

HPTN 084: Scenarios

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Scenario 1: PPT Pregnant at Step 6, Week 96

Background

A participant on Step 6 tests positive for pregnancy at the Week 96 visit; the final visit. This site is participating in the ViiV Rollover Protocol and is enrolling participants.

Question

What should the site do?



Scenario 1: PPT Pregnant at Step 6, Week 96

Answer

In the clinic:

- Confirm pregnancy on independent sample
- Discuss what is known about CAB LA and pregnancy with the PPT
- Offer Step 4d, Pregnancy and Infant sub-study
- PPT agrees to join 4d
- Refer for ultrasound at 12 weeks of gestational age and prenatal care
- Alert CMC

CRFs to be completed:

- Pregnancy Test Results-OLE, Pregnancy Report-OLE, Consent
Pregnancy and Infant Sub-study, Pregnancy History (if not yet completed)
- At 12 Week Visit or visit when results available, Ultrasound –OLE

Labs/Samples to be performed:

- Collect samples as per the 4d SOE.



Scenario 2: PPT Pregnant at Step 5, Week 12

Background

A participant, who took CAB LA during the blinded period and the beginning of the open-label period, stopped taking CAB LA. The study site discussed the PK tail with the participant and she agreed to take TDF/FTC on Step 5. At the Week 12 visit of Step 5 the participant tests positive for pregnancy.

Question

What should the site do?



Scenario 2: PPT Pregnant at Step 5, Week 12

Answer

In the clinic:

- Confirm pregnancy on independent sample
- Discuss what is known about CAB LA & pregnancy with PPT
- Offer the Pregnancy and Infant sub-study (Step 4d)
- Alert CMC

The participant declines to join Step 4d. Now what does the site do?



Scenario 2: PPT Pregnant t Step 5, Week 12

Answer

In the clinic:

- Continue to follow PPT on Step 5
- Refer for ultrasound at 12 weeks of gestational age and prenatal care



CRFs to be completed:

- Step 5, Week 12 include Pregnancy Test Results-OLE, Pregnancy Report-OLE, Pre Pregnancy History (if not yet completed)
- When delivery occurs, add Delivery-OLE visit, complete only Pregnancy Outcome Log-OLE
- When infant is 48 weeks add Infant Assessment visit, complete Abbreviated Infant Assessment (new CRF)
- In the event of infant SAEs:
 - Generate Infant PTID; then add details of SAE to Infant Adverse Event form and update Pregnancy Outcome-OLE form to include Infant PTID

Labs/Samples to be performed:

- Collect routine samples as indicated in the SOE for Step 5, Week 12.

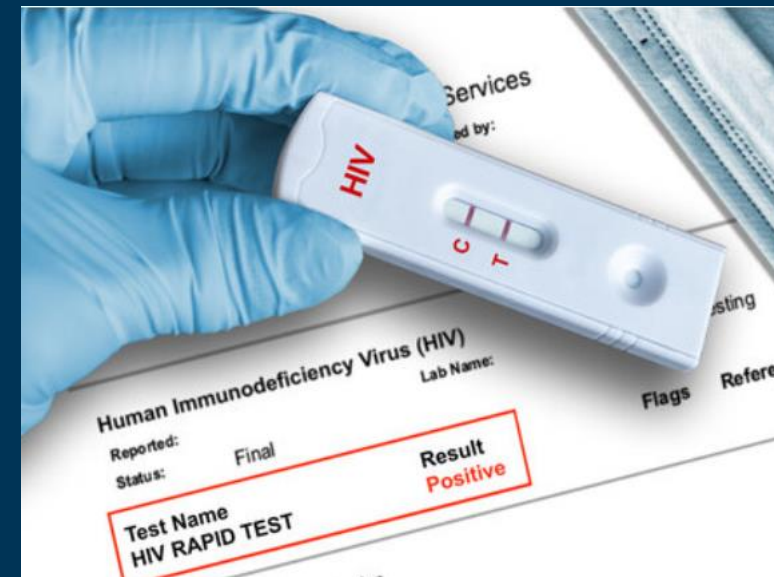
Scenario 3: Positive Rapid Test, Step 6, Week 64

Background

A participant on Step 6 has two positive rapid tests at the Week 64 visit.

