Ryan White Part A
Quality Management

Outpatient/Ambulatory Medical Care Service Delivery Model

Broward County/Fort Lauderdale Eligible Metropolitan Area (EMA)

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Definition:

**Outpatient/Ambulatory Medical Care (Health services)** is the provision of professional diagnostic and therapeutic services rendered by a physician, physician’s assistant, clinical nurse specialist, or nurse practitioner in an outpatient setting. Settings include clinics, medical offices, and mobile vans where clients generally do not stay overnight. Emergency room services are not outpatient settings. Services includes diagnostic testing, early intervention and risk assessment, preventive care and screening, practitioner examination, medical history taking, diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, education and counseling on health issues, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties). **Primary medical care** for the treatment of HIV infection includes the provision of care that is consistent with the Public Health Service’s guidelines. Such care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies.

**Practitioner Definition:**
Physicians, Nurse Practitioners, and Physician Assistants with current prescribing privileges in the state Florida.

**Practitioner Continuing Education Recommendation:**
Practitioners are strongly encouraged to complete at least 30 hours of HIV-related Continuing Medical Education (CME) Category 1 credits within a period of two years. When a new practitioner is working with a contracted practitioner, new practitioner is encouraged to comply within one year.
## OUTCOMES, OUTCOME INDICATORS, STRATEGIES AND DATA SOURCES

<table>
<thead>
<tr>
<th>Client Outcome</th>
<th>Outcome Indicators</th>
<th>Inputs</th>
<th>Strategies</th>
<th>Data Source</th>
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<tbody>
<tr>
<td>1. Slow/prevent clients’ HIV disease progression.</td>
<td>1.1. 80% of clients with CD4 ≤ 500 are prescribed ART.</td>
<td>Funding</td>
<td>1.1. Complete appropriate diagnostic testing</td>
<td>1.1.1. Clients Chart</td>
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<tr>
<td></td>
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<td>Staff</td>
<td>1.2. The clinician should refer to appropriate guidelines for treatment strategies</td>
<td>1.1.2. PHS Guidelines, DHHS Guidelines, IAS Guidelines</td>
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<td>Clients</td>
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<td>Tests/Labs</td>
<td>1.2. Monitor and follow-up</td>
<td>1.1.3. Clients Chart</td>
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<tr>
<td>1.2. 70% of clients on ART for &gt; 6 months will have a viral load &lt;400.</td>
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### STANDARDS OF CARE

Note: Data source is client chart unless stated otherwise.

#### Documentation of HIV Infection

<table>
<thead>
<tr>
<th>Standard</th>
<th>Indicator</th>
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<tbody>
<tr>
<td>1. Documentation of HIV infection is in medical record.</td>
<td>1.1. 100% of client charts have documentation of HIV positive status. Diagnosed by a rapid HIV test or a conventional enzyme-linked immunosorbent assay (ELISA) and confirmed by Western blot or indirect immunofluorescence assay OR a detectable viral load.</td>
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#### Laboratory Testing

