

Routine HIV Monitoring

Guideline of the HIV/AIDS Division at San Francisco General Hospital

Statement of Guideline: Patients will be routinely evaluated and monitored for HIV parameters, antiretroviral treatment effectiveness and toxicity, and related issues at a safe and appropriate frequency.

Patient evaluation and laboratory monitoring are important for the care of patients at all stages of HIV infection. With our current understanding of HIV pathogenesis and effective medications to treat HIV, our primary objective for treatment in all patients is virologic suppression. The goals of routine monitoring are to ensure virologic suppression and assess the safety of treatment. In the current era, CD4 count is used primarily to determine the need for prophylaxis against opportunistic infections and has a diminished role in routine monitoring, particularly when CD4 count is in the normal range.

This guideline applies only to **routine** monitoring of HIV. Patients may require additional evaluation and monitoring based on clinical signs or symptoms, co-morbidities, or at the determination of the patient or provider.

Patient evaluation:

- Patients will have a minimum of one annual visit with their primary care provider
- Patients on antiretroviral therapy (ART) will have a minimum of two assessments of ART adherence annually

HIV laboratory monitoring for patients NOT on ART:

ART is recommended in all patients regardless of CD4 count, unless there exists a reason to defer therapy (*see 'Universal Antiretroviral Therapy Initiation' Guideline*). For patients in whom such a reason exists and ART is not initiated, the following monitoring is recommended:

- HIV Viral Load (RNA)
 - At clinic entry
 - No need to repeat thereafter, as long as patient remains untreated with ART
 - Exceptions include acute HIV infection and elite/viremic controllers, in which cases following HIV RNA may be helpful
- CD4 Count
 - At entry into clinic
 - Repeat every 3-6 months thereafter, as long as patient is not on ART

- Frequency depends on level of CD4 (ie, proximity to threshold for OI prophylaxis), rate of decline of CD4, and other factors
- HIV Genotype
 - At clinic entry
 - No need to repeat thereafter, prior to initiation of ART
- Safety labs (complete blood count, electrolytes, renal function, liver panel, glucose, fasting lipids)
 - Annually

HIV laboratory monitoring for patients initiating ART:

- HIV Viral Load (RNA)
 - At ART initiation
 - 1 month after ART initiation
 - Repeat every 2-3 months until undetectable
 - (Then see “HIV laboratory monitoring for patients stable on ART”)
 - *Note: The main purpose of measuring HIV RNA in the first 3-6 months is as an assessment of adherence and to provide positive reinforcement to the patient.*
- CD4 Count
 - At ART initiation
 - Repeat CD4 measurements:
 - Last CD4 <200 – Every 3-6 months
 - Last CD4 201-500 – Annually
 - Last CD4 >500 – Do not repeat
 - (Then see “HIV laboratory monitoring for patients stable on ART”)
- Safety labs (complete blood count, electrolytes, renal function, liver panel, glucose, fasting lipids)
 - At ART initiation
 - 1 month after ART initiation
 - Sooner if concern due to underlying medical conditions
 - Liver panel at 2 weeks if on nevirapine
 - If on tenofovir, measure renal function every 4-6 months and perform urinalysis at baseline and annually

HIV laboratory monitoring when changing ART for virologic failure:

- HIV Viral Load (RNA)
 - Prior to ART change
 - 1 month after ART change
 - Repeat every 2-3 months until undetectable
 - (Then see “HIV laboratory monitoring for patients stable on ART”)
- CD4 Count
 - Prior to ART switch
 - Repeat CD4 measurements:
 - Last CD4 <200 – Every 3-6 months
 - Last CD4 201-500 – Annually
 - Last CD4 >500 – Do not repeat
 - (Then see “HIV laboratory monitoring for patients stable on ART”)
- Safety labs (complete blood count, electrolytes, renal function, liver panel, glucose, fasting lipids)
 - Prior to ART switch

- 1 month after ART switch
 - Sooner if concern due to underlying medical conditions
 - Liver panel at 2 weeks if on nevirapine
- If on tenofovir, measure renal function every 4-6 months and perform urinalysis at baseline and annually

HIV laboratory monitoring when changing ART for reasons other than virologic failure:

- HIV Viral Load (RNA)
 - Prior to ART change
 - 1 month after ART change
 - If HIV Viral Load remains undetectable, then see “HIV laboratory monitoring for patients stable on ART”
- CD4 Count
 - Prior to ART switch
 - Repeat CD4 measurements:
 - Last CD4 <200 – Every 3-6 months
 - Last CD4 201-500 – Annually
 - Last CD4 >500 – Do not repeat
 - (Then see “HIV laboratory monitoring for patients stable on ART”)
- Safety labs (complete blood count, electrolytes, renal function, liver panel, glucose, fasting lipids)
 - Prior to ART switch
 - 1 month after ART switch
 - Sooner if concern due to underlying medical conditions
 - Liver panel at 2 weeks if on nevirapine
 - If on tenofovir, measure renal function at every 4-6 months and perform urinalysis at baseline and annually