Question

What should the site do?



Scenario 3: Positive Rapid Test, Step 6, Week 64

Answer

In the clinic:

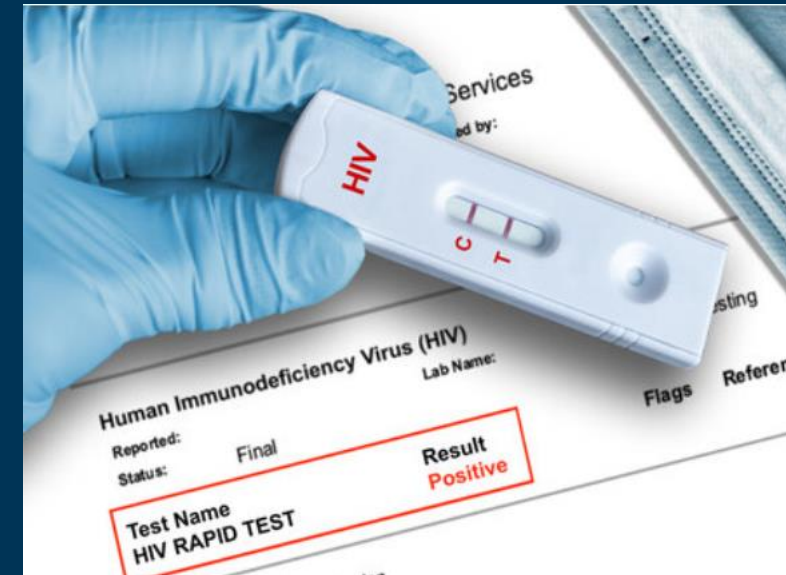
- Do not give CAB LA injection
- Provide supportive counseling until serostatus is confirmed
- Follow HIV Testing Algorithm
- Alert HIV alias and CMC

CRFs to be completed:

- Week 64 assessments including HIV Test Results
- Complete other CRFs per assessments advised by the HIV alias

Labs/Samples to be performed:

- Draw confirmatory HIV test samples.

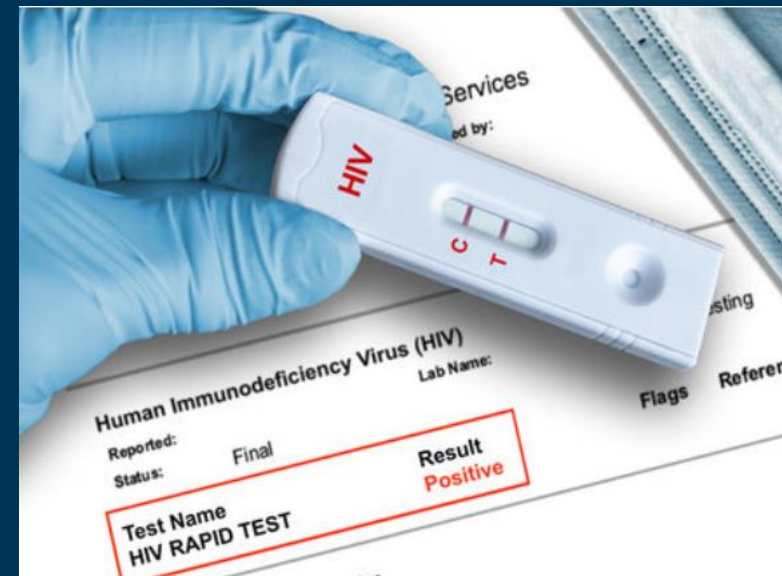


Scenario 3: Positive Rapid Test, Step 6, Week 64

Question

The participant goes home and then misses her next appointment.

Now what does the site do?



Scenario 3: Positive Rapid Test, Step 6, Week 64

Answer

**Continue to contact PPT,
within reason.**

**There is no time limit for
rolling a PPT off of the trial
and into HIV care.**

