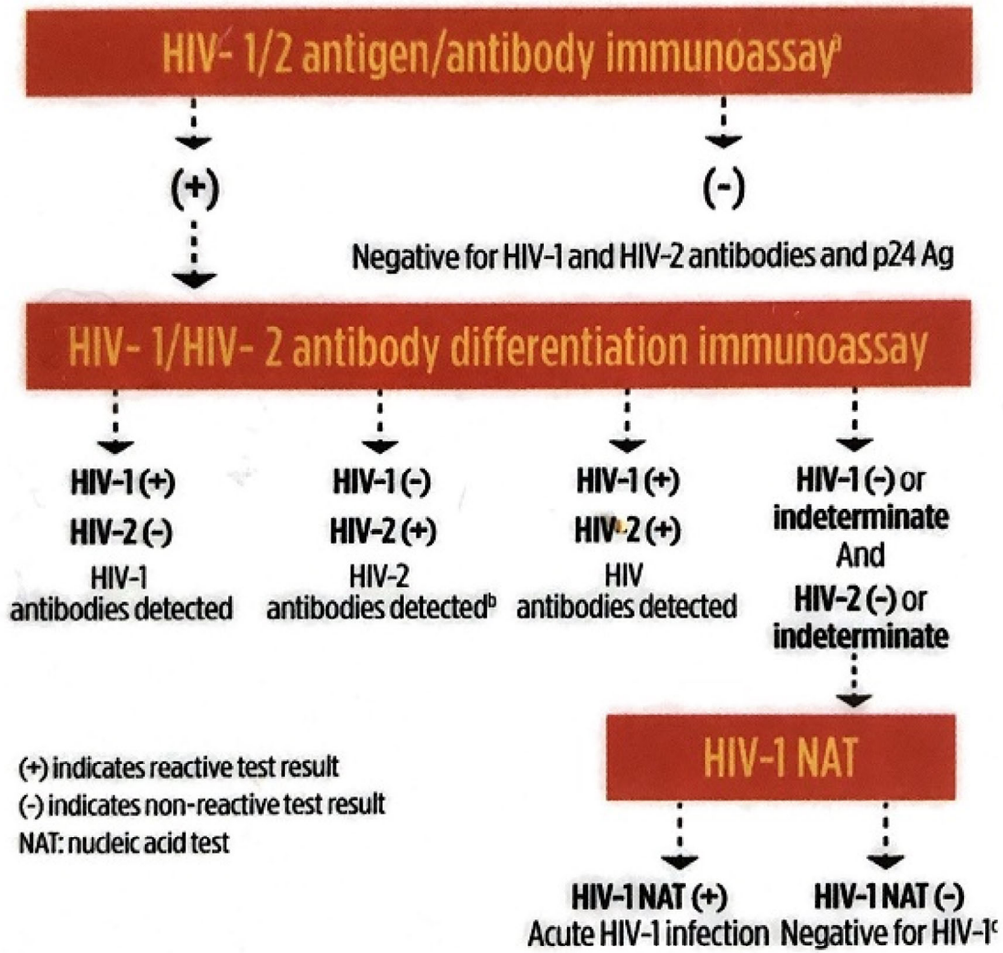
RECOMMENDED LABORATORY HIV TESTING ALGORITHM FOR SERUM OR PLASMA SPECIMENS



a. The FDA-approved single-use rapid HIV-1/HIV-2 antigen/antibody immunoassay can be used as the initial assay in the laboratory HIV testing algorithm for serum or plasma. If any instrumented antigen/antibody test is available, it is preferred due to its superior sensitivity for detecting HIV during acute infection.

b. This includes specimens reported as HIV-2 positive with HIV-1 cross-reactivity.

c. A negative HIV-1 NAT result and repeatedly HIV-2 indeterminate of HIV indeterminate antibody differentiation immunoassay result should be referred for testing with a different validated supplemental HIV-2 test (antibody test or NAT) or repeat the algorithm in 2 to 4 weeks, starting with an antigen/antibody immunoassay.

