Annotated

Case Report Forms

For

Protocol RV329 / WRAIR 1897

Version 1.7

Dec. 26, 2013

African Cohort Study (AFRICOS)

Study Conducted by US Military HIV Research Program

Study Supported by

Data Coordinating and Analysis Center, (DCAC), MHRP
Henry M. Jackson Foundation (HJF)
# Summary of RV329 CRFs

<table>
<thead>
<tr>
<th>Case Report Form</th>
<th>Page #</th>
<th>Total #</th>
<th>Visit</th>
<th>Source Document</th>
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<tbody>
<tr>
<td>1. Eligibility / Enrollment</td>
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<td>2. Demographics</td>
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<td>3. HIV Status</td>
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<td>4. Medical Record Extraction (HIV Positive)</td>
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<td>5. WHO Classification</td>
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<td>6. Medical History</td>
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<td>7. Medication Record</td>
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<td>8. Recent Symptoms</td>
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<td>9. Vital Signs / Physical Exam</td>
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<td>10. Specimen Collection</td>
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<td>11. Blood Chemistry</td>
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<td>12. Hematology</td>
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<td>13. Urinalysis</td>
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<td>14. Lymphocyte Subset Profile</td>
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<td>15. Additional Microbiology</td>
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<td>16. Viral Load (HIV Positive)</td>
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<td>17. Serology (HIV Positive &amp; Negative)</td>
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<td>18. Serology (HIV Negative Only)</td>
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<td>19. Resistance Test (HIV Positive)</td>
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<td>20. Cognitive Evaluation</td>
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<td>21. Current Medical Conditions</td>
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<td>22. Acute Febrile Illness</td>
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<td>23. Hospitalization / Serious/Acute Visit</td>
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<td>25. Past/Current Obstetric History (Female)</td>
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<td>26. Cervical Cancer Screening (Female)</td>
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<td>27. Missed Visit</td>
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<td>28. Status Change</td>
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<td>SV</td>
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<td>29. Pathology</td>
<td>42</td>
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</table>

Initial = Visit 1 (initial visit)  
SV = Subsequent Visits  
All = both Initial and all Subsequent Visits  
Annual=Initial Visit and all Annual SVs  

1 Eligibility / Enrollment CRF also used in cases of re-enrollment  
2 Questions 2d – 2f apply to all scheduled visits; see CRF for details  
3 As needed
## RV329 AFRICOS – CASE REPORT FORMS
### MENU OF CODE LISTS

<table>
<thead>
<tr>
<th>CODE</th>
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### HIV Negative

**Inclusion Criteria**

1. Consents to HIV testing, and to pre-test and post-test counseling

2. Adult aged 18 years or older

3. Ability and willingness to sign/mark/thumbprint the Informed Consent form

4. Intends to be a long term resident of the area (i.e., for at least 24 months)

5. Willing to provide location or contact information and be contacted by study staff

6. Consents to data and specimen collection and storage for future use

7. Must understand English or local language as approved by IRB

**Exclusion Criteria**

1. The subject is known to be HIV infected

2. Any significant condition (including medical and psychological/psychiatric disorder) that in the opinion of the study investigator might interfere with the conduct of the study

3. The subject is known to be pregnant

4. The subject is currently a prisoner

### HIV Positive

**Inclusion Criteria**

1. Known HIV infection

2. Adult aged 18 years or older

3. Ability and willingness to sign/mark/thumbprint the Informed Consent form

4. Intends to be a long term resident of the area and to undergo long term HIV care at AFRICOS participating clinic (i.e., for at least 24 months)

5. Willing to provide location or contact information and be contacted by study staff

6. Consents to data and specimen collection and storage for future use

7. Must understand English or local language as approved by IRB

**Exclusion Criteria**

1. Any significant condition (including medical and psychological/psychiatric disorder) that in the opinion of the study investigator might interfere with the conduct of the study

2. The subject is known to be pregnant

3. The subject is currently a prisoner

### Protocol Enrollment

1. Did subject meet the eligibility criteria?
2. Did subject sign an Informed Consent Form?
3. Date Informed Consent was signed:
4. Did subject agree to host genetic testing?
5. Subject was recruited for enrollment based on (Mark all that apply):
   - Representative of general clinic population
   - Identified as member of a serodiscordant couple
   - Subject in prior study (refer to Study Code List): Study #:
   - Suspected long term non-progressor
   - Other, Specify:

