CATALYST – Ruling Out Acute HIV Infection Job Aid (CAB PrEP)

New CAB PrEP Client or Returning Non-adherent* CAB PrEP Client

STEP 1 RAPID TEST

What was the **client's HIV rapid test result** per the national algorithm?

- **POSITIVE** → **Do not start or continue CAB PrEP.** Conduct confirmatory testing and verify HIV status per the national algorithm.
- **NEGATIVE** →

STEP 2 PEP SCREEN

Is there a **high indication for PEP** by clinician assessment?

- **YES** → **Do not start or continue CAB PrEP. Recommend PEP**

Follow Table 1 for clinical management and lab instructions.

- **NO** →

STEP 3 AHI SCREEN

Is there a **high suspicion of acute HIV infection** (AHI) by clinician assessment?

- **YES** → **Do not start or continue CAB PrEP.**
  Defer further CAB PrEP screening.
  1. Request expedited RNA PCR on today's sample
  2. Offer use of PrEP ring pending RNA PCR result

Follow Table 1 for clinical management and lab instructions.

- **NO** → **HIV infection has been ruled out** to the extent possible. Proceed with assessment for other contraindications to CAB PrEP.

Returning Adherent** CAB PrEP Client

STEP 1 RAPID TEST

What was the **client's HIV rapid test result** per the national algorithm?

- **POSITIVE** → **Do not continue CAB PrEP.** Conduct confirmatory testing and verify HIV status per the national algorithm.
- **NEGATIVE** →

STEP 2 & 3 PEP & AHI SCREEN

Continue CAB PrEP, regardless of potential exposure or AHI signs/symptoms
Document:
- Possible HIV exposure(s) within past 72 hours (timing and exposure details)
- Signs and/or symptoms of AHI and possible exposures within 14 days of sign/symptom onset

TABLE 1: Today's Visit to Initiate/Continue *CAB PrEP*

Use this table to determine whether to start/continue CAB PrEP, start PEP instead, or defer start of/pause CAB PrEP in a client with a **NEGATIVE 3rd generation rapid diagnostic test (3rd gen RDT) AND clinically assessed as having PEP indication or suspected of acute HIV infection.** All notation of 3rd generation RDT is in accordance with RDTs specified in your national testing algorithm.

New CAB PrEP Clients + Returning CAB PrEP Clients: Non-adherent*

HIGH PEP INDICATION:

- Do not initiate or continue CAB PrEP
- Start one-month PEP course
- Request expedited RNA PCR on sample collected same day as 3rd gen RDT (prior to PEP) through CATALYST. **Do not wait for RNA PCR result to start PEP.**
  - If RNA detectable, refer to HIV care and treatment for HIV confirmation
  - If RNA undetectable, complete one-month PEP course
- Post-PEP, re-screen for CAB PrEP, depending on 28-day PEP adherence:
  - PEP adherent***: rule-out HIV infection with 3rd gen RDT(s) (Step #1); PEP and AHI assessment (Steps #2 and #3) not needed
  - PEP non-adherent: rule-out HIV infection with Steps 1-3 (3rd gen RDT, PEP assessment, AHI assessment)
  - If CAB PrEP initiated or restarted post-PEP, inject CAB PrEP upon completion of PEP (no break between PEP and PrEP). Request expedited RNA PCR per CATALYST study requirements.

HIGH SUSPICION OF AHI:

- Do not initiate or continue CAB PrEP
- Do not start PEP
- If biomedical prevention is desired, PrEP Ring may be offered; do not offer oral PrEP
- Request expedited RNA PCR on sample collected same day as 3rd gen RDT (prior to PEP) through CATALYST.
  - If RNA detectable, refer to HIV care and treatment for HIV confirmation
  - If RNA undetectable, re-screen for CAB PrEP with Steps 1-3 (3rd gen RDT, PEP assessment, AHI assessment)
- In one-month, re-screen for CAB PrEP with Steps 1-3 (3rd gen RDT, PEP assessment, AHI assessment)

Returning CAB PrEP Clients: Adherent**

- PEP is not indicated among adherent CAB PrEP clients. Continue CAB PrEP regardless of potential exposure or AHI signs and symptoms.