| 2. Basic laboratory tests shall be obtained. | 2.1. 100% of client charts have basic screening labs done by second visit.  
2.2. 100% of client charts have complete labs per protocol.  
2.3. 100% of client charts screen for Hepatitis A, B, and C. |
| 3. CD4 T-cell count laboratory tests shall be obtained before and after start of antiretroviral (ART) therapy. | 3.1. 100% of clients have documentation of CD4 T-Cell count at entry into care and before ART initiation.  
3.2. 100% of clients have documentation of CD4 T-Cell count at least every 6-12 months if client is documented as adherent with suppressed HIV Viral Load and stable clinical and immunologic status for >2-3 years.  
3.3. 100% of clients have documentation of CD4 T-Cell count every 3-6 months for all patients not meeting criteria in 3.2. |
| 4. HIV RNA laboratory tests shall be obtained. | 4.1. 100% of clients have documentation of HIV RNA at entry into care and before ART initiation.  
4.2. 100% of clients have documentation of HIV RNA every 3-6 months. Interval MAY be extended to 6 months only if patient is documented as adherent with suppressed HIV Viral Load and stable clinical and immunologic status for >2-3 years. |
| 5. Resistance tests shall be obtained | 5.1. 100% of naïve clients have documentation of genotype resistance tests at entry into care.  
5.2. 100% of clients have documentation of resistance tests at treatment failure with HIV viral load ≥ 1000 copies/mL.  
If drug resistance is suspected, client should be on failing regimen at time of test or within 4 weeks of regimen discontinuation. For client with suspected treatment failure due to issues of adherence, medication intolerance, or pharmacokinetic reasons, resistance testing is not warranted until these reasons are addressed. |
| 6. HLA-B*5701 laboratory test shall be obtained if considering start of abacavir. | 6.1. 100% of clients have documentation of HLA-B*5701 if considering start of abacavir. |
| 7. Tropism testing shall be obtained when considering use of CCR5 antagonist | 7.1. 100% of clients have documentation of Tropism Testing if considering use of CCR5 antagonist. |
| 8. Basic chemistry [Serum Na, K, HCO3, Cl, BUN, creatinine, glucose (preferably fasting)] , Liver function tests (ALT, AST, T. bili, & D. bili) , CBC with differential shall be obtained. | 8.1. 100% of clients have documentation of basic chemistry at entry into care.  
8.2. 100% of clients have documentation of basic chemistry follow-up at least every 3-6 months.  
8.3. 100% of clients have documentation of basic chemistry before ART initiation or modification.  
8.4. 100% of clients have documentation of basic chemistry 2-8 weeks post-ART initiation or modification. |
| 9. Fasting lipid profile shall be obtained. | 9.1. 100% of clients have documentation of fasting lipid profile at entry into care.  
9.2. 100% of clients have documentation of fasting lipid profile annually (if normal at last measurement) or every six months (if... |
<table>
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<tr>
<th>Service Delivery Model</th>
<th>Outpatient/Ambulatory Medical Care</th>
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### Urinalysis** shall be obtained.

10.1. 100% of clients have documentation of urinalysis at entry into care.

10.2. 100% of clients have documentation of urinalysis at least every 12 months.

### Hepatitis A screening** shall be obtained.

11.1. 100% of clients have documentation of Hepatitis A Screening - Hepatitis A total antibody (HAVAb) or IgG (not IgM).

### Hepatitis B screening** shall be obtained.

12.1. 100% of clients have documentation of Hepatitis B Screening - Hepatitis B core antibody (HBcAb) total or IgG (not IgM), Hepatitis B surface antibody (HBsAb), and Hepatitis B surface antigen (HBsAg).

12.2. 100% of clients with documentation of positive HBsAg, have further Hepatitis B testing; HBeAg, HBeAb and Viral Load by DNA PCR.

### Hepatitis C screening** shall be obtained.

13.1. 100% of clients have documentation of Hepatitis C Screening - Hepatitis C antibody (HCVAb).

13.2. 100% of clients with documentation of positive HCVAb, have Hepatitis C (HCV) Viral Load, HCV genotype, and a treatment plan in the record.

### Syphilis, N. gonorrhea (GC), and C. trachomatis (Chlamydia) screening shall be obtained**

14.1. 100% of clients have documentation of Syphilis screening at baseline and annually thereafter.

14.2. 100% of female clients who report sexual activity since their last screening have documentation of N. gonorrhea (GC) and C. trachomatis (Chlamydia) screening annually.

### Immunizations/Treatments

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15. Clients are offered immunizations.

15.1. 100% of client’s are offered pneumococcal vaccine** and a follow up booster 5 years later.

15.2. 100% of clients are offered influenza immunization**.

15.3. 100% of non immune clients are offered Hepatitis A and B vaccine**.