NEW YORK STATE HIV TESTING GUIDELINE KEY POINTS

- One time offer of HIV testing must be made to persons 13 and older receiving care from an MD, DO, NP, PA, or CNM or when receiving hospital or primary care services, with limited exceptions.
- HIV-related information, must be made available to the patient being tested either orally, in writing, through signage, or in audio-visual format.
- HIV testing is voluntary and patients have the right to refuse.
- Advisement of HIV testing and any objection to testing must be documented in the medical record.
- For patients with ongoing risk of HIV, order HIV tests annually. Some patients may require more frequent testing based on risk factors.
- HIV testing is strongly recommended for pregnant patients during the 1st and 3rd trimester and for patients presenting in labor with unknown HIV status.
- For point-of-care screening, an FDA approved antigen/antibody combo test is preferred.

IF NEGATIVE:

- Provide information about pre-exposure prophylaxis (PrEP), and post- exposure prophylaxis (PEP).
- Discuss HIV risk factors from sexual and needle-sharing activities; provide risk reduction counseling.

IF POSITIVE:

- Provide supportive counseling and education on HIV diagnosis.
- Person ordering the HIV test, or representative, must schedule follow-up appointment for medical care with patient consent. **Referral alone is not enough.**
- Provider/facility of follow-up appointment must be documented in the medical record.
- Report HIV diagnosis to the to the NYSDOH via the Medical Provider Report Form within 14 days of diagnosis.

For more information on HIV clinical guidelines, go to: www.hivguidelines.org

To speak with a clinician experienced in managing HIV call the CEI Line at 866-637-2342

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PEP TRIAGE PROTOCOL

(Note: Exposure to HIV is a Medical Emergency)

STEP 1: EVALUATE EXPOSURE: IS PEP INDICATED?

Did a puncture, mucous membrane, or sexual exposure to potentially HIV-infected fluid occur?

NO → PEP not indicated. Consider PrEP if ongoing exposure

YES

Is patient presenting within 72 hours?

NO → PEP not recommended. Serial HIV testing (Baseline, 4, and 12 weeks), provide risk reduction counseling, and educate on acute HIV symptoms. Assess for Hep B and C exposure.

YES

STEP 2: INITIATE FIRST DOSE OF PEP REGIMEN A.S.A.P.

Initiate PEP as soon as possible (ideally within 2 hours and no later than 72 hours post-exposure). Refer to recommended and alternative regimens on back of card.

STEP 3: PERFORM BASELINE TESTING

EXPOSED PERSON:

- HIV 1/2 Ag/Ab combo test
- Pregnancy test
- GC/CT NAAT based on exposure site(s) *not required for sexual assault*
  - For sexual assault, treat empirically for GC/CT and trich
- RPR for syphilis *not required for sexual assault*
- Assess for Hep B and C
- Liver and renal function tests

SOURCE PERSON:

PEP should not be delayed while source is being evaluated.

- *If known to have HIV AND undetectable Viral Load* (<200 copies/ml) AND adherent to ARV, explain that HIV will not be transmitted through sex
- *If known to have HIV with unknown or detectable Viral Load* (>200 copies/ml), obtain viral load and resistance information
  - Continue PEP while awaiting HIV RNA and resistance results
- If HIV status unknown, provide HIV test with turnaround time of <1 hour
  - If results are not immediately available: continue PEP while awaiting results
  - If result is negative but there may have been exposure to HIV in previous 4 weeks OR PrEP use, obtain plasma HIV RNA assay
    - Continue PEP until results of HIV RNA are available

STEP 4: PROVIDE COUNSELING AND REFERRAL

- Reinforce need for adherence to PEP regimen
- Review symptoms for acute HIV and need to report flu-like symptoms to medical provider
- Provide risk reduction counseling; consider need for intensive risk reduction services
- For persons with ongoing risk behavior, discuss future use of PrEP whether or not PEP is indicated
- Refer for mental health and/or substance use services when indicated
- For sexual assault, refer for appropriate social work and legal services
- Schedule or refer for post-exposure follow-up:
  - 48 hour check-in for adherence and tolerability, serial HIV tests at weeks 4 & 12
  - STI and Hepatitis B and C screening

RECOMMENDED PEP REGIMENS

For exposed patients > 40kg

28-DAY REGIMEN

Tenofovir disoproxil fumarate (TDF) 300 mg/Emtricitabine 200 mg (or TDF/Lamivudine 300 mg) PO daily