HIV laboratory monitoring for patients stable on ART:

- Definition of “stable on ART”
 - On ART without change in regimen for at least 3 months
 - No disruptions in ART adherence
 - HIV Viral Load undetectable on most recent determination
- HIV Viral Load (RNA)
 - Every 6 months
- CD4 Count
 - Last CD4 <200 – Every 3-6 months
 - Last CD4 201-500 – Annually
 - Last CD4 >500 – Do not repeat
- Safety labs (complete blood count, electrolytes, renal function, liver panel, glucose, fasting lipids)
 - Annually
 - If on tenofovir, measure renal function every 4-6 months and perform urinalysis annually

For additional information, please see HIV/AIDS Division Clinical Operations Manual, **Policy Number 3.40: Health Care Maintenance Guidelines**

Frequently Asked Questions:

Am I able to get labs more frequently than indicated in the guideline?

Yes. The guideline should be applied to the **routine** monitoring of HIV-associated laboratory parameters only. Evaluation of changes in clinical status may include any appropriate laboratory tests, based on the clinician assessment. Initiation of or changes to medications other than ART may prompt safety monitoring appropriate to that clinical situation. Patients with co-morbidities (e.g., diabetes, renal disease, viral hepatitis) may require more frequent safety monitoring. Patients who experience lapses in ART adherence may require more frequent monitoring. Clinical judgment should always supersede adherence to this guideline in patient management.

Why is this guideline different from DHHS and other guidelines?

We recognize the changing nature of HIV epidemic, particularly with respect to ART treatment and its success in maintaining durable virologic control in the majority of patients who remain adherent to modern ART regimens. We also acknowledge the resource constrained environment of the public health system in which we practice and want to be responsible citizens within the larger medical community. This guideline aims to incorporate these considerations while prioritizing patient safety and appropriate care and monitoring of HIV infection.

Where do these recommendations come from?

Most recommendations contained in this guideline are based on expert opinion of clinicians within the HIV/AIDS Division and not based on rigorous clinical trials. They are generally classified as level B-II or B-III evidence.

References:

DHHS. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. December 1, 2009; 1-161. (Accessed at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>)

Aberg JA, 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. 2009 Sep 1;49(5):651-81.

Table. Summary of HIV-specific **routine** laboratory monitoring.

Laboratory Parameter	Baseline	Month 1	Month 3	Month 6	Month 12	Routine Repeat
Patients NOT on ART						
HIV Viral Load (RNA)	X					None ²
CD4 Count	X		Repeat every 3-6 months ³			Every 3-6 months ³
HIV Genotype	X					None
Safety Labs ¹	X					Annually
Patients Initiating ART						
HIV Viral Load (RNA)	X	X	Repeat every 2-3 months until undetectable			See "Patients Stable on ART"
CD4 Count	X		Last CD4 <200 – Every 3-6 months Last CD4 201-500 – Annually Last CD4 >500 – Do not repeat			
Safety Labs ^{1,4}	X	X ⁴				Annually
Patients Changing ART for Virologic Failure						
HIV Viral Load (RNA)	X	X	Repeat every 2-3 months until undetectable			See "Patients Stable on ART"
CD4 Count	X		Last CD4 <200 – Every 3-6 months Last CD4 201-500 – Annually Last CD4 >500 – Do not repeat			
Safety Labs ^{1,3}	X	X ⁵				Annually
HIV Resistance Testing	X ⁶					None
Patients Changing ART for Reasons Other Than Virologic Failure						
HIV Viral Load (RNA)	X	X		X	X	See "Patients Stable on ART"
CD4 Count	X		Last CD4 <200 – Every 3-6 months Last CD4 201-500 – Annually Last CD4 >500 – Do not repeat			
Safety Labs ^{1,4}	X	X ⁵				Annually
Patients Stable on ART⁷						

HIV Viral Load (RNA)	X			X	X	Every 6 months
CD4 Count	X		Last CD4 <200 – Every 3-6 months Last CD4 201-500 – Annually Last CD4 >500 – Do not repeat			None
Safety Labs ^{1,4}	X					Annually

¹ Safety labs include complete blood count, electrolytes, renal function, liver panel, glucose and fasting lipids

² Exceptions include patients with acute HIV infection and elite/viremic controllers, in which cases following HIV RNA may be helpful

³ Frequency depends on level of CD4 (ie, proximity to threshold for OI prophylaxis or ART initiation), rate of decline of CD4, and other factors

⁴ If on tenofovir, measure renal function every 4-6 months and perform urinalysis at baseline and annually

⁵ Liver panel at 2 weeks if on nevirapine

⁶ Which HIV resistance tests are done at virologic failure is determined by treatment history and clinical judgment

⁷ Definition of “Stable on ART:”

- On ART without change in regimen for at least 3 months
- No disruptions in ART adherence
- HIV Viral Load undetectable on most recent determination