16. Anti-Retroviral therapy shall be prescribed.

16.1. 100% of clients have documentation of consideration and discussion of ART therapy at the times of CD4 T-Cell count and HIV RNA monitoring.

17. Treatment for opportunistic infections and prophylaxis for opportunistic infections shall be provided.\*x

17.1. 100% of clients have documentation of treatment, when indicated, for opportunistic infections.

17.2. 100% of clients have documentation of prophylaxis for opportunistic infections, when indicated, and prophylaxis is discontinued, when indicated.

### Additional Assessments

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18. Consenting female clients are given PAP test\*, at least annually.

18.1. 100% of charts of female clients show a PAP test and pelvic exam offered annually.

18.2. 90% of female clients for which a PAP test and pelvic exam were appropriate are successfully completed.

18.3. 100% of charts of female clients with abnormal PAP tests or with lesions present show referral to a gynecologist and the outcome will be documented.
19. Client is tested for Tuberculosis\textsuperscript{a} annually.
19.1. 75% of client charts document TB reading within 48-72 hours.
19.2. 75% of charts of clients who do not have test read within 48-72 hours have it repeated and read within 48-72 hours with completion within 1 month.
19.3. 100% of charts of clients with a positive PPD reading are assessed for history of TB.
19.4. 100% of client charts show client with a positive PPD reading is referred for chest x-ray and prophylactic treatment. Interferon gamma releasing assays (IGRAs) may be considered in place of PPD.

20. Mammogram\textsuperscript{v} (females) shall be provided.
20.1. 100% of female clients, starting at age 40, have documentation of offering mammogram annually.
20.2. 100% of female clients with documentation of abnormal mammogram have documented plan of care in record.

21. Colon and Rectal Cancer Screening\textsuperscript{ix} shall be provided.
21.1. 100% of clients have documentation of colorectal cancer screening by being offered a colonoscopy starting at age 50. If unable to perform or if patient refuses, a fecal occult blood test (FOBT)\textsuperscript{xiii} should be performed every year. For FOBT used as a screening test, the take-home multiple sample method should be used. A FOBT done during a digital rectal exam in the practitioner’s office is not adequate for screening. High risk groups should have screening earlier or more frequently based on USPSTF guidelines.
21.2. 100% of clients with documentation of abnormal screening have documented plan of care in record.

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<tr>
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<tr>
<td>22. Clients are educated about medication adherence.</td>
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<tr>
<td>22.1. 90% of clients with HIV infection, as part of their primary care, will be assessed and counseled for adherence at every visit.</td>
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<tr>
<td>23. Clients with HIV infection attend 2 or more medical visits annually.</td>
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<tr>
<td>23.1. 90% of clients with HIV infection attend 2 or more medical visits annually.</td>
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<tr>
<td>23.2. 100% of clients not adherent to 23.1 have documentation of attempts to re-establish in care.</td>
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<tr>
<td>24. Clients with CD4 T-cell counts below 200 are prescribed PCP prophylaxis.</td>
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<tr>
<td>24.1. 95% of clients with CD4 T-cell counts below 200 are prescribed PCP prophylaxis</td>
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<tr>
<td>24.2. 95% of clients with Toxoplasma gondii, CD4&lt;100, and Toxo Ab positive are prescribed prophylaxis.</td>
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<tr>
<td>25. Pregnant women are prescribed antiretroviral therapy.</td>
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<tr>
<td>25.1. 100% of pregnant women are prescribed antiretroviral therapy</td>
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<tr>
<td>26. Cytomegalovirus (CMV) screening for patients with CD4 T-cell count &lt; 50mm\textsuperscript{3}.</td>
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<tr>
<td>26.1. 100% of clients with CD4 T-cell count &lt; 50mm\textsuperscript{3}, have documentation of referral to ophthalmology.</td>
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<tr>
<td>27. Nutritional health education shall be assessed.</td>
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<tr>
<td>27.1. 100% of clients have documentation of annual nutritional assessment.</td>
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<td>28. Oral health education/care shall be provided.</td>
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<tr>
<td>28.1. 75% of clients have documentation of annual oral health assessment referral to a dentist.</td>
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<td>29. Mental health assessment/care shall be provided.</td>
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<tr>
<td>29.1. 100% of clients have documentation of annual mental health assessment/care.</td>
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<td>29.2. 100% of clients with documentation of depression have documented plan of care in record.</td>
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<tr>
<td>30. Drugs/Alcohol/ assessment/education shall be performed.</td>
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<tr>
<td>30.1. 100% of clients have documentation of drug/alcohol education/assessment at least annually.</td>
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<td>31. Tobacco (including smokeless tobacco) assessment/education shall be performed.</td>
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<tr>
<td>31.1. 100% of clients who have used tobacco products within one year have documentation of tobacco (including smokeless tobacco) education/assessment at least annually.</td>
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32. Sexual health education, to include birth control method, discussion of condom use, and risk identification, shall be provided.

