

***ADDITIONAL CRFs REQUIRED FOR PARTICIPANTS
WITH CONFIRMED HIV INFECTION***

Visit at time of diagnosis

- CD4/Viral Load Results (CDV-1)
- Specimen Storage–All Participants (SS-1)
- Tissue Subset Specimen Storage–Blood (TSB-1)

Week 49 or Last Study Visit

Visit Code: 11.0

- CD4/Viral Load Results (CDV-1)
- Specimen Storage–All Participants (SS-1)

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HPTN 069 (109)

CDV-1 (325)

Visit Code

1

Participant ID

--
Site Number Participant Number Chk

CD4/Viral Load Results

Initial Collection Date

dd MMM yy

Not done/
Not collected **Alternate Collection Date**
dd MMM yy

1. Absolute CD4+

Unable to analyze

cells/mm³

not available

. % OR

Not done/
Not collected **Alternate Collection Date**
dd MMM yy

2. HIV-1 RNA PCR of Plasma

> = <

viral copies/mL

undetectable

OR

Comments: _____

CD4/Viral Load Results (CDV-1)

General Information/Instructions: This form is used for seroconverters only.

- **Visit Code:** For the diagnosis visit, the visit code must match that of the HIV Test Results where HIV infection is confirmed.
- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. Complete date required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. Complete date required.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
 - If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
 - It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
 - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

Item-specific Instructions:

- **Item 2:** Mark the less than (<), equal to (=), or greater than (>) box as appropriate and record the value. For example, if the value is 3100 copies, mark the equal to (=) box and record "00003100" in the value. For any value, if the value reported is < 400 copies, mark the less than (<) box and record "00000400" in the value.



Visit Code

1

HPTN 069 (109)

SS-1 (240)

Participant ID

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Site Number Participant Number Chk

Specimen Storage—
All Participants

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min

:

1. Plasma for storage

stored not stored not collected

Reason not stored or not collected: _____



Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

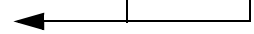
hr min

:

2. Viable PBMC
(for immunological testing)

stored not stored not collected not required

Reason not stored or not collected: _____



Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min

:

3. PBMC for CCR5 genotyping

stored not stored not collected not required

Reason not stored or not collected: _____



Comments: _____

Specimen Storage—All Participants (SS-1)

Purpose: This form is used to document the collection and storage of specimens that will be tested at a lab other than the site local laboratory.

Initial Specimen Collection Date: Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.

Alternate Collection Date: This date is to be completed **ONLY** if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

Item-specific Instructions:

- **Items 1–3:**
- Mark the “not stored” box if the specimen was collected as required at this visit but was not stored.
- Mark the “not collected” box if the specimen is required to be collected and stored at this visit but was not collected.
- Mark the “not required” box if a specimen is not required to be collected and stored at this visit.



Visit Code

1

HPTN 069 (109)

TSB-1 (220)

Page 1 of 1

Participant ID

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Site Number Participant Number Chk

Tissue Subset Specimen Storage—Blood

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min
 :

1. Plasma for PK

stored not stored not collected

Reason not stored or not collected: _____

Alternate Collection Date

Time Collected (24-hr clock)

dd MMM yy

hr min
 :

2. PBMC for PK

stored not stored not collected

Reason not stored or not collected: _____

Comments: _____

Tissue Subset Specimen Storage—Blood (TSB-1)

Purpose: This form is used to document the collection and storage of specimens that will be tested at a lab other than the site local laboratory.

Initial Specimen Collection Date: Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.

Alternate Collection Date: This date is to be completed **ONLY** if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

Item-specific Instructions:

- **Items 1–2:**
 - Mark the “not stored” box if the specimen was collected as required at this visit but was not stored.
 - Mark the “not collected” box if the specimen is required to be collected and stored at this visit but was not collected.