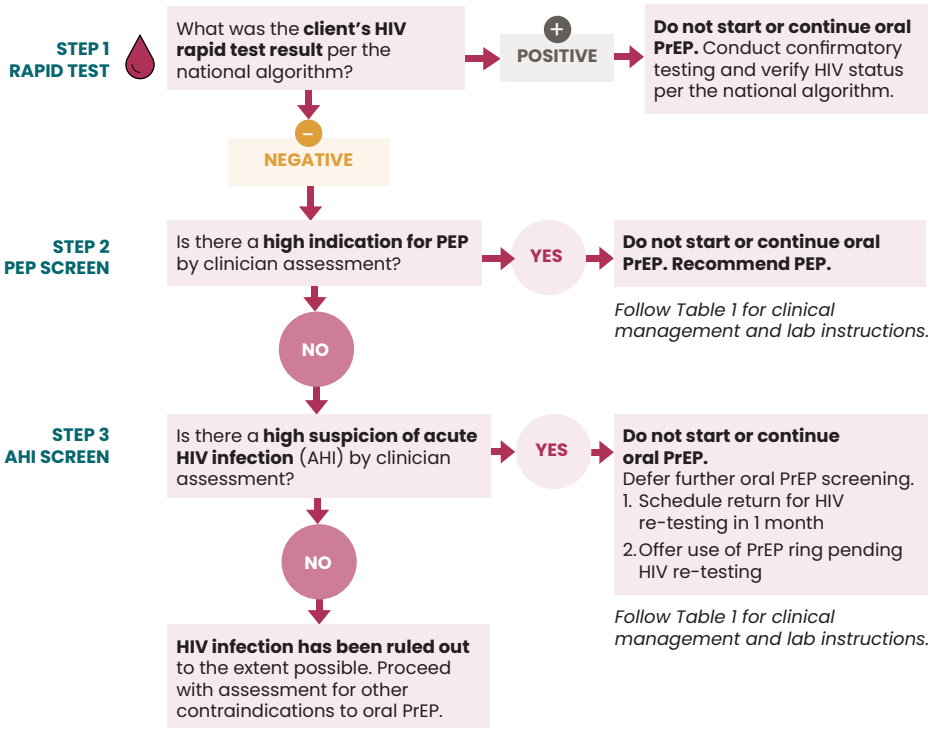
*CAB PrEP Non-adherent: Prior injection was initiation injection 1 and > 2 months ago; prior injection was initiation injection 2 or follow-up and > 3 months ago

**CAB PrEP Adherent: Prior injection was initiation injection 1 and ≤ 2 months ago; or prior injection was initiation injection 2 or follow-up and < 3 months ago

***PEP Adherent: At time of assessment, client reports completion of the one-month PEP regimen

CATALYST – Ruling Out Acute HIV Infection Job Aid (Oral PrEP)

New Oral PrEP Client or Returning Non-adherent* Oral PrEP Client



Returning Adherent** Oral PrEP Client

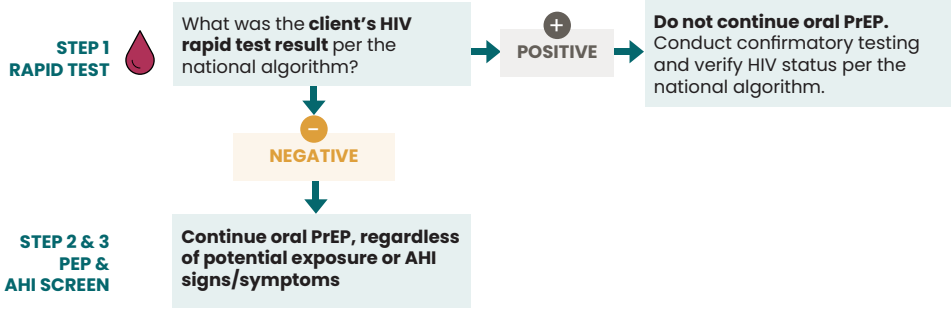


TABLE 1: Today's Visit to Initiate/Continue *Oral PrEP*

Use this table to determine whether to start/continue oral PrEP, start PEP instead, or defer start of/pause oral PrEP in a client with a **NEGATIVE 3rd generation rapid diagnostic test (3rd gen RDT) AND clinically assessed as having PEP indication or suspected of acute HIV infection.** All notation of 3rd generation RDT is in accordance with RDTs specified in your national testing algorithm.

New Oral PrEP Clients + Returning Oral PrEP Clients: Non-adherent*

HIGH PEP INDICATION:

- Do not initiate or continue oral PrEP. Option to request expedited RNA PCR.[1]
- Start one-month PEP course
- Post-PEP, re-screen for oral PrEP, depending on one-month PEP adherence
  - PEP adherent***: rule-out HIV infection with 3rd gen RDT(s) (Step #1); PEP and AHI assessment (Steps #2 and #3) not needed
  - PEP non-adherent: rule-out HIV infection with Steps 1-3 (3rd gen RDT, PEP assessment, AHI assessment)
  - If oral PrEP initiated or restarted post-PEP, dispense oral PrEP upon completion of PEP (no break between PEP and PrEP)

HIGH SUSPICION OF AHI:

- Do not initiate or continue oral PrEP. Option to request expedited RNA PCR.[1]
- Do not start PEP
- If biomedical prevention desired, PrEP ring may be offered; do not offer oral PrEP
- In 28 days, re-screen for oral PrEP with Steps 1-3 (3rd gen RDT, PEP assessment, AHI assessment)

Returning Oral PrEP Clients: Adherent**

- PEP is not indicated among adherent oral PrEP clients. Continue oral PrEP regardless of potential exposure or AHI signs and symptoms.

