

PK PBMC Scenarios for sites NOT doing Fingerstick HIV Rapid Tests

Note: the following scenarios apply to sites that have received all necessary approvals from the study management team and the local IRB for PBMC collection, and apply to participants who have provided the optional consent for PBMC collection.

Scenario 1: A site collects a venous sample for rapid HIV tests. The results are discordant.

Action: Contact NL to inform regarding discordant rapids. Send specimen to processing lab for Sample 1 Western Blot. Do not collect PBMC or Sample 2 until the Sample 1 WB result is returned. If the WB result is positive, schedule the participant to return to the site as soon as possible for collection of Sample 2 specimens (WB, plasma archive, CD4 and viral load) and PBMC.

Scenario 2: A site collects a venous sample for HIV rapid tests. Both rapid test results are positive and the site informs the participant that a second blood draw is needed for PBMC and Sample 2 specimens. The participant does not want to have her blood redrawn that day.

Action: Send the sample to the lab for a Sample 1 Western Blot. Schedule her to come back and obtain her Western Blot results as soon as they are available and attempt to collect Sample 2 specimens and PBMC, ideally within 7 days of the positive rapid tests.

Scenario 3: A site collects a venous sample for HIV rapid tests. Both rapid test results are positive and the site informs the participant that a second blood draw is needed for PBMC and Sample 2 specimens. The participant does not want to have her blood redrawn that day. They attempt to schedule her within 14 days (ideally within 7) but she only returns in 5 weeks.

Action: Collect Sample 2 specimens, but do not collect PBMC since more than 14 days have passed since product was held due to the HIV positive rapid results. No further PBMC collections are required if the participant is confirmed HIV-infected per the protocol algorithm.

Scenario 4: A participant has been on a site-initiated product hold for 2 months. The site collects a venous sample for HIV rapid tests. Both rapid test results are positive.

Action: Do not collect PBMC since the participant has been on a continuous, site-initiated product hold for more than 14 days. Proceed with testing per the HIV algorithm.

Scenario 5: A site is collecting a venous sample for HIV rapid testing. It's a tough stick and they only get enough sample for the two rapid tests. These are positive. There is not enough specimen left for Western Blot.

Action: Attempt to re-draw the participant. First collect specimen for Sample 1 Western Blot. If possible, collect PBMC at this draw also. Do not attempt to collect a Sample 2 specimen at this same visit.

If you are able to get a specimen for Sample 1 but not enough for PBMC, attempt to get the participant back for Sample 2 and PBMC within 14 days (ideally within 7 days). If the participant does not return

within 14 days, only collect Sample 2 specimens. No further PBMC collections are required if the participant is confirmed HIV-infected per the protocol algorithm.

Scenario 6: A participant comes in for an interim visit and site staff instruct her to permanently discontinue study product use. She has a monthly visit 7 days later that has a scheduled PBMC Collection.

Action: Collect PBMC at the monthly visit since it occurs within 14 days of when product use was permanently discontinued. Then discontinue PBMC collections for all future visits.

Scenario 7: A participant comes in for a quarterly visit where she has a positive pregnancy test. She is put on product hold. A PBMC collection is scheduled at this visit.

Action: Collect PBMC at this visit and then discontinue future PBMC collections while she is on product hold. If and when the participant resumes product use, PBMC collection should resume per her original collection schedule.

Scenario 8: A participant is on a continuous, site-initiated product hold for a month because of a lab-related AE. She comes in for a quarterly visit that has a scheduled PBMC collection. The lab AE is now resolved and she may resume product use.

Action: Do not collect PBMC since the participant has been on a continuous, site-initiated product hold for more than 14 days . PBMC collection should resume as her next scheduled PBMC collection, per her original collection schedule.

Scenario 9: A participant experiences symptoms that cause her to stop using product. She comes in for a monthly visit and informs the clinic of the symptoms and says she has been off product for 25 days. There is a PBMC collection scheduled at this visit.

Action: Collect PBMC and chart note that the participant has been off product. PBMC collection should only be stopped when the site initiates a product hold or permanent discontinuation.

Scenario 10: A participant is presumed lost to follow-up, then returns to the clinic after three months of missed visits.. During these 3 months, she missed one scheduled PBMC collection.

Action: The missed PBMC collection should not be made up, and missed visits do not affect the PBMC collection schedule. The participant should have PBMC collected at the next scheduled time point and every 6 months thereafter, per her original PBMC collection schedule.