HIV Screening Guidelines

Washington State Clinical Laboratory Advisory Council
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FOR EDUCATIONAL PURPOSES ONLY
The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.

Washington State Department of Health
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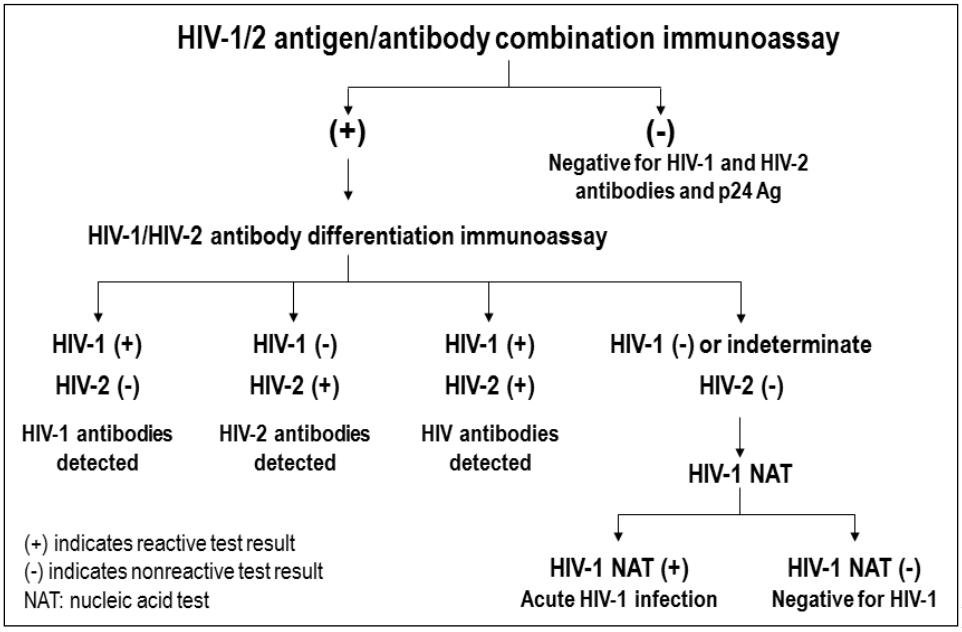
The Centers for Disease Control and Prevention (CDC) recommends routine HIV screening for all patients ages 13-64 seeking health care for a ny reason, without regard to the patient's known risks for HIV infection; and recommends annual HIV screening for patients known to be at high risk.

Washington State: Substitute Senate Bill 5728 - Clinicians shall screen for HIV infection consistent with the United States Preventive Services Task Force recommendations uspstf for all patients age 15 – 65 and for all pregnant women. SSB5728

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



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1) Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody combination immunoassay* that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to screen for established infection with HIV-1 or HIV-2 and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial immunoassay.

2) Specimens with a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody combination immunoassay and the HIV- 1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, undifferentiated.

3) Specimens that are reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT).

- A reactive HIV-1 NAT result and nonreactive HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence for acute HIV-1 infection.

- A reactive HIV-1 NAT result and indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates the presence of HIV-1 infection confirmed by HIV-1 NAT.
- A negative HIV-1 NAT result and nonreactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates a false-positive result on the initial immunoassay.

4) Laboratories should use this same testing algorithm, beginning with an antigen/antibody combination immunoassay, with serum or plasma specimens submitted for testing after a reactive (preliminary positive) result from any rapid HIV test.

5) **** Exception: As of April 2014, data are insufficient to recommend use of the FDA-approved single-use rapid HIV- 1/HIV-2 antigen/antibody combination immunoassay as the initial assay in the algorithm.***

Abbreviations: Ag/Ab, antigen/antibody; RNA, ribonucleic acid.

Reference: Adapted from *Interim Guidelines for Laboratories on the Use of a New Diagnostic Testing Algorithm for Human Immunodeficiency Virus (HIV) Infection.* New York State Department of Health

CLASSIFICATION SYSTEM FOR HIV INFECTION

MMWR Revised 2014 Case Definitions

TABLE. HIV infection stage* based on age-specific CD4+ T-lymphocyte count or CD4+ T-lymphocyte percentage of total lymphocytes

Stage	Age on date of CD4+ T-lymphocyte test					
	<1 yr		1–5 yrs		≥6 yrs	
	Cells/μL	%	Cells/μL	%	Cells/μL	%
1	≥1,500	≥34	≥1,000	≥30	≥500	≥26
2	750–1,499	26–33	500–999	22–29	200–499	14–25
3	<750	<26	<500	<22	<200	<14

