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HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION		

INTRODUCTION

The treatment recommendations in this policy are meant to serve as **guidelines**. The guidelines are **not** intended to substitute for the judgement of a physician with expertise in the care of HIV infected individuals. The treatment of all HIV infected offenders, where possible, should be directed by a physician with experience in the care of these patients. When this is not possible, the offender should be scheduled for consultation with an infectious disease specialist. This may be accomplished via telemedicine where available. If the offender refuses, contact the Infectious Disease clinic to obtain a **verbal** Individual Treatment Plan (ITP) or contact an experienced HIV treatment practitioner for ITP recommendations which may include pharmacotherapy consultation from a clinical pharmacist.

POLICY:

Screening and evaluation of offenders at risk for HIV will be standardized. HIV counseling will be conducted by a licensed health care provider or an employee who has completed a TDCJ Health Services-approved training course in HIV counseling. All offenders with a positive HIV test must receive post test counseling and HIV negative offenders should receive information about the meaning of the negative test and risk reduction. All HIV test dates must be entered on the mainframe Medical Profile Screen. Medical Alert codes must be entered within seven (7) days of receipt of reactive (i.e., positive) HIV-1 nucleic acid test (NAT) confirming HIV (+) status. Posttest counseling for all HIV offenders must be completed within seven (7) days-of lab results. All offenders reporting a history of HIV/AIDS are to have a HIV-1 nucleic acid test (NAT) completed to confirm HIV status. Any required counseling must be documented in the medical record. The following basic management protocol for offenders with AIDS (Acquired Immune Deficiency Syndrome) or HIV infection should be followed.

PROCEDURES

I. HIV ANTIGEN/ANTIBODY TESTING

A. ROUTINE ANTIGEN/ANTIBODY TESTING. HIV antigen/antibody testing will be available to all offenders upon request. Requests for voluntary tests need not be honored any more frequently than every six months. Because TDCJ wishes to encourage HIV screening, HIV tests should be considered to be TDCJ-directed testing and not subject to co-pay. HIV testing shall be done on all offenders entering TDCJ unless the offender specifically refuses testing. (see Section I.B for instructions on managing refusals of mandatory tests) or if they are documented to be already infected. Routine testing should also be offered to individuals in the following categories whenever they are identified during their incarceration, if they have not

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previously been tested:

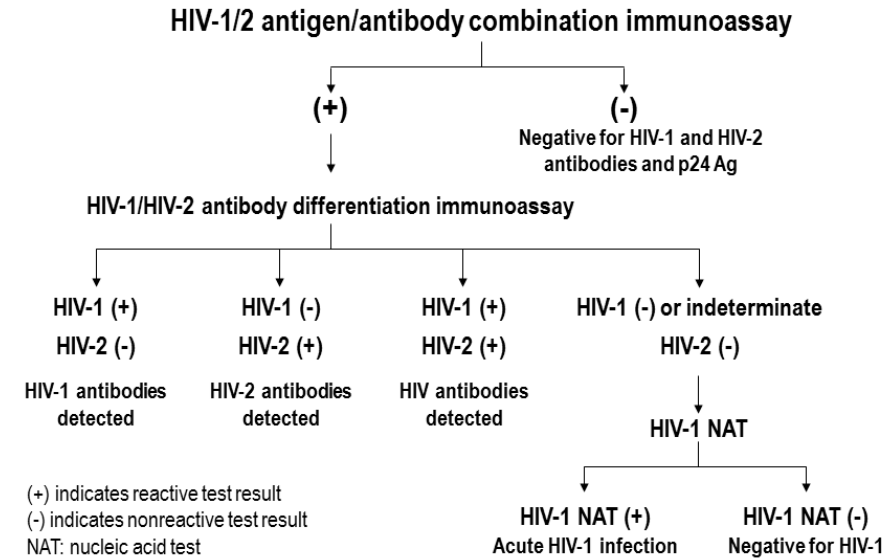
- Unprotected sexual activity with multiple sex partners.
- Injection drug users (specifically, sharing of unsterilized drug injection equipment) and their sexual partners.
- Offenders who are on dialysis.
- Hemophiliacs.
- Psychiatric inpatients that are acutely psychotic and display clinical symptoms consistent with AIDS-related dementia complex (at the discretion of the treating psychiatrist).
- Offenders who report a previous positive HIV test that has not been confirmed in TDCJ.
- Offenders who sexually assault other offenders during incarceration.
- As required by the Texas Department of Health if determined to be in the best interest of the public health.
- Offenders with a confirmed history of TB disease or a PPD \geq 5 mm, syphilis, or any other sexually transmitted disease. (e.g., genital herpes, genital warts, human papilloma virus, chlamydia, trichomoniasis, cervical dysplasia/CIN.)

