PK PBMC Scenarios for sites doing Fingerstick HIV Rapid Tests

Note: the following scenarios apply to sites that have received all necessary approvals from study management 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 fingerstick 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 Sample 1 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 fingerstick sample for HIV rapid tests. Both rapid test results are positive.

Action: Collect specimens for sample 1 WB and PBMC on the same day as fingerstick testing. Do not collect sample 2 at this visit (since this would require a third blood collection, which we want to avoid). Schedule the participant to come back to the site as soon as possible (to receive her Sample 1 WB result, post-test counseling, and any additional labs needed) when the WB result is expected to be available.

Scenario 3: A participant has been on a site-initiated product hold for 2 months. The site collects a fingerstick 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 4: A participant comes in for an interim visit and is instructed by site staff 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 5: 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 6: 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 at her next scheduled PBMC collection, per her original collection schedule.

Scenario 7: 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 8: 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.