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<th>32.1. 100% of clients have documentation of sexual health education, to include birth control method, discussion of condom use, and risk identification, once a year.</th>
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33. Transgender health care.

|   | 33.1. 100% of transgender clients will have documentation of birth sex and self-reported gender identity.  
33.2. 100% of transgender clients will receive routine health care within this document’s standards appropriate for their birth sex as anatomically permitted.  
33.3. 100% of transgender clients are assessed for additional medical and mental health needs in addition to those inherent in birth sex and including those incurred from additional anatomical changes. |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### Charting/Documentation

|   | 34. Current Medication List is in medical record.  
34.1. 100% of client charts have a current Medication List in client chart. (Data Source: Medication List)  
35. Clients sign a written informed consent for vaccinations.  
35.1. 100% of client charts show consent for each vaccine.  
35.2. 100% of charts for children, show consent signed by a parent or guardian.  
36. Client chart shall contain problem list.  
36.1. 100% of client charts contain a problem list.  
37. Client chart shall contain allergy list.  
37.1. 100% of client charts contain an allergy list.  
38. Client chart shall contain immunization list.  
38.1. 100% of client charts contain an immunization list. |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
References


xv Definition by representatives of TLCA forum, January 2001.
PROTOCOLS

The Outpatient/Ambulatory Medical Care Protocol identifies the specific ways to implement medical care standards and processes inherent to this service category. Providers are also expected to comply with applicable standards and guidelines that are relevant to individual service categories (i.e., Public Health Service Clinical Guidelines for the Treatment of AIDS-Related Disease, HAB HIV Core Clinical Performance Measures for Adults Clients, etc.). The delivery of ambulatory/outpatient medical care shall be conducted by culturally competent service providers.

Provider staff shall have a client grievance process that shall be discussed with client during intake. Provider staff shall explain that if a client is dissatisfied after completing the agency grievance process, the client has a right to present a grievance to the Broward County HIV Health Services Planning Council.

Accessing Outpatient/Ambulatory Medical Care
The medical staff will contact the Centralized Eligibility Intake Worker to determine the new client’s eligibility. Once eligibility is determined and approved, the Centralized Eligibility Intake Worker will refer the new client to access outpatient/ambulatory medical care at one of the Ryan White Part A outpatient/ambulatory medical care providers.

NOTE: Please be mindful that clients have the right to choose their medical provider. Clients should be advised as to their choices of providers. Be sure to inform clients of providers that have the shortest wait time for an appointment so that they can make an informed decision.

Retention & Adherence to Medical Care
If medical staff is unable to reach a client who has missed an appointment or when a client has missed 2 appointments in a row, the medical provider will contact the medical case management provider first (if client receives this service).