B. INTERPRETING RESULTS

1. Initial testing should be completed 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. If nonreactive, no further testing is required.
2. If reactive during initial testing with combination immunoassay, complete testing with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies.
3. If reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay, test 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 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.

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Figure 1:



Adapted from Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection

C. MANDATORY TESTING. An offender may refuse routine testing. Special requests for permission to compel testing may be submitted to the Division Director for Health Services for approval in accordance with TDCJ Administrative Directive (A.D.) 6.60, Section V.B.

Mandatory testing of an offender who exposes a staff member to blood or body fluids will be done according to procedures in Correctional Managed Health Care Policy B-14.27. The order for mandatory testing requires approval from the TDCJ Health Services Director. Use of force to obtain blood for this testing is not permitted without a court order. Instead, the offender disciplinary process must be used when an offender does not comply with an order for mandatory testing.

Mandatory testing for HIV must be done prior to the release of an offender from a TDCJ Correctional Institutions Division (TDCJ-CID) facility in accordance with Sections 501.054(i) and 507.023(b) of the Texas Government Code. Processes for this are found in Procedure XII, below.

Every offender who is not already known to be HIV positive must be tested for HIV infection during the intake evaluation, as required by Section 501.054 of the Texas Government Code. Although the test is mandatory under law, verbal consent for testing must still be obtained. If the offender refuses to consent to mandatory testing, this must be documented in the medical record and the offender must be informed

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that the test is required by state law and that they may receive a major disciplinary case if they do not cooperate with testing. If the offender still refuses, the unit Practice Manager or equivalent position will inform the Major by providing a written statement that the offender has refused a test required by state law.

Intake units must report the number of tests done, number of refusals and number of diagnostic evaluations done to the Office of Public Health on a monthly basis as outlined in Procedure XII.

II. CONSENT FOR HIV ANTIGEN/ANTIBODY TESTING. A *verbal informed consent* must be obtained prior to drawing a blood sample to test for the presence of HIV. Documentation of the verbal consent will be recorded by the clinician on the clinical note form (HSM-1) in the offender's medical record.

III. INITIAL EVALUATION OF HIV+ INDIVIDUALS

A. **Medical history**, including sexual history, social history, medication history and history of opportunistic infections. If offender was known to be HIV positive prior to entering TDCJ, or on a previous TDCJ incarceration, obtain records of previous treatment.

B. **Physical examination** [including vitals, weight, general exam, neurologic examination and pelvic exam with PAP and GC/Chlamydia tests.]

C. Baseline diagnostic testing

1. CBC with differential
2. Chemistry profile to include LFTs, serum creatinine, fasting blood sugar and lipid profile
3. Hepatitis serology: HbsAg, Anti-HBs, anti-HBc total antibody, anti-HCV and anti-HAV total antibody.
4. Syphilis screen, e.g., RPR
5. Urinalysis
6. Calculated estimate of creatinine clearance (see disease management pathway)
7. CD4⁺ lymphocyte analysis
8. HIV RNA viral load determination
9. Varicella-Zoster Immune Status
10. Chest X-ray
11. PPD skin test

D. Newly identified offenders with HIV infection should receive an initial dose of pneumococcal vaccine if not previously vaccinated, or a booster dose if they have not

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previously had one and more than 5 years have elapsed since their initial dose. They must be offered hepatitis A and/or hepatitis B vaccination if they are susceptible.

- E. Initiate prophylactic medication(s) for opportunistic infection(s) as indicated (see HIV Disease Management Guidelines).
- F. Refer to dental for oral/periodontal evaluation within 30 days of initial chronic care visit.
- G. Refer all HIV + offenders regardless of CD4 count to the CMC Virology Clinic offered via DMS (UTMB sector) or the designated physician (Texas Tech sector) for evaluation for antiretroviral treatment (ART). Expedited referrals should be obtained for patients that are symptomatic or have a CD4 count < 200 cells/mm³. If the offender refuses, contact the CMC Virology Clinic (UTMB sector) or designated Physician (Texas Tech sector) for drug therapy and individual treatment plan recommendations.

