline		√	
Basic Chemistry ^{ij}	√	√	√	√				√	√ Every 6-12 months
ALT, AST, T. bilirubin	√	√	√	√				√	√ Every 6-12 months
CBC with Differential	√	√	√ If on ZDV	√ If on ZDV or if CD4 testing is done	√			√	√ Every 3-6 months
Fasting Lipid Profile ^k	√	√			√ If abnormal at last measurement	√ If normal at last measurement		√	√ If normal at baseline, annually
Fasting Glucose or Hemoglobin A1C	√	√		√ If abnormal at last measurement		√ If normal at last measurement		√	√ If normal at baseline, annually
Urinalysis ^{il}	√	√			√ If on TAF or TDF ^l	√		√	
Pregnancy Test		√ In women with child-bearing potential						√	

^a This table pertains to laboratory tests done to select an ARV regimen and monitor for treatment responses or ART toxicities. Please refer to the HIV Primary Care guidelines for guidance on other laboratory tests generally recommended for primary health care maintenance of HIV patients.¹

^b If ART initiation occurs soon after HIV diagnosis and entry into care, repeat baseline laboratory testing is not necessary.

^c ART is indicated for all HIV-infected individuals and should be started as soon as possible. However, if ART initiation is delayed, patients should be retained in care, with periodic monitoring as noted above.

^d If HIV RNA is detectable at 2 to 8 weeks, repeat every 4 to 8 weeks until viral load is suppressed to <200 copies/mL, and thereafter, every 3 to 6 months.

^e In patients on ART, viral load typically is measured every 3 to 4 months. However, for adherent patients with consistently suppressed viral load and stable immunologic status for more than 2 years, monitoring can be extended to 6-month intervals.

^f Based on current rates of transmitted drug resistance to different ARV medications, standard genotypic drug-resistance testing in ARV-naive persons should focus on testing for mutations in the reverse transcriptase (RT) and protease (PR) genes. If transmitted integrase strand transfer inhibitor (INSTI) resistance is a concern, providers should also test for resistance mutations to this class of drugs. In ART-naive patients who do not immediately begin ART, repeat testing before initiation of ART is optional if resistance testing was performed at entry into care. In virologically suppressed patients who are switching therapy because of toxicity or for convenience, viral amplification will not be possible; therefore, resistance testing should not be performed. Results from prior resistance testing can be helpful in constructing a new regimen.

^g If HBsAg is positive, TDF or TAF plus either FTC or 3TC should be used as part of the ARV regimen to treat both HBV and HIV infections. Preliminary data from clinical trials have demonstrated TAF activity against HBV. Final results from ongoing clinical trials will help to define the role of TAF in the treatment of HBV/HIV coinfection.

^h If HBsAg, HBsAb, and anti-HBc are negative, hepatitis B vaccine series should be administered. Refer to HIV Primary Care and Opportunistic Infections guidelines for more detailed recommendations.^{1,2}

ⁱ Serum Na, K, HCO₃, Cl, BUN, creatinine, glucose (preferably fasting), and creatinine-based estimated glomerular filtration rate. Serum phosphorus should be monitored in patients with chronic kidney disease who are on TAF- or TDF-containing regimens.³

^j Consult the Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America for recommendations on managing patients with renal disease.³ More frequent monitoring may be indicated for patients with evidence of kidney disease (e.g., proteinuria, decreased glomerular filtration) or increased risk of renal insufficiency (e.g., patients with diabetes, hypertension).

^k Consult the National Lipid Association's recommendations for management of patients with dyslipidemia.⁴

^l Urine glucose and protein should be assessed before initiating TAF- or TDF-containing regimens, and monitored during treatment with these regimens.

Key to Acronyms: 3TC = lamivudine; ABC = abacavir; ALT = alanine aminotransferase; ART = antiretroviral therapy; AST = aspartate aminotransferase; BUN = blood urea nitrogen; CBC = complete blood count; Cl = chloride; CrCl = creatinine clearance; EFV = efavirenz; FTC = emtricitabine; HBsAb = hepatitis B surface antibody; HBsAg = hepatitis B surface antigen; HBV = hepatitis B virus; HCO₃ = bicarbonate; K = potassium; NA = sodium; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; ZDV = zidovudine

References

1. Aberg JA, Gallant JE, Ghanem KG, Emmanuel P, Zingman BS, Horberg MA. Primary care guidelines for the management of persons infected with HIV: 2013 update by the HIV medicine association of the Infectious Diseases Society of America. *Clin Infect Dis*. Jan 2014;58(1):e1-34. Available at <http://www.ncbi.nlm.nih.gov/pubmed/24235263>.
2. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf. Accessed June 6, 2016.
3. Lucas GM, Ross MJ, Stock PG, et al. Clinical practice guideline for the management of chronic kidney disease in patients infected with HIV: 2014 update by the HIV Medicine Association of the Infectious Diseases Society of America. *Clin Infect Dis*. Nov 1 2014;59(9):e96-138. Available at <http://www.ncbi.nlm.nih.gov/pubmed/25234519>.
4. Jacobson TA, Ito MK, Maki KC, et al. National lipid association recommendations for patient-centered management of dyslipidemia: part 1—full report. *J Clin Lipidol*. Mar-Apr 2015;9(2):129-169. Available at <http://www.ncbi.nlm.nih.gov/pubmed/25911072>.