LABORATORY TESTING

Laboratory Testing for Initial Assessment and Monitoring of People With HIV

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Several laboratory tests are important for initial evaluation of people with HIV upon entry into care. Some tests should be performed 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.

Two surrogate markers have been used to monitor people with HIV: (1) plasma HIV RNA (viral load) to assess the level of HIV viremia and (2) CD4 T lymphocyte (CD4) cell count to assess immune function. Standard (reverse transcriptase and protease) genotypic drug-resistance testing should be used to guide selection of an ARV regimen; if integrase strand transfer inhibitor (INSTI) resistance is a concern due to potential transmitted resistance or previous use of an INSTI for pre-exposure prophylaxis (e.g., long-acting cabotegravir), post-exposure prophylaxis, or treatment, providers should ensure that genotypic resistance testing also includes the integrase gene (see Drug-Resistance Testing). For guidance on the choice of ARV regimens before drug-resistance testing results become available, clinicians should consult the What to Start and Early (Acute or Recent) HIV Infection sections. A viral tropism assay should be performed before initiation of a CCR5 antagonist or at the time of virologic failure if a person is receiving a CCR5 antagonist. HLA-B*5701 testing should be performed before initiation of abacavir (ABC) to reduce the risk of hypersensitivity reaction, and HLA-B*5701-positive people should not be prescribed ABC. People should be screened for hepatitis B virus (HBV) and hepatitis C virus infections before initiating ART and, if indicated, periodically after ART initiation, because treatment of these coinfections may affect the choice of ART and likelihood of drug-induced hepatotoxicity. Before initiating nucleoside reverse transcriptase inhibitor (NRTI)–sparing or NRTI-limited ARV regimens, HBV serology testing should be performed in people who are not known to have chronic HBV (see Hepatitis B Virus/HIV Coinfection). The rationale for and utility of some of these laboratory tests are discussed in the corresponding sections of the guidelines.

Currently available newer ARVs are generally easy to take and typically do not cause significant laboratory abnormalities. Most people with HIV achieve and maintain viral suppression and have improvement in CD4 count within 1 year after starting ART. Table 3 provides general guidance on the frequency of laboratory monitoring before initiation of and throughout treatment with ART. However, more frequent monitoring of selected tests may be needed as clinically indicated, based on issues such as responses to therapy, underlying medical conditions, drug-related adverse effects, engagement in care, and adherence to therapy. ART is recommended for all people with HIV **(AI);** Table 4 provides guidance for laboratory monitoring in the rare occasions when ART initiation is deferred.

Table 3. Laboratory Testing Schedule Before and After Antiretroviral Therapy Initiation[a]

This table provides general guidance for laboratory monitoring for people with HIV before and after antiretroviral therapy (ART) initiation. Clinicians should use their clinical judgment to determine the monitoring frequency for an individual person based on clinical needs. This schedule is not intended to be a guide on how often people with HIV should undergo clinical evaluation, as some individuals may need to be seen more frequently to accomplish other aspects of clinical care. Please refer to Table 4 for laboratory monitoring guidance if ART initiation is deferred.

Laboratory Test	Timepoint or Frequency of Testing							
	Entry Into Care	ART Initiation[b] or Modification	After ART Initiation or Modification	Every 3–4 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated
HIV Antigen/ Antibody Test	✓ If HIV diagnosis not confirmed							
HIV Viral Load	✓	✓	✓[c] At 4–8 weeks	✓[d]	✓[d]		✓	✓
CD4 Count	✓	✓	✓ 3 months (after ART initiation only)	✓[e] If CD4 count is <300 cells/mm^3	✓ During the First 1–2 Years on ART and With Viral Suppression, if CD4 Count Is ≥300 Cells/mm^3: • Every 6 months After 1–2 Years on ART With Consistently Suppressed Viral Load and CD4 Count ≥300 Cells/mm^3: • Optional unless clinically indicated		✓ Monitor CD4 count every 3–6 months.	✓

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	Entry Into Care	ART Initiation[b] or Modification	After ART Initiation or Modification	Every 3–4 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated
Genotypic Resistance Testing (PR/RT Genes)[f]	✓	✓					✓	✓
Genotypic Resistance Testing (Integrase Genes)[f]	✓ If transmitted INSTI resistance is suspected or if there is a history of CAB-LA use for PrEP or INSTI use for PEP	✓ If transmitted INSTI resistance is suspected or if there is a history of INSTI use					✓ If there is a history of INSTI use for treatment or prevention	✓
Tropism Testing		✓ If considering a CCR5 antagonist					✓ If considering a CCR5 antagonist, or upon virologic failure on a CCR5 antagonist	✓
HLA-B*5701 Testing		✓ If considering ABC (perform once; keep result in health record)						