Tests performed within 2 months prior to the diagnosis of HIV infection may be considered baseline and do not need to be repeated unless clinically indicated or required by other sections of this policy.

- V. **CLASSIFICATION OF HIV INFECTION:** The classification system for HIV infection among adults categorizes persons on the basis of clinical conditions associated with HIV infection and CD4⁺ T-lymphocyte counts. The system is based on three ranges of CD4⁺ T-lymphocyte counts, the percentage of total lymphocyte count represented by the CD4⁺ count, and three clinical categories.

All HIV+ individuals must be classified by a Physician, FNP, or PA according to CDC guidelines. The 1993 CDC Revised Classification System for HIV Infection and recorded on the Master Problem List and PULHES upon initial evaluation and periodically thereafter as conditions change. Classification categories dependent on the CD4+ count should be based on the patient's **lowest** CD4+ count.

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TABLE 1

CDC Classification System for HIV Infected Adults

*

CD4+T-CELL CATEGORIES	CLINICAL CATEGORIES		
	(A) Asymptomatic, acute (primary) HIV, or PGL **	(B) Symptomatic, not (A) or (C) conditions	(C) AIDS- indicator condition s***
(1) $\geq 500/\text{cells}/\text{mm}^3$ or $>29\%$	A1	B1	C1
(2) $200 - 499/\text{cells}/\text{mm}^3$ or $14-29\%$	A2	B2	C2
(3) $<200/\text{cells}/\text{mm}^3$ or 14%	A3	B3	C3

* Persons with AIDS-indicator conditions (Category C) as well as those with CD4+T-lymphocyte counts less than 200/cell/mm³ (categories A3 or B3) are reportable as AIDS cases.

** PGL = persistent generalized lymphadenopathy. Clinical Category A includes acute (primary) HIV infection.

*** See Attachment A and Table II

An appropriate medical alert code must be entered on every offender with HIV infection. The following codes apply:

- 0420 – Asymptomatic HIV infection (CDC Classification A1, A2)
- 0421 – Symptomatic HIV infection (CDC Classification (B1, B2)
- 0422 – AIDS (CDC Classification A3, B3, C1, C2, C3)

VI. INDICATIONS FOR PLASMA HIV RNA TESTING The amount of HIV in a person's blood is the viral load. Plasma HIV RNA levels indicates the magnitude of HIV replication and it's associated rate of CD4+positive T cell destruction, while CD4+positive T cell counts indicate the extent of HIV induced immune damage already suffered.

The laboratory parameters of plasma HIV RNA (viral load) and the CD4+ positive T cell count as well as the clinical condition of the patient gives the practitioner important information about the **virologic** and **immunologic** status of the patient and the risk of disease progression to AIDS.

The viral load test is important in decisions to **initiate** or **change** antiretroviral therapies. Measurement of the plasma HIV RNA level using quantitative methods may be

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performed as outlined in Table II.

Table II. Indications for Plasma HIV RNA Testing*		
Clinical Indication	Information	Use
Syndrome consistent with acute HIV infection	Establishes diagnosis when HIV antibody test is negative or indeterminate	Diagnosis
Initial evaluation of newly diagnosed HIV infection	Baseline viral load set point	Decision to start or defer therapy
Every 3-6 months In patients not on therapy	Changes in viral load	Decision to start therapy
2-8 weeks after initiation of antiretroviral therapy	Initial assessment of drug efficacy	Decision to continue or change therapy
4-8 weeks until viral load is suppressed to <200 copies/mL	Maximal effect of therapy	Decision to continue or change therapy
Every 3-6 months in patients on therapy	Durability of antiretroviral effect	Decision to continue or change therapy
Every 6 months in patients on therapy after 2 years on ART with suppressed viral load	Durability of antiretroviral effect	Decision to continue or change therapy
Clinical event or decline in CD4 ⁺ T cells	Association with changing or stable viral load	Decision to continue, initiate, or change therapy

* Acute illness (e.g., bacterial pneumonia, tuberculosis, HSV, PCP) and immunizations can cause increases in plasma HIV RNA for 2-4 weeks; viral load testing; should not be performed during this time.

HIV RNA should be measured using the same laboratory and the same assay.

