Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens

- Perform rapid HIV 4th-generation test first, then confirm reactive result with 4th-generation or 3rd-generation laboratory-based HIV test. (A2)
- Perform HIV testing immediately according to guidelines for the evaluation of acute HIV, including an HIV viral load test and a laboratory-based 4th-generation HIV test. (A2)
- At least every 6 months for the duration of use of TDF/FTC; adjustments to the ART regimen can be made if indicated once genotypic resistance test results are available or if the patient experiences side effects.

Monitoring and Ongoing Laboratory Testing

- Perform repeat HIV RNA testing and repeat HIV diagnostic testing for patients who have a reactive HIV test result while a definitive diagnosis is sought, unless suspicion for acute HIV is low. (A2)
- Perform quantitative HIV RNA testing, if not already obtained, as part of the diagnostic algorithm for suspected acute HIV, to measure viral load and perform genotypic resistance testing. (A2)
- Assess for opportunistic infections related to HIV/AIDS, as part of a sexual history and treat these infections empirically based on symptoms while results are pending. (A2+)
- Assess for potential risk exposures since the previous testing. (A*)
- Obtain a 4th-generation or 3rd-generation laboratory-based HIV test. (A2)
- Ask about potential risk exposures since the previous visit. (A2)
- Ask about signs and symptoms of acute HIV since the previous testing. (A*)
- Obtain an HIV viral load test and perform genotypic resistance testing. (A2)
- Perform urinalysis at baseline and annually, assessing for urine glucose and protein. (B3)
- At the following intervals, clinicians should perform renal function testing, including testing creatinine level and calculated glomerular filtration rate: (A3)
- At least every 6 months for the duration of use of TDF/FTC; adjustments to the ART regimen can be made if indicated once genotypic resistance test results are available or if the patient experiences side effects.
- At least every 6 months for the duration of use of TDF/FTC as PrEP; more frequent screening may be required in patients at higher risk for renal disease. (A3)
- Clinicians should discontinue TDF/FTC as PrEP if a patient develops a confirmed calculated CrCl ≤50 mL/min. (A3)
- Clinicians should perform urinalysis at baseline and annually, assessing for urine glucose and protein. (B3)
- Clinicians should perform annual HCV testing for at-risk patients using a laboratory-based 4th-generation or 3rd-generation laboratory-based HCV test. (A2)
- Clinicians should obtain annual HCV testing for at-risk patients using a laboratory-based 4th-generation or 3rd-generation laboratory-based HCV test. (A2)
- Clinicians should perform tuberculosis testing for people who are using PrEP. (A3)
- At every 3 months, a care provider should assess patients for signs of new or worsening symptoms of oral mucosal lichenoid drug eruption. (A3)
- Clinicians should closely monitor patients who have chronic HBV for potential viral rebound when PrEP with TDF/FTC or TAF/FTC is stopped. (A2)
- In patients who have a reactive HIV test result while a definitive diagnosis is sought, unless suspicion for acute HIV is low, clinicians should perform immediate ART that will be active against virus with potential mutations for TDF/FTC. (A1)
- At the following intervals, clinicians should perform renal function testing, including testing creatinine level and calculated glomerular filtration rate: (A3)
- At least every 6 months for the duration of use of TDF/FTC; adjustments to the ART regimen can be made if indicated once genotypic resistance test results are available or if the patient experiences side effects.
- At least every 6 months for the duration of use of TDF/FTC as PrEP; more frequent screening may be required in patients at higher risk for renal disease. (A3)
- Clinicians should discontinue TDF/FTC as PrEP if a patient develops a confirmed calculated CrCl ≤50 mL/min. (A3)
- Clinicians should perform urinalysis at baseline and annually, assessing for urine glucose and protein. (B3)
KEY POINTS—AFTER PrEP HAS BEEN STARTED

