Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

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Laboratory Testing

Laboratory Testing for Initial Assessment and Monitoring While on Antiretroviral Therapy (Last updated February 12, 2013; last reviewed February 12, 2013)

A number of laboratory tests are important for initial evaluation of HIV-infected patients upon entry into care, during follow-up (if antiretroviral therapy (ART) has not been initiated), and before and after the initiation or modification of therapy to assess 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's recommendations for 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 assess the immune function and level of HIV viremia: CD4 T-cell count (CD4 count) and plasma HIV RNA (viral load). 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; and HLA-B*5701 testing should be performed before initiation of abacavir (ABC). The rationale for and utility of these laboratory tests are discussed below.

Table 3. Laboratory Monitoring Schedule for Patients Before and After Initiation of Antiretroviral Therapy[a] (page 1 of 2)

	Entry into care	Follow-up before ART	ART initiation or modification[b]	Follow-up 2–8 weeks post-ART initiation or modification	Every 3–6 months	Every 6 months	Every 12 months	Treatment failure	Clinically indicated
HIV serology	√ If diagnosis has not been confirmed								
CD4 count	√	√ Every 3–6 months	√		√	In clinically stable patients with suppressed viral load, CD4 count can be monitored every 6–12 months (see text).		√	√
HIV viral load	√	√ Every 3–6 months	√	√[c]	√[d]			√	√
Resistance testing	√		√[e]					√	√
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	√
Hepatitis B serology[f]	√		√ May repeat if HBsAg (-) and HBsAb (-) at baseline						√
Hepatitis C serology, with confirmation of positive results	√								√
Basic chemistry[g,h]	√	√ Every 6–12 months	√	√	√				√

Table 3. Laboratory Monitoring Schedule for Patients Before and After Initiation of Antiretroviral Therapy[a] (page 2 of 2)

	Entry into care	Follow-up before ART	ART initiation or modification[b]	Follow-up 2–8 weeks post-ART initiation or modification	Every 3–6 months	Every 6 months	Every 12 months	Treatment failure	Clinically indicated
ALT, AST, T. bilirubin	√	√ Every 6–12 months	√	√	√				√
CBC with differential	√	√ Every 3–6 months	√	√ If on ZDV	√				√
Fasting lipid profile	√	√ If normal, annually	√	√ Consider 4–8 weeks after starting new ART regimen that affects lipids		√ If abnormal at last measurement	√ If normal at last measurement		√
Fasting glucose or hemoglobin A1C	√	√ If normal, annually	√		√ If abnormal at last measurement	√ If normal at last measurement			√
Urinalysis[g]	√		√			√ If on TDF[i]	√		√
Pregnancy test			√ If starting EFV						√

[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] ART may be modified for treatment failure, adverse effects, or regimen simplification.

[c] If HIV RNA is detectable at 2 to 8 weeks, repeat every 4 to 8 weeks until suppression to <200 copies/mL, then every 3 to 6 months.

[d] Viral load typically is measured every 3 to 4 months in patients on ART. However, for adherent patients with suppressed viral load and stable immunologic status for more than 2 to 3 years, monitoring at 6 month intervals may be considered.

[e] In ART-naive patients, if resistance testing was performed at entry into care, repeat testing before initiation of ART is optional. The exception is pregnant women; repeat testing is recommended in this case. For virologically suppressed patients who are switching therapy for toxicity or convenience, viral amplification will not be possible and therefore resistance testing should not be performed. Results from prior resistance testing can be used to help in the construction of a new regimen.

[f] If HBsAg is positive at baseline or before initiation of ART, TDF plus either FTC or 3TC should be used as part of the ARV regimen to treat both HBV and HIV infections. If HBsAg, and HBsAb, and anti-HBc are negative at baseline, hepatitis B vaccine series should be administered.

[g] Serum Na, K, HCO_3, Cl, BUN, creatinine, glucose (preferably fasting). Some experts suggest monitoring the phosphorus levels of patients on TDF. Determination of renal function should include estimation of CrCl using Cockcroft-Gault equation or estimation of glomerular filtration rate based on MDRD equation.

[h] For patients with renal disease, 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.[2]

[i] More frequent monitoring may be indicated for patients with evidence of kidney disease (e.g. proteinuria, decreased glomerular dysfunction) or increased risk of renal insufficiency (e.g., patients with diabetes, hypertension).

Acronyms: 3TC = lamivudine, ABC = abacavir, ALT = alanine aminotransferase, ART = antiretroviral therapy, AST = aspartate aminotranserase, CBC = complete blood count, CrCl = creatinine clearance, EFV = efavirenz, FTC = emtricitabine, HBsAb = hepatitis B surface antibody, HBsAg = hepatitis B surface antigen, HBV = hepatitis B virus, MDRD = modification of diet in renal disease (equation), TDF = tenofovir, ZDV = zidovudine

References

1. Aberg JA, Kaplan JE, Libman H, et al. Primary care guidelines for the management of persons infected with human immunodeficiency virus: 2009 update by the HIV medicine Association of the Infectious Diseases Society of America. *Clin Infect Dis*. Sep 1 2009;49(5):651-681. Available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=19640227.
2. Gupta SK, Eustace JA, Winston JA, et al. 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. *Clin Infect Dis*. Jun 1 2005;40(11):1559-1585.Available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15889353.