VII. TREATMENT

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- A. See the HIV Clinical Pathway for guidelines for initiating antiretroviral therapy and for prophylactic therapy of patients with AIDS.
- B. A virtual phenotype test will be done before initiating treatment in a treatment naïve patient. Virtual phenotypes may be done at other times as determined by the specialty consultant.

VIII. COMPREHENSIVE FOLLOW-UP FOR HIV+ INDIVIDUALS:

- A. **Housing:** HIV+ individuals should be housed *according to their behavior* and the housing guidelines established in A.D. 6.60, Section X (i.e., single cells, dormitory, general population, etc.) and Infection Control Manual Policy B-14.50.

When indicated according to the above-referenced policies, the unit **medical director** should update the offenders *Health Summary for Classification* (HSM-18) to reflect special housing (house patient with like medical condition). Should offenders with HIV infection, chronic HBV or chronic HCV require special housing, they should be housed with another offender with like conditions. HIV+ offenders should *not* be housed with those who have hepatitis B or C unless they are already co-infected with the same organisms.

- B. HIV infected individuals should be evaluated in chronic disease clinic at least every six months, unless more frequent clinical monitoring is indicated or they are being seen more frequently in infectious disease clinic. Patients who consent to drug therapy **will** be referred to a designated physician or infectious disease specialist. Specialist evaluations may be done by telemedicine. Expedited referrals should be obtained for patients that are symptomatic or have a CD4 count < 200 cells/mm³.
- C. HIV infected individuals with CD4+ < 100 should be referred to ophthalmology clinic for a retinal examination to rule out HIV retinopathy and CMV retinitis.
- D. For security reasons, the unit health authority may report to the warden, upon request, the names of offenders with a possible blood borne infectious disease (i.e., HBV, HCV, or HIV). The physician **must not** disclose the specific infectious disease the offender has.
- E. Offenders with confirmed positive HIV test results shall **not** be assigned to **work** in the medical department, in order to protect the offender from exposure to communicable diseases. There are no other work restrictions, except as dictated by the patient's clinical status.
- F. HIV-infected individuals may require **counseling and support systems**, consisting of:

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physicians, psychiatrists, psychologists, dentists, nurses, chaplains, patient advocates and correctional counselors. These individuals may be involved as deemed necessary on a case-by-case determination.

IX. ADHERENCE TO TREATMENT AND DISCONTINUATION OF THERAPY – PREVENTING DRUG RESISTANCE

- A. Antiretroviral medications will be administered by directly administered therapy (DAT). The drugs will not be given KOP.
- B. Adherence to therapy will be monitored, and offenders will be counseled about the importance for adherence, and encouraged to improve adherence to therapy.
- C. Adherence will be measured after each month of therapy. If adherence to any of the antiretroviral drugs falls below 90%, the patient will be counseled and adherence reassessed in one month. Counseling should be documented in the medical record. If adherence is below 90%, also consider the possibility of drug intolerance and consider changing treatment regimen if necessary.
- D. If adherence is below 85% for two consecutive months the patient should be referred to the clinical pharmacist whenever possible for adherence counseling. Repeated referrals to the clinical pharmacist are not required if the patient continues to be non-compliant. See paragraph IX.E below.
- E. If compliance remains below 85% for 2 months or more, an expedited referral to a designated physician or infectious disease specialist will be made. This appointment may be at the referral center or by telemedicine or digital medical service (DMS). Patients referred for compliance problems will be reviewed by the specialist every 2-4 weeks to determine the subsequent management of the case and possible discontinuation of antiretroviral treatment. Only the consultant may discontinue antiretroviral medications for low compliance.
- F. Consideration should also be given to discontinuing antiretroviral drugs when the offender is not benefiting from the treatment. If this is done, it should be done in consultation with an infectious disease specialist.

X. TREATMENT FAILURE

- A. If the viral load becomes detectable while on antiretroviral therapy after being non-detectable, or if the viral load increases by a factor of 3 or more, the patient should be evaluated within one month by a designated physician or infectious disease specialist. If an appointment cannot be scheduled within that time frame, telephone consultation should be obtained. Therapy should continue unchanged pending the specialty evaluation.
- B. Before determining that consultation is necessary:
 - 1. Assess compliance and counsel for improvement if necessary.
 - 2. Determine whether the patient wishes to continue treatment

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XI. PRE-RELEASE TESTING

- A. Pre-release testing- All HIV tests must be completed by the HIV test date indicated on the HIVRL report.
- B. Every offender incarcerated in TDCJ-CID must be tested for HIV prior to release unless they are already known to be infected with HIV. Offenders leaving on bench warrant are not included as they are expected to return to TDCJ without being released. Although a test done within the last 6 months of incarceration may be counted as a pre-release test, every effort must be made to test offenders as close to the time of discharge as possible while still allowing time to inform the offender of the result (if positive) and to notify the Texas Department of State Health Services to carry out partner notification prior to release.
- C. Offenders who require testing can be identified by running the HIVRL report for your unit. This report is found under the SO00 screen on the mainframe. It is updated daily with offenders scheduled to be released within the next 6 months. It is very important to obtain this list at least weekly because offenders being released under discretionary mandatory supervision will not appear on the list until 7-14 days before their release.
- D. It is the responsibility of the unit of assignment prior to release to perform the HIV test. However, an offender who is not tested on his last assigned unit must be tested as soon as he is identified, even if they are in transit or have already arrived at the unit from which they are being released.
- E. Highest priority for testing should be those scheduled for release within the next month.
- F. Offenders must receive pre-test counseling and give consent for the test, even though it is mandatory. Verbal consent is acceptable if it is documented in the medical record and the test is done more than 30 days before release. If the test is done less than 30 days before release, a written consent must be obtained using the "Consent for Pre-release HIV Testing" form. Post release locating information must be recorded on this form in case the offender must be contacted after release to receive a positive result.
- G. If an offender refuses mandatory pre-release testing, the refusal must be documented in the medical record. The offender must be informed that the test is required by state law and that they may receive a major disciplinary case if they do not cooperate with testing. If the offender still refuses, the unit Practice Manager or equivalent position will inform the Major by providing a written statement that the offender has refused a test required by state law.
- H. The HIV test must be designated as a pre-release HIV test. A specific "Pre-release HIV Test" is available when ordering the test on the Electronic Health Record (EHR). Otherwise, "pre-release test" must be recorded on the laboratory request slip.
- I. The date of the HIV test must be entered by updating the MEDI screen. It is vital to

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do this promptly, as the information cannot be entered after the offender is released. The information may also be entered through the AD option under the HI00 screen on the mainframe.

- J. Offenders with a positive result must receive individual post-test counseling. Because release is imminent, this counseling must be offered promptly when the result is received. During counseling the offender must receive information about services available in their area. In addition, partner elicitation must be carried out and include at a minimum the name and address of a spouse or significant other to whom the offender will be returning after release.
- K. Positive pre-release HIV results and partner information must be reported to the Office of Public Health within one business day.

XII. REPORTING

- A. All monthly HIV statistical reports are due to Office of Public Health (OPH) by the 5th day of each month.
- B. Reporting – All positive HIV antigen/antibody tests and HIV-1 NAT results must be reported to Office Public Health within 7 days of receipt on unit. All CD4 and HIVVL results must be reported to OPH within seven (7) days of receipt on unit. Reporting and confidentiality of HIV antigen/antibody results will be governed by the provisions of the Texas Communicable Disease Prevention and Control Act (Art. 81.001 et seq, *Texas Health and Safety Code*). All HIV information shall be sent by U.S. mail, double enveloped, and labeled "**Medically Confidential**".

XIII. DISCHARGE PLANNING

- A. 3-6 months before the projected release date, counseling about preparing for continuity of care after release should be initiated with the offender. Discharge plans are prepared for HIV positive offenders during this time frame by the Texas Correctional Office on Offenders with Medical or Mental Impairments (TCOOMMI). Offenders should be encouraged to cooperate with the TCOOMMI Continuity of Care worker, and to consider contacting community based organizations in their community prior to release.
- B. Prior to release the offender should be provided copies of his last HIV chronic care note, last infectious disease clinic note, latest viral load and CD4+ results and his medication pass.
- C. The medical certification page of the Texas HIV Medication Program (Attachment A) application should be filled out and given to the offender along with the medical records listed in XII.B. This form requires the signature of a physician or midlevel staff, but can be filled out by anyone having access to and understanding of the information required.

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XIV. EDUCATION AND TRAINING OF STAFF AND OFFENDERS:

Refer to TDCJ Administrative Directive 6.60, Section XI.

REFERENCES:

1. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at <http://stacks.cdc.gov/view/cdc/23447> . Published June 27, 2014.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services Available at <http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGI.pdf>, May 1, 2014.