[1] CATALYST Stage 2 participants have consented to the possibility of expedited RNA PCR testing even if they choose oral PrEP. RNA PCR tests can be requested to expedite confirmation of HIV status and connections to treatment if needed.

*Oral PrEP Non-adherent: 4+ doses missed each week in week before and week after each day of sex

**Oral PrEP Adherent: ≤ 3 doses missed each week in week before and week after each day of sex

***PEP Adherent: At time of assessment, client reports completion of the one-month PEP regimen

CATALYST – Ruling Out Acute HIV Infection Job Aid (PrEP Ring)

New PrEP Ring Client or Returning Non-adherent* PrEP Ring Client

STEP 1 RAPID TEST

What was the **client's HIV rapid test result** per the national algorithm?

- **POSITIVE** → **Do not start or continue PrEP ring.** Conduct confirmatory testing and verify HIV status per the national algorithm.
- **NEGATIVE** → **STEP 2 PEP SCREEN**

STEP 2 PEP SCREEN

Is there a **high indication for PEP** by clinician assessment?

- **YES** → **Do not start or continue PrEP ring. Recommend PEP.** *Follow Table 1 for clinical management and lab instructions.*
- **NO** → **STEP 3 AHI SCREEN**

STEP 3 AHI SCREEN

Is there a **high suspicion of acute HIV infection** (AHI) by clinician assessment?

- **YES** → **Client may initiate or continue PrEP ring use.** Schedule:
  - Repeat HIV testing in 1 month (Step 1)

  Follow Table 1 for clinical management and lab instructions.
- **NO** → **HIV infection has been ruled out** to the extent possible. Proceed with assessment for other contraindications to PrEP ring.

Returning Adherent** PrEP Ring Client

STEP 1 RAPID TEST

What was the **client's HIV rapid test result** per the national algorithm?

- **POSITIVE** → **Do not continue PrEP ring.** Conduct confirmatory testing and verify HIV status per the national algorithm.
- **NEGATIVE** → **STEP 2 PEP SCREEN**

STEP 2 PEP SCREEN

Is there a **high indication for PEP** by clinician assessment?

- **YES** → Provide **client options**:
  If **high indication for PEP**, recommend PEP
  Schedule:
  -Repeat HIV testing in 1 month (Step 1)
  Otherwise, continue PrEP ring

  Follow Table 1 for clinical management and lab instructions.
- **NO** → **STEP 3 AHI SCREEN**

STEP 3 AHI SCREEN

Client may continue PrEP ring use regardless of AHI signs/symptoms

TABLE 1: Today's Visit to Initiate/Continue *PrEP Ring*

Use this table to determine whether to start/continue PrEP ring or start PEP instead in a client with a **NEGATIVE 3rd generation rapid diagnostic test (3rd gen RDT) AND clinically assessed as having PEP indication or suspected of acute HIV infection.** All notation of 3rd generation RDT is in accordance with RDTs specified in your national testing algorithm.

New PrEP Clients + Returning PrEP Ring Clients: Non-adherent*

HIGH PEP INDICATION:

- Do not initiate or continue PrEP ring. Option to request expedited RNA PCR.[1]
- Start one-month PEP course
- Post-PEP, re-screen for PrEP ring, depending on one-month PEP adherence
  - PEP adherent***: rule-out HIV infection w/ 3rd gen RDT(s) (Step #1); PEP and AHI assessment (Steps #2 and #3) not needed
  - PEP non-adherent: rule-out HIV infection with Steps 1-3 (3rd gen RDT, PEP assessment, AHI assessment)
  - If PrEP ring initiated or restarted post-PEP, dispense PrEP ring (no break between PEP and PrEP)

HIGH SUSPICION OF AHI:

- PrEP ring use is permissible despite AHI suspicions: start or continue PrEP ring despite AHI suspicions. Option to request expedited RNA PCR.[1]
- Do not start PEP
  - Continue with HIV re-testing by 3rd Gen RDT as per scheduled visits (at least quarterly)

Returning PrEP Ring Clients: Adherent**

- Provide option of HIV prevention approach based on likelihood and recency of potential HIV exposure:
  - If particularly high likelihood of exposure within 72 hours, offer the option to stop PrEP ring and switch to one-month course of PEP
  - Continue PrEP ring if lesser likelihood or beyond 72 hours, or per client preference

[1] CATALYST Stage 2 participants have consented to the possibility of expedited RNA PCR testing even if they choose PrEP ring. RNA PCR tests can be requested to expedite confirmation of HIV status and connections to treatment if needed.

*PrEP Ring Non-adherent: Ring not continuously in place the day before and day of vaginal sex; any reported anal sex without a condom should be considered PrEP ring non-adherent

**PrEP Ring Adherent: Ring in place continuously day before and day of sex for each day of vaginal sex

***PEP Adherent: At time of assessment, client reports completion of the one-month PEP regimen