



PrEP to Prevent HIV and Promote Sexual Health

Lead author: Rona M. Vail, MD, with the *Medical Care Criteria Committee*, updated February 2020

Table 2: Recommended Laboratory Tests to Be Obtained Before Prescribing TDF/FTC or TAF/FTC as PrEP	
<i>Note: PrEP may be initiated while results are pending.</i>	
Test (rating)	Comments
Baseline HIV test (A*)	<ul style="list-style-type: none"> Obtain a 4th-generation (recommended) or 3rd-generation (alternative) HIV screening test [a].
HIV RNA testing (A3)	<ul style="list-style-type: none"> Perform HIV RNA testing [a] in patients who: <ul style="list-style-type: none"> Have had symptoms of acute HIV in the past 6 weeks [Chin, et al. 2013]. Report condomless anal or vaginal sex during the previous 4 weeks. Have shared injection drug needles in the past 4 weeks.
Metabolic panel (A*)	<ul style="list-style-type: none"> Obtain serum creatinine and calculated CrCl. TDF/FTC as PrEP should not be initiated in patients with a confirmed calculated CrCl <60 mL/min. TAF/FTC should not be initiated in patients with a confirmed CrCl <30 mL/min.
Pregnancy test for all individuals of childbearing capacity (A3)	<ul style="list-style-type: none"> Discuss the importance of preventing HIV during pregnancy with anyone contemplating pregnancy or who becomes pregnant while taking PrEP. Discuss overall risks and benefits and available data, which suggest that TDF/FTC does not increase risk of birth defects. (See <i>Pregnancy Screening and Management</i> in this guideline.)
HBV serologies: HBsAg, anti-HBs, and anti-HBc [IgG or total] (A2†)	<ul style="list-style-type: none"> Vaccinate nonimmune patients (A2). Chronic HBV: Treat and monitor HBV as per treatment guidelines [b], or refer to an HBV specialist.
Gonorrhea and chlamydia screening (A2†)	<ul style="list-style-type: none"> Perform NAATs for gonococcal and chlamydial infections [c] for all patients at all sites of reported exposure. For all men who have sex with men and transgender women, routinely perform 3-site testing (genital, rectal, and pharyngeal) regardless of sites of reported exposure. Genital testing [CDC 2014]: <ul style="list-style-type: none"> To detect urethral infection, urine specimens are preferred over urethral specimens. For vaginal/cervical testing, vaginal swabs are preferred over urine-based testing. For transgender women with a neovagina, there are insufficient data to make a recommendation regarding urine-based testing vs. vaginal swab [d]. Self-collected swabs from the pharynx, vagina, and rectum are reasonable options for patients who may prefer them over clinician-obtained swabs. [Geelen, et al. 2013; Paudyal, et al. 2015]. <ul style="list-style-type: none"> See <i>STI Screening</i> in this guideline for further details.
Syphilis screening (A2†)	<ul style="list-style-type: none"> Screen for syphilis [e] according to the laboratory’s testing algorithm. <ul style="list-style-type: none"> See <i>Standard Protocol for Syphilis Screening and Diagnosis</i> and <i>Alternative, Reverse Algorithm for Syphilis Screening and Diagnosis</i>.



CLINICAL GUIDELINES PROGRAM

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV · HCV · SUBSTANCE USE · LGBT HEALTH

Table 2: Recommended Laboratory Tests to Be Obtained Before Prescribing TDF/FTC or TAF/FTC as PrEP

Note: PrEP may be initiated while results are pending.

Test (rating)	Comments
HCV serology (A3)	<ul style="list-style-type: none"> Inform patients with HCV about the risk of transmission and offer or refer for treatment. <ul style="list-style-type: none"> See the NYSDOH AI guideline <i>Treatment of Chronic HCV with Direct-Acting Antivirals</i>.
HAV serology (good practice)	<ul style="list-style-type: none"> Obtain for individuals at high risk for HAV, including MSM and those who: <ul style="list-style-type: none"> Have chronic liver disease or conditions that can lead to chronic liver disease (e.g., chronic HBV, chronic HCV, alcohol use, or genetic liver diseases). Are travelers to or from countries with high or intermediate endemicity of HAV infection. Use illicit drugs, particularly injection drugs. Are unstably housed/homeless. Live in a community identified by the local health department as experiencing an outbreak of HAV infection. Have clotting-factor disorders. Want to reduce their risk for HAV infection. Are at occupational risk and are not otherwise required to receive HAV vaccination. Are at risk of HAV-related morbidity or mortality. Vaccinate nonimmune patients.
Serum liver enzymes (good practice)	<ul style="list-style-type: none"> Increased serum liver enzymes may indicate acute or chronic viral hepatitis infection and require further evaluation.
Urinalysis (good practice)	<ul style="list-style-type: none"> As part of standard primary care, urinalysis is used to identify preexisting renal disease, proteinuria, and glycosuria. Only calculated CrCl is used to guide decisions regarding use of TDF/FTC and TAF/FTC as PrEP based on renal function.

Abbreviations: anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody; CrCl, creatinine clearance; GFR, glomerular filtration rate; HAV, hepatitis A virus; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; IgG, immunoglobulin G; MSM, men who have sex with men; NAAT, nucleic acid amplification test; STI, sexually transmitted infection; TAF/FTC, tenofovir alafenamide/emtricitabine; TDF/FTC, tenofovir disoproxil fumarate/emtricitabine.

Notes:

- See NYSDOH AI guideline *HIV Testing*.
- See NYSDOH AI guideline *HBV-HIV Coinfection*.
- See NYSDOH AI guideline *Management of Gonorrhea and Chlamydia in Patients with HIV*.
- See UCSF *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People*.
- See NYSDOH AI guideline *Management of Syphilis in Patients with HIV*.

REFERENCES

CDC. Recommendations for the laboratory-based detection of Chlamydia trachomatis and Neisseria gonorrhoeae--2014. *MMWR Recomm Rep* 2014;63(RR-02):1-19. [PMID: 24622331] <https://www.ncbi.nlm.nih.gov/pubmed/24622331>

Chin T, Hicks C, Samsa G, et al. Diagnosing HIV infection in primary care settings: missed opportunities. *AIDS Patient Care STDs* 2013;27(7):392-397. [PMID: 23802143] <https://www.ncbi.nlm.nih.gov/pubmed/23802143>



CLINICAL GUIDELINES PROGRAM

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV · HCV · SUBSTANCE USE · LGBT HEALTH

Geelen TH, Rossen JW, Beerens AM, et al. Performance of cobas(R) 4800 and m2000 real-time assays for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in rectal and self-collected vaginal specimen. *Diagn Microbiol Infect Dis* 2013;77(2):101-105. [PMID: 23891224] <https://www.ncbi.nlm.nih.gov/pubmed/23891224>

Paudyal P, Llewellyn C, Lau J, et al. Obtaining self-samples to diagnose curable sexually transmitted infections: a systematic review of patients' experiences. *PLoS One* 2015;10(4):e0124310. [PMID: 25909508] <https://www.ncbi.nlm.nih.gov/pubmed/25909508>