- If the client is not receiving medical case management services, the medical provider will refer the client to outreach providers by telephone call, fax, or through the PE system.
- If the client is receiving medical case management services and the client’s medical case management provider cannot bring the client back to care, medical case managers will refer the client to outreach providers by telephone call, fax, or through the PE system.
- Within 2 weeks, outreach providers will fax the final progress notes as follow-up on the case to the medical provider.

Basic Laboratory Tests
Complete laboratory tests include:
- Complete blood count
- Chemistries
- RPR, hepatitis profile:
  - Hepatitis A Screening - At initial screening, Hepatitis A total antibody (HAVAb) or IgG (not IgM). Unless Hepatitis B or Hepatitis C infected, may consider administering immunization when CD4 cell count greater than 200 cells/mm³.
  - Hepatitis B Screening - At initial screening, Hepatitis B core antibody (HBcAb) total or IgG (not IgM), Hepatitis B surface antibody (HBsAb), and Hepatitis B surface antigen (HBsAg). If HBsAg is positive, evaluate Hepatitis B Viral Load by DNA PCR, and obtain Hep Be Ag and Ab
  - Hepatitis C Screening - At initial screening, Hepatitis C antibody (HCVAb). If HCVAb is positive evaluate Hepatitis C (HCV) Viral Load, genotype, and include treatment plan in record; If negative and active Injection Drug User or other HCV risk factor, repeat HCVAb in 12 months; If there is an unexplained chronic LFT elevation, Hepatitis C viral load should be evaluated (even if HCVAb is negative)
- Toxoplasma antibody
- Lymphocyte profile
- Viral load
- Resistance testing as appropriate
**Medications**  
Medications will be documented in all clients’ charts with start and end dates.

**CD4 and Viral Load Monitoring**  
Practitioner shall do CD4 and Viral Load monitoring following PHS guidelines.

**Tuberculosis Documentation**  
Practitioner shall test clients for tuberculosis. Practitioner shall treat based on most updated PHS guidelines.

**PAP Test for Women**  
Practitioner shall give a PAP test a minimum of once annually.  
Practitioner shall test for gonorrhea and chlamydia at time of PAP test.

**Immunizations**  
Practitioner must offer immunizations per PHS guidelines to all clients.

**Opportunistic Infection Prophylaxis**  
Assessment of Opportunistic Infections shall be completed and prophylaxis shall be given per most updated USPHS/IDSA Guidelines.

**Combination Antiretroviral Therapy**  
If less than 500 CD4 count and not on combination drug therapy, document reason in the chart.

**Pregnancy**  
Under state law all pregnant women should be recommended to receive HIV counseling and testing early during their pregnancy. Subsequently, all women with HIV infection should be offered an antiretroviral treatment regimen in accordance with USPHS, Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV-1 for Maternal Health and for Reducing Prenatal HIV-1 Transmission in the United States.

**Specialist Referrals**  
Practitioner shall refer client to appropriate specialist based on the client clinical status. Examples of referrals are:  
Female client charts show gynecology referral of patient with a cervical lesion or identifies atypical squamous cells (ASCUS and ASC-H), low-grade squamous intraepithelial lesion (LSIL, CIN1), high-grade squamous intraepithelial lesion (HSIL, CIN2-3, carcinoma-in-situ) and invasive carcinoma level PAP.  
Ophthalmology for patient with CD4 count less than 50/ul or with ocular manifestations.  
Psychological/psychiatric for patient presenting with mental health needs.

Practitioner may make appropriate Medical Nutritional Therapy (MNT) referral out when client reports any of the following and agrees to a MNT referral:  
1. Physical changes/weight concerns  
2. Oral/GI Symptoms  
3. Barriers to nutrition, living environment, functional status  
4. Changes in diagnosis requiring nutrition intervention

**Adherence**  
Practitioner shall assess and document adherence to medication.

**Co-morbidities**  
Practitioner shall assess and document co-morbidities, minimally:  
Hepatitis B, C  
STDs  
Substance abuse  
Severe mental illness
Transgender Care
Transgender individuals are defined as individuals whose gender identity, expression, or behavior is not traditionally associated with their birth sex.