PLUS

Raltegravir 400 mg PO bid or Raltegravir HD* 1200 mg PO daily
or Dolutegravir** 50 mg PO daily

PREFERRED ALTERNATIVE REGIMENS

Elvitegravir 150 mg/Cobicistat 150 mg/Emtricitabine 200 mg/TDF 300 mg PO daily

OR

TDF 300 mg/Emtricitabine 200 mg (or TDF/Lamivudine 300 mg) PO daily

PLUS

Darunavir 800 mg PO daily or Atazanavir 300 mg PO daily
or Fosamprenavir 1400 mg PO daily

AND

Ritonavir 100 mg PO daily

*Raltegravir HD formulation should not be given to pregnant patients
**Refer to AI guidelines on use of Dolutegravir in first trimester of pregnancy

Provide full 28-day course of PEP

If patient does not have immediate access to full supply, dispense a 7-day starter pack and prescription for remainder. *Note: Following sexual assault, NYS law requires dispensing of 7 days if ≥ 18 years; 28 days if ≤ 18 years*

Speak with a clinician experienced in managing PEP if exposed patient is <40kg, pregnant, breastfeeding, or requires an alternative regimen.

For more information regarding occupational PEP, non-occupational PEP, or sexual assault PEP guidelines, go to
www.hivguidelines.org

To speak with a clinician experienced in managing PEP, call the CEI line 24/7 at
866-637-2342

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PrEP INITIATION AND FOLLOW-UP

Starting PrEP: PrEP may be initiated while lab tests are pending unless the individual had a recent risk encounter that requires PEP (in last 72 hours), acute HIV (AHI) is suspected, or there is a history of renal disease or Hepatitis B.

BEFORE PRESCRIBING PrEP OBTAIN:

1. **HIV diagnostic test:** HIV 1/2 Ag/Ab combo test. Perform RNA viral load if AHI is suspected or high-risk activity reported during the last 4 weeks.
2. **Metabolic panel:** Include serum creatinine and creatinine clearance (CrCl).
3. **Pregnancy test:** For individuals of childbearing capacity. If positive, discuss known benefits and risks.
4. **Hepatitis screening:** Liver enzymes + serologies for hepatitis A, B, and C.
5. **STI screening:** Perform GC/CT for all sites of exposure (genital, rectal, pharyngeal). Self-collected swabs may be used. Routine 3-site testing for GC/CT is recommended for MSM and transgender women unless declined.
6. **Syphilis screening:** Screen for syphilis according to the laboratory's testing algorithm.
7. **Urinalysis:** Perform urinalysis to identify preexisting renal disease.

FOR ONGOING MONITORING OBTAIN:

1. **HIV testing every 3 months:** Obtain HIV test 1 month after initiation for individuals with risk exposure in the month prior to starting PrEP.
2. **HIV RNA testing:** If symptoms of AHI, or PrEP was interrupted in the past month and a potential exposure has occurred.
3. **Serum creatinine and CrCl:** at 3 months and then every 6 months.
4. **STI Screening:** Test for syphilis, gonorrhea, and chlamydia, regardless of symptoms, every 3 months and on patient request. Frequency can occur less often in patients at lower risk of exposure. Perform GC/CT for all sites of exposure (genital, rectal, pharyngeal). Self-collected swabs may be used. Routine 3-site testing for GC/CT is recommended for MSM and transgender women unless declined.
5. **HCV serology:** Annually for individuals at risk.
6. **Urinalysis:** Annually.
7. **Pregnancy test:** If the possibility of pregnancy is indicated during assessment.

Please note: If a patient misses a scheduled lab or visit, do not withhold PrEP. Every attempt should be made to continue PrEP and reschedule follow-up at times and locations convenient to the patient.

RECOMMENDED PrEP REGIMEN

TDF/FTC (TRUVADA®) 1 tablet daily

(Tenofovir disoproxil fumarate/emtricitabine)
is perferred for most individuals with CrCl ≥ 60 mL/min.