* The stage is based primarily on the CD4+ T-lymphocyte count; the CD4+ T-lymphocyte count takes precedence over the CD4 T-lymphocyte percentage, and the percentage is considered only if the count is missing. There are three situations in which the stage is not based on this table: 1) if the criteria for stage 0 are met, the stage is 0 regardless of criteria for other stages (CD4 T-lymphocyte test results and opportunistic illness diagnoses); 2) if the criteria for stage 0 are not met and a stage-3-defining opportunistic illness has been diagnosed (Appendix), then the stage is 3 regardless of CD4 T-lymphocyte test results; or 3) if the criteria for stage 0 are not met and information on the above criteria for other stages is missing, then the stage is classified as unknown.

Appendix ref: See (C)AIDS Indicator Conditions for a truncated listing

A. INITIAL SYMPTOMS AND STAGES OF HIV INFECTION

Viral transmission - incubation period of 2-3 weeks followed by Acute Retroviral Syndrome, lasting 2-3 weeks.
Acute HIV infection usually presents as flu-like illness, e.g. fever, swollen lymph nodes, sore throat, rash, body aches. Also can be asymptomatic. CD4 cell counts drop precipitously and HIV viral RNA is very high.
Symptomatic recovery - viral RNA declines and CD4 counts climb to normal. HIV infection is now widespread. HIV antibody tests are positive (seroconversion) after 14 days in most people, virtually all by 6 months. Some people develop Persistent Generalized Lymphadenopathy (PGL).
Asymptomatic, chronic HIV infection phase affecting most people lasting an average of 8 yrs. The virus continues to replicate actively, CD4 counts decline and HIV RNA levels gradually increase.

B. SYMPTOMS OF CHRONIC HIV INFECTION (NOT ASYMPTOMATIC, PGL, OR ACUTE HIV INFECTION; AND NOT AIDS-INDICATOR CONDITIONS)

Symptomatic conditions not included in Category C that are
a) attributed to HIV infection or indicative of a defect in cell-mediated immunity, or
b) considered to have a clinical course or management complicated by HIV infection.

Examples include: oral thrush, persistent vaginal candidiasis, bacillary angiomatosis, cervical dysplasia or carcinoma in situ, constitutional symptoms such as severe fatigue, persistent fever or diarrhea, oral hairy leukoplakia, herpes zoster involving two episodes or muti- dermatomal, idiopathic thrombocytopenic purpura (ITP), listeriosis, pelvic inflammatory disease (PID) and peripheral neuropathy.

C

AIDS-INDICATOR CONDITIONS

Late-stage disease is characterized by opportunistic infections, selected malignancies, wasting and neurologic complications. Untreated, the median survival after an AIDS-defining complication is 1.3 years. Conditions present at time of AIDS diagnosis in decreasing frequency:

Pneumocystis carinii pneumonia (38%)
HIV-associated wasting (18%)
Candidiasis of esophagus, trachea, bronchi or lungs (16%),
Mycobacterium tuberculosis, pulmonary (7%), extra pulmonary (2%)
CMV of eye or any organ other than liver, spleen or lymph nodes (7%)
Kaposi's sarcoma (7%)
Cryptococcosis, extrapulmonary (5%)
Herpes simplex with ulcer >1 month or bronchitis, pneumonitis, esophagitis (5%)
HIV-associated dementia (5%)
Mycobacterim avium, disseminated (5%)
Pneumonia, recurrent-bacterial (5%)
Toxoplasmosis of internal organ (4%)
Lymphoma, Burkitt's (0.7%), immunoblastic (2.3%), primary CNS (0.7%)
Cryptosporidiosis with diarrhea >1 month (1.3%)
Progressive Multifocal Leukoencephalopathy (1%)
Histoplasmosis, extra pulmonary (0.9%)
Cervical cancer, invasive (0.6%)
Coccidioidomycosis, intrapulmonary (0.3%)
Salmonella septicemia (nontyphoid), recurrent (0.3%)
Isosporiasis with diarrhea >1 month.

D.

RISK FACTORS

HIV testing is recommended for persons (or partners of persons) who currently or in the past have had a history of the following risks:

- unprotected sexual intercourse (anal, vaginal or oral);
- injection drug use, especially sharing needles and/or other equipment;
- sex for money or drugs;
- blood transfusions, between 1977-1985; sexually transmitted disease (STD);
- is an infant or child of a HIV-infected mother; and,
- sex/shared injection drug equipment with someone who is known to be HIV infected.
- Risk Estimates

RESOURCES:

Pre-exposure prophylaxis - PrEP
Post-exposure prophylaxis – PEP