Professional Standards
Practitioner must have current prescribing privileges within the State of Florida.

Practitioners are strongly encouraged to complete at least 30 hours of HIV-related Continuing Medical Education (CME) Category 1 credits within a period of two years. When a new practitioner is working with a contracted provider, a new practitioner is encouraged to comply within one year.

Treat and monitor patients in adherence with current DHHS Guidelines and other standards of care, to include, but not limited to:
  a. DHHS Clinical Guidelines
     http://www.aidsinfo.nih.gov/Guidelines/
  b. American Cancer Society Guidelines for the Early Detection of Cancer
  c. European AIDS Clinical Society (EACS) guidelines on the prevention and management of metabolic diseases in HIV
  d. Lipid Disorders subset of the AIDS Education and Training Centers
  e. CDC Recommended Adult Immunization Schedule
  f. Incorporating HIV Prevention into the Medical Care of Persons Living with HIV
     http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5212a1.htm
Appendix A – Quick Guideline for Laboratory Testing
(Current as of 10/11/09)

The following is a minimal guideline based upon the current DHHS Guidelines
Additional labs should be ordered as clinically needed and appropriate

Baseline labs
CD4 T-cell count
HIV RNA
Resistance testing
Basic chemistry - Serum Na, K, HCO3, Cl, BUN, creatinine, glucose (preferably fasting)
ALT, AST, T. bili, D. bili
CBC w/ differential
Fasting Lipid Profile (12 hours fasting)
Fasting Glucose (12 hours fasting)
Urinalysis
Hepatitis A total antibody (HAVAb) or IgG (not IgM)
Hepatitis B core antibody (HBcAb) total or IgG (not IgM)
Hepatitis B surface antibody (HBsAb)
Hepatitis B surface antigen (HBsAg)
Hepatitis C antibody (HCVAb)
Syphilis (RPR)
N. gonorrhea (GC)
C. trachomatis (Chlamydia)

3-6 month labs, before ART
CD4 T-cell count
HIV RNA
CBC w/ differential

6-12 month labs, before ART
Basic chemistry - Serum Na, K, HCO3, Cl, BUN, creatinine, glucose (preferably fasting)
ALT, AST, T. bili, D. bili
Fasting Lipid Profile (12 hours fasting)
Fasting Glucose (12 hours fasting)

3-6 month labs, post ART
CD4 T-cell count
HIV RNA
Fasting Lipid Profile (12 hours fasting)
Fasting Glucose (12 hours fasting)
Urinalysis

12 months
Prostate-specific antigen (PSA) Screening (males)
Syphilis (RPR)
N. gonorrhea (GC)
C. trachomatis (Chlamydia)
Urinalysis

ART initiation or switch
CD4 T-cell count
HIV RNA
Resistance testing
Basic chemistry - Serum Na, K, HCO3, Cl, BUN, creatinine, glucose (preferably fasting)
ALT, AST, T. bili, D. bili
CBC w/ differential
Fasting Glucose (12 hours fasting)
Urinalysis

2-8 weeks post-ART initiation
HIV RNA
Basic chemistry - Serum Na, K, HCO3, Cl, BUN, creatinine, glucose (preferably fasting)
ALT, AST, T. bili, D. bili
CBC w/ differential
Fasting Lipid Profile (12 hours fasting)

Treatment Failure
CD4 T-cell count
HIV RNA
Resistance testing

Special Circumstance
HLA-B*5701 - If considering start of abacavir and document in record carrying data forward to most current volume

Tropism testing – If considering use of CCR5 antagonist (HIV viral load must be ≥ 1000) or if clinically indicated. If performed, record carried forward to most current volume

Pregnancy test (females) – if starting an efavirenz containing regime