It is the only option for:
- cisgender women and transgender individuals who have receptive vaginal sex
- individuals who use injection drugs

On-demand dosing (2-1-1*) is an alternative option for cisgender MSM*; however daily dosing is perferred

*2 pills 2-24 hours before sex + 1 pill 24 hours after initial dose + 1 pill 48 hours after initial dose.

TAF/FTC (DESCOVY®) 1 tablet daily

(Tenofovir alafenamide/emtricitabine)
is an alternative option for cisgender MSM and transgender women;
It is the preferred option for
cisgender MSM and transgender women with:
- renal disease
- osteoporosis

Do not start TAF/FTC if CrCL <30ml/min.

Questions about using PrEP with a patient who has HBV, is pregnant or attempting to conceive, is taking nephrotoxic drugs, or is at risk for osteoporosis?

Call the CEI Line at

866-637-2342

TO SPEAK WITH A CLINICIAN EXPERIENCED IN MANAGING PrEP

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*For more information on PrEP, including on-demand dosing, go to:
www.hivguidelines.org
celtraining.org

PrEP ON-DEMAND (2-1-1) COUNSELING AND PRESCRIBING

Daily PrEP remains the preferred dosing strategy for all PrEP users. For cisgender men who have sex with men (MSM) there is the option of on-demand (2-1-1) dosing regimen with TDF/FTC (Truvada) when lifestyle, sexual practices, and/or stated preferences make it a more acceptable choice for the individual. Please note: TAF/FTC (Descovy) cannot be used on-demand.

On-Demand Dosing May be an Option for Cisgender MSM:	On-Demand Dosing is NOT Recommended for:
• for whom daily dosing is a barrier to adherence • with impaired kidney function • who prefer episodic dosing	• individuals who engage in vaginal sex • individuals who use injection drugs • individuals with HBV • transgender women who take estrogen

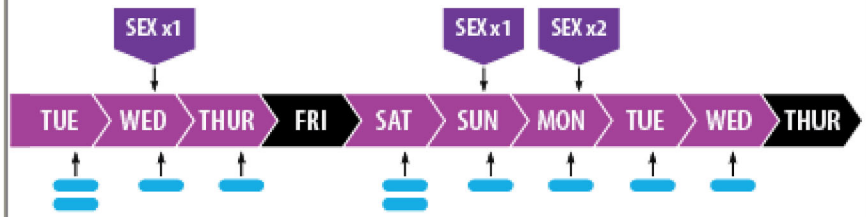
Talking Points when Counseling around PrEP On-Demand

- On-demand PrEP works best when you know ahead of time when you will have sex.
- If you think you might have sex, take 2 pills between 2 and 24 hours before sex and 1 additional tablet at 24 and 48 hours after sex (see diagram on other side of card).
  - Taking the first 2 PrEP pills closer to 24 hours before sex is more effective, but taking the first dose as little as 2 hours before sex also helps protect against HIV.
  - You can stop taking PrEP if you do not have sex.
- Rare cases of HIV transmission have occured, despite correctly taking on-demand or daily PrEP.
- Condoms provide additional protection against HIV and other STIs.
- If you forget to take PrEP and have condomless sex, emergency PEP can prevent HIV if started within 72 hours.
- Your medication supply should last longer when you use PrEP on-demand, but you should still have testing for HIV and other STIs every 3 months.

PRESCRIBING PrEP ON-DEMAND

PrEP REGIMEN AND DOSING

Regimen	Instructions
TDF/FTC (TRUVADA®) (Tenofovir 300mg + Emtricitabine 200mg)	Remember "2-1-1" • Take 2 tablets at least 2 hours before sex (ideally closer to 24 hours) • Take 1 tablet 24 hours after first dose • Take 1 tablet 48 hours after first dose • If sexual activity continues, take 1 tablet every 24 hours until 48 hours after last sex



If there are fewer than seven days between the end of one on-demand dosing period and the beginning of another, you only need to take one single PrEP tablet when you restart.

INITIATION, FOLLOW UP, AND MONITORING

Individuals using PrEP on-demand should receive the same baseline and follow-up tests as patients using daily PrEP. Please note: If a patient misses a scheduled lab or visit, do not withhold PrEP. Every attempt should be made to continue PrEP and reschedule follow-up at times and locations convenient to the patient.