Form Completed by: FORMBY
Date: __________

QC/QA: QC_QA SIGNED.
Data Entry: 1st __________ 2nd __________
DEMOGRAPHICS

Subject ID: __________-________-________
Visit Date: __________-________-________
Visit: _____

1. Date of Birth: __________-________-________

2. Gender:
   ○ 1. Male
   ○ 2. Female

3. Tribal:
   3a. Kenya
      ○ 1. Kalenjin
      ○ 2. Kisii
      ○ 3. Luhya
      ○ 4. Luo
      ○ 90. Other, Specify: ________

   3b. Nigeria
      ○ 1. Hausa
      ○ 2. Yoruba
      ○ 3. Igbo
      ○ 90. Other, Specify: ________

   3c. Tanzania
      ○ 1. Nyakyusa
      ○ 2. Safwa
      ○ 3. Nyiha
      ○ 4. Ndali
      ○ 5. Kinga
      ○ 90. Other, Specify: ________

   3d. Uganda
      ○ 1. Ganda
      ○ 2. Soga
      ○ 3. Gisu
      ○ 90. Other, Specify: ________

4. Religion:
   ○ 1. Catholic Christian
   ○ 2. Non-Catholic Christian
   ○ 3. Muslim
   ○ 4. Traditionalist
   ○ 7. Don’t Know
   ○ 8. Refused
   ○ 90. Other, Specify: ________

5. At what age did you have your first sexual intercourse?
   ○ 0. Never had sex
   ○ 1. < 13
   ○ 2. Between 13 – 18
   ○ 3. > 18
   ○ 8. Refused

Form Completed by: ________________ Date: __________-________-________

QC/QA: __________ Data Entry: 1st __________ 2nd __________
**HIV STATUS**

<table>
<thead>
<tr>
<th>Subject ID:</th>
<th>Visit Date:</th>
<th>Visit:</th>
</tr>
</thead>
</table>

**1. Date of last Negative HIV test (Visit 1 only):**

<table>
<thead>
<tr>
<th>Date of last Negative HIV test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
</tr>
</tbody>
</table>

**2. HIV Status (Visit 1 only):** HIVSTAT NEGPOSNK.

- 0. Negative ➔ *(if 0. Negative, Skip to 3.)*
- 1. Positive* ➔ *(if 1. Positive, Continue to 2a.)*
- 7. Unknown ➔ *(if 7. Unknown, Skip to 3.)*

*If Positive:

**Visit 1 only:**

- 2a. Diagnosis Date: [___-____-____-____-____-____-____-____-____]  
- 2b. Date first enrolled in HIV care: [___-____-____-____-____-____-____-____-____]  
- 2c. Date enrolled in HIV care at this clinic: [___-____-____-____-____-____-____-____-____]

**Visit 1 or at Subsequent Visit if subject not medically eligible at Visit 1:**

- If subject is not medically eligible for ART at Visit 1, mark “NA, not on ART.”
- If subject becomes medically eligible for ART after Visit 1, complete 2d., 2e., and 2f.

**2d. Date medically eligible for ART:** [___-____-____-____-____-____-____-____-____]

**2e. Why was the subject eligible for ART? (Mark all that apply):**

- a. Clinical stage ELIG_A – ELIG_D
- b. Low CD4 count
- c. High Viral Load
- d. Plan B+
- 7. Unknown ELIG_NK

**2f. Date started ART:** [___-____-____-____-____-____-____-____-____]

3. Is the subject’s partner currently enrolled in RV329?

- 1. Yes*  
- 0. No  
- 5. NA

3a. *If Yes,*

Partner’s RV329 Subject ID: [___-____-____-____-____-____-____-____-____]

Form Completed by: FORMBY SIGNED.  
Date: [___-____-____-____-____-____-____-____-____]

QC/QA: ___________  
Data Entry: 1st ___________ 2nd ___________  
6
MEDICAL RECORD EXTRACTION

Subject ID:      | Visit Date:      | Visit:      
----------------|------------------|------------

Mark if All Unknown (no medical data)       NA (HIV Negative) NAHIVNEG

Data closest to the time of HIV Diagnosis (1-9):

1. WHO Clinical Stage: WHOHOSTG WHOHOSTG.
   - 1. I
   - 2. II
   - 3. III
   - 4. IV
   - 7. Unknown

2. Function: FUNCTION FUNCTION.
   - 1. Unimpaired
   - 3. Bedridden
   - 2. Impaired but ambulatory
   - 7. Unknown

3. Height: ________ cm HT

4. Weight: ________ kg WT

5. CD4:