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Hepatitis B Serology (HBsAb, HBsAg, HBcAb total)[g,h,i] Also see Hepatitis B Virus/HIV Coinfection	✓	✓ In people not immune to HBV, repeat testing if switching to a regimen that does not contain TAF or TDF.						✓ Before starting HCV DAA In people not immune to HBV and at high risk for HBV,[j] periodic testing may be considered.
Hepatitis C Screening (HCV antibody or, if indicated, HCV RNA)[k]	✓					✓ Repeat HCV screening for at-risk people.[j]		✓
Basic Metabolic Panel[l,m]	✓	✓	✓ At 4–8 weeks For people with preexisting conditions or at risk of laboratory changes after ART initiation		✓ Every 6–12 months			✓

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ALT, AST, Total Bilirubin	✓	✓	✓ At 4–8 weeks For people with preexisting conditions, at risk for laboratory changes after ART initiation, or with HBV coinfection		✓ Every 6–12 months			✓
CBC With Differential[n]	✓	✓		✓ When monitoring CD4 count (if required by lab)	✓ When monitoring CD4 count (if required by lab)	✓ When no longer monitoring CD4 count		✓
Lipid Profile[o]	✓	✓	✓ At 3–6 months once viral suppression is reached			✓ If on a statin (Every 1–3 years if not on a statin)		✓ If there are changes in CV risk factors[p]
Random or Fasting Glucose[q]	✓	✓						✓

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	Entry Into Care	ART Initiation[b] or Modification	After ART Initiation or Modification	Every 3–4 Months	Every 6 Months	Every 12 Months	Treatment Failure	Clinically Indicated
Urinalysis[m,r]	✓							✓ e.g., in people with CKD or DM
Pregnancy Test[s]	✓	✓ For ART initiation; for modification only if clinically indicated						✓

[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 Medicine Association of the Infectious Diseases Society of America's (HIVMA/IDSA) Primary Care Guidance for Providers Who Care for Persons With HIV for other laboratory tests generally recommended for primary health care maintenance of HIV people.[1]

[b] If ART is initiated soon after HIV diagnosis and entry into care, repeat baseline laboratory testing is not necessary.

[c] If HIV RNA is detectable at 4–8 weeks, repeat testing every 4–8 weeks until viral load is suppressed to <50 copies/mL. Thereafter, repeat testing every 3–6 months.

[d] For people on ART, viral load is typically measured every 3–6 months. More frequent monitoring may be considered in individuals having difficulties with ART adherence or at risk for nonadherence. However, for adherent people with consistently suppressed viral load and stable immunologic status for more than 1 year, monitoring can be extended to 6-month intervals.

[e] After 1–2 years of consistently suppressed HIV RNA, less frequent monitoring (e.g., every 6 months) may be considered.

[f] Standard genotypic drug-resistance testing in ARV-naive persons should focus on testing for mutations in the PR and RT genes. If transmitted INSTI resistance is a concern, or if a person may have a history of INSTI use as PrEP, PEP, or treatment, or a person presents with viremia while on an INSTI, providers also should test for resistance mutations in the integrase gene. In people who are ARV-naive and who do not immediately begin ART, repeat testing before initiation of ART is optional if drug-resistance testing was performed at entry into care. In people with virologic suppression who are switching therapy because of toxicity or for convenience, viral amplification will not be possible; see the Drug-Resistance Testing section for a discussion of the potential limitations and benefits of proviral DNA assays in this situation. Results from prior drug-resistance testing should be used in constructing a new regimen.

[g] If a person has HBV infection (as determined by a positive HBsAg or HBV DNA test result), TDF or TAF plus either FTC or 3TC should be used as part of the ARV regimen to treat both HBV and HIV infections (see the Hepatitis B Virus/HIV Coinfection section).

[h] If HBsAg, HBsAb, and HBcAb test results are negative, HBV vaccine series should be administered. Refer to the HIVMA/IDSA's Primary Care Guidance for Persons With HIV and the Adult and Adolescent Opportunistic Infection Guidelines for detailed recommendations.[1,2]

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[i] Most people with isolated HBcAb have resolved HBV infection with loss of HBsAb. Consider performing an HBV viral load test for confirmation. If the HBV viral load test is positive, the person may be acutely infected (and will usually display other signs of acute hepatitis) or chronically infected. If the test is negative, the person should be vaccinated. Refer to the HIVMA/IDSA's Primary Care Guidance for Persons With HIV and the Adult and Adolescent Opportunistic Infection Guidelines for more detailed recommendations.[2]

[j] Injection drug users, people with a history of incarceration, men with HIV who have unprotected sex with men, and people with percutaneous/parenteral exposure to blood in unregulated settings are at risk of HBV or HCV infection.

[k] The HCV antibody test may not be adequate for screening in the setting of recent HCV infection (acquisition within the past 6 months) or advanced immunodeficiency (CD4 count <100 cells/mm^3). HCV RNA screening is indicated in persons who have been successfully treated for HCV or who spontaneously cleared prior infection. HCV antibody-negative people with elevated ALT may need HCV RNA testing.

[l] Serum Na, K, HCO_3, Cl, BUN, creatinine, glucose, and Cr-based eGFR. Serum P should be monitored in people with CKD who are on TDF-containing regimens.[3]

[m] Consult the HIVMA/IDSA's Clinical Practice Guideline for the Management of Chronic Kidney Disease in People Infected With HIV for recommendations on managing people with renal disease.[3] More frequent monitoring may be indicated for people with evidence of kidney disease (e.g., proteinuria, decreased glomerular function) or increased risk of renal insufficiency (e.g., people with diabetes, hypertension).

[n] CBC with differential should be done when a CD4 count is performed. When CD4 count is no longer being monitored, the recommended frequency of CBC with differential is once a year. More frequent monitoring may be indicated for people receiving medications that potentially cause cytopenia (e.g., TMP-SMX).

[o] If random lipids are abnormal, fasting lipids should be obtained. Consult the American College of Cardiology/American Heart Association/Multisociety Dyslipidemia Guideline for diagnosis and management of people with dyslipidemia.[4]

[p] Changes in CV risk factors such as new diagnosis of hypertension, weight gain, or new medications (including ART) that may raise lipid levels or overall CV risk.

[q] If random glucose is abnormal, fasting glucose should be obtained. HbA1C is no longer recommended for diagnosis of diabetes in people with HIV on ART (see the American Diabetes Association Guidelines).[5]

[r] Urine glucose and protein should be assessed before initiating TAF- or TDF-containing regimens and monitored during treatment with these regimens.

[s] For women of reproductive potential.

Key: 3TC = lamivudine; ABC = abacavir; ALT = alanine aminotransferase; ART = antiretroviral therapy; ARV = antiretroviral; AST = aspartate aminotransferase; BUN = blood urea nitrogen; CAB-LA = cabotegravir long-acting; CBC = complete blood count; CD4 = CD4 T lymphocyte; CKD = chronic kidney disease; Cl = chloride; Cr = creatinine; CV = cardiovascular; DAA = direct-acting antiviral; DM = diabetes mellitus; eGFR = estimated glomerular filtration rate; FTC = emtricitabine; HbA1C = hemoglobin A1c; HBcAb = hepatitis B core antibody; HBsAb = hepatitis B surface antibody; HBsAg = hepatitis B surface antigen; HBV = hepatitis B virus; HCO_3 = bicarbonate; HCV = hepatitis C virus; INSTI = integrase strand transfer inhibitor; K = potassium; Na = sodium; P = phosphorus; PEP = post-exposure prophylaxis; PR = protease; PrEP = pre-exposure prophylaxis; RT = reverse transcriptase; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; TMP-SMX = trimethoprim-sulfamethoxazole

Table 4. Laboratory Monitoring If ART Is Deferred

Antiretroviral therapy (ART) is recommended for all people with HIV **(AI).** People with HIV should be advised to begin ART as soon as feasible to reduce morbidity and mortality and to prevent transmission of HIV to others. This table provides guidance for laboratory monitoring in the rare occasions when ART initiation is deferred.

Laboratory Test	Initial Assessment	Monitoring Frequency If ART Is Deferred	Comments
CD4 Count	✓	Every 3–6 months	To assess for urgency of ART initiation and the need for OI prophylaxis
HIV Viral Load	✓	Every 3–6 months	
Genotypic Resistance Testing (PR/RT +/- integrase gene) See Drug Resistance Testing for more information.	✓		Repeat genotypic resistance testing at the time of ART initiation is optional.
Hepatitis B Serology (HBsAb, HBsAg, HBcAb) See Hepatitis B in the Adult OI Guidelines for more detailed guidance.	✓	Clinically indicated	Before starting HCV DAA If HBsAg Positive: • ART with HBV-active drugs that include TAF or TDF should be initiated. If Not Immune at Baseline: • Repeat after vaccination or before starting an NRTI-sparing (or limited) ART regimen.
Hepatitis C Screening (HCV antibody, or, if indicated, HCV RNA)	✓	Every 12 months for at-risk people, or if clinically indicated	
Basic Metabolic Panel	✓	Every 6–12 months or if clinically indicated	
ALT, AST, Total Bilirubin	✓	Every 6–12 months or if clinically indicated	
CBC With Differential	✓	When monitoring CD4 count or if clinically indicated	
Pregnancy Test (when pregnancy is possible)	✓	If clinically indicated	ART should be initiated as soon as possible after confirming pregnancy to prevent perinatal HIV transmission.

Key: ALT = alanine aminotransferase; ART = antiretroviral therapy; AST = aspartate aminotransferase; CBC = complete blood count; CD4 = CD4 T lymphocyte; DAA = direct-acting antiviral; HBcAb = hepatitis B core antibody; HBsAb = hepatitis B surface antibody; HBsAg = hepatitis B surface antigen; HBV = hepatitis B virus; HCV = hepatitis C virus; NRTI = nucleoside reverse transcriptase inhibitor; OI = opportunistic infection; PR = protease; RT = reverse transcriptase; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate

References

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