For more about PrEP guidelines, go to:
www.hivguidelines.org

To speak with a clinician experienced in managing PrEP, call the CEI Line at:

866-637-2342

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STANDARD OF CARE FOR RAPID INITIATION OF ART WITHIN 72 HOURS OF DIAGNOSIS

Clinicians should recommend antiretroviral therapy (ART) for all patients with a diagnosis of HIV infection.
Clinicians should offer rapid initiation of ART (preferably on the same day or within 72 hours) to anyone with:

- New reactive point-of-care HIV test result or
- New HIV diagnosis or
- Known HIV

+ No or limited prior ARV use +

No evidence of TB, Cryptococcal Meningitis or CMV retinitis

Does the patient meet all 3 criteria and wants to start ART?

NO ▸ Discuss benefits of ART and arrange appointment for HIV care.

YES

ORDER BASELINE TESTING

- HIV-1/2 antigen/antibody assay
- HIV viral load
- HIV resistance testing
- CD4 count
- HAV, HBV, HCV
- Metabolic panel (creatinine clearance, hepatic profile)
- Pregnancy test for individuals with childbearing potential
- STI screening
- Urinalysis

PROVIDE HEALTH LITERATE COUNSELING AND EDUCATION

- HIV diagnosis
- Medication benefits
- Importance of adherence and how to deal with possible side effects
- Disclosure
- Use of safer-sex practices and avoidance of needle-sharing

INITIATE ART

- On same day or within 72 hours
- Choose preferred regimen based on patient characteristics and preferences (see back of card)
- Administer the first dose on site if possible

ASSESS AND REFER

- NYS Uninsured Care Programs (UCP) can help New Yorkers with costs (for those with or without insurance)
- Identify and address medical and psychosocial barriers to treatment and adherence
- Refer for Partner Services
- Refer for substance use treatment, behavioral health services, housing assistance, as needed

FOLLOW UP

- Contact the patient between 24-48 hours by phone (or their preferred method)
  - Assess medication tolerance
  - Assess and reinforce adherence
- Schedule in-person or telehealth visit with medical provider within 7 days
- Review initial lab and resistance testing and if indicated adjust the initial ART regimen
- Obtain a viral load test 4 weeks after ART initiation to assess the response to therapy

RAPID ART REGIMENS

RAPID ART REGIMENS FOR NON-PREGNANT ADULTS

Preferred Regimens	Notes*
Tenofovir alafenamide/emtricitabine/bictegravir (TAF 25mg/FTC/BIC) *Biktarvy*	• TAF/FTC should not be used if CrCl <30 mL/min • Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after BIC • Single tablet taken once daily
Tenofovir alafenamide/emtricitabine and dolutegravir (TAF 25 mg/FTC and DTG) *Descovy and Tivicay*	• TAF/FTC should not be used if CrCl <30 mL/min • Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after DTG • Two tablets taken once daily
Tenofovir alafenamide/emtricitabine/darunavir/cobicistat (TAF 10 mg/FTC/DRV/COBI) *Symtuza*	• TAF/FTC should not be used if CrCl <30 mL/min • Check guidelines for drug-drug interactions related to COBI • Single tablet taken once daily

*Refer to http://www.hivguidelines.org/antiretroviral-therapy/ for additional information such as: specific factors to consider and discuss with patients; alternative ART regimens; drug-drug interactions; dosing adjustments for patients with hepatic or renal impairment; benefits of early initiation; and other best practices.

Consult the clinical guidelines for specific recommendations regarding:

- Pregnant adults
- Individuals with CrCl < 30mL/min
- Adults with exposure to TDF/FTC or TAF/FTC as PrEP since last negative HIV test

Paying for Rapid ART Initiation

The NYS Department of Health Uninsured Care Programs support access to the wide range of options for payment for health care services and medications for persons living with or at risk of acquiring HIV. New York State residents who have no health insurance or have health insurance but need help with the out-of-pocket costs (copays, deductibles, etc.); and whose household income is less than 500% of the Federal Poverty Level (FPL) may be eligible. Toll Free 1-800-542-2437 or 1-844-682-4058

To speak with a clinician experienced in managing ART, call the CEI line at

866-637-2342

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