Monitoring and Ongoing Laboratory Testing
- Flexibility regarding frequency of in-person visits may help improve PrEP uptake and persistence.
- Education regarding the importance of and strategies to support PrEP adherence may improve adherence to PrEP and recommended monitoring.
- The minimal degree of adherence to TDF/FTC as PrEP required for protection against HIV varies by site of exposure. Nevertheless, a high degree of adherence is important.
- Use of TDF/FTC does not lower estrogen levels, and addressing this directly with transgender women may improve willingness to take and adhere to PrEP.
- Side effects associated with TDF/FTC used as PrEP are generally mild and resolve within 3 months after initiation.
- In clinical trials, rash was not a commonly observed side effect among participants taking TDF/FTC as PrEP (see Managing a Positive HIV Test Result in the full guideline).
- TAF/FTC is an acceptable alternative to TDF/FTC in MSM and transgender women who are at risk for or exhibit renal or bone toxicity.
- Routine HIV testing is an integral component of the safe use of PrEP.
- HIV testing does not have to be linked to an in-office visit.
- If an individual taking PrEP misses a scheduled testing appointment, do not interrupt PrEP. Instead, encourage continuation of PrEP and work with the individual to reschedule any necessary visits and laboratory testing.
- Frequent screening for HIV infection is performed to prevent development of drug-resistant virus and to protect against transmission of HIV if HIV seroconversion has occurred.
- STI testing, including extragenital testing for gonorrhea and chlamydia, at close intervals and prompt treatment of STIs are integral components of PrEP management.
- STI rates decline more rapidly as higher numbers of at-risk individuals initiate PrEP, with an even greater reduction in STIs the more frequently STI testing occurs, even in the event of a 40% to 80% decrease in condom use.
- Although discussion of condom use is an important part of prevention messaging, PrEP initiation and treatment should not be tied to condom use.
- Because the sensitivity and specificity of self-collected rectal, vaginal, and pharyngeal swabs are comparable to those collected by a clinician, self-collected swabs are reasonable alternatives for patients who may prefer these methods.
- Pregnancy is not a contraindication to PrEP.
- The use of antiretroviral medications during pregnancy is monitored through the Antiretroviral Pregnancy Registry (APR).
- Information regarding medications used during breastfeeding is available through the LactMed database.

Discontinuing PrEP
- PrEP can be discontinued for those no longer at risk of HIV acquisition because they have eliminated the sex or drug use behaviors that put them at risk.

Managing a Positive HIV Test Result
- Because false-positive 4th-generation HIV test results do occur and there is risk of HIV infection if PrEP is discontinued, clinicians will have to decide whether to continue the PrEP regimen or intensify to a full HIV treatment regimen while awaiting confirmatory test results, based on degree of suspicion for a false-positive versus a true-positive HIV test result.
- Consult with an experienced HIV care provider to manage a positive or ambiguous HIV test result.

PrEP MANAGEMENT CHECKLIST: FOLLOW-UP & MONITORING

AT EVERY FOLLOW-UP Visit (Note: The frequency of follow-up visits should be individualized. Stable individuals may need to be seen only 1 to 2 times per year, with laboratory testing performed in the interim.)
- Assess adherence and discuss strategies for maintaining adherence; explore and address potential barriers to ongoing use of and adherence to PrEP.
- Discuss risk reduction in the context of the individual’s sexual health or injection drug use; offer condoms and, if appropriate, syringe access.
- Assess for possibility of pregnancy and offer birth control and pregnancy testing when appropriate.
- Inquire about side effects and offer advice for management if needed.
- Partner with providers who can provide needed services, including subspecialty medical care, mental health and substance use treatment, case management, navigation and linkage services, housing assistance, and income/benefits assessments.
- Make every effort to avoid discontinuing PrEP or withholding it from a patient at risk of acquiring HIV.
- Ask about symptoms suggestive of STIs and test those at risk.
- Screen for symptoms of acute HIV and test if indicated.

TESTING: EVERY 3 MONTHS (Note: An in-person visit is not required for laboratory testing.)
- Test for HIV infection, using a 4th-generation or a 3rd-generation test.
- Test for syphilis, gonorrhea, and chlamydia; may consider less frequent screening in those at lower risk.
- Perform NAATs for gonococcal and chlamydial infections for all patients at all sites of reported exposure.
- For all MSM and transgender women, routinely perform 3-site testing (genital, rectal, and pharyngeal) for gonorrhea and chlamydia regardless of sites of reported exposure, unless declined.
- Obtain serum creatinine and calculated CrCl at 3 months after initiation of TDF/FTC as PrEP and every 6 months thereafter.
- There are no data for adjusting TDF/TAF dosing in those with CrCl <50 mL/min; discontinue TDF if confirmed CrCl <50 mL/min; discontinue TAF if confirmed CrCl <30 mL/min. (See Renal Function Testing in the full guideline.)
- Consider more frequent screening in those at higher risk (e.g., age >40 years) or who have comorbidities.

EVERY 6 MONTHS (Note: An in-person visit is not required for laboratory testing.)
- Obtain serum creatinine and calculated CrCl at 3 months after initiation of TDF/FTC as PrEP and every 6 months thereafter.

ANNUALLY
- Urinalysis.
- HCV serology for those at risk; may obtain more frequently for those at higher risk.

HIV REPORTING IN NYS
- Clinicians must report confirmed cases of HIV according to NYS law.
- Clinicians should offer assistance notifying partners or should refer patients to other sources for partner notification assistance.
- Reporting of suspected seroconversion: Clinicians who manage the care of patients on PrEP are strongly encouraged to immediately report any cases of suspected PrEP/PEP breakthrough HIV infection as follows:
  - NYC: Report cases to the NYC Department of Health and Mental Hygiene immediately by calling 212-442-3388 and following the directions detailed in the attached Health Alert.
  - Rest of State: Report cases to NYSDOH by calling 518-474-4284 or using DOH-4189 and contacting their local Partner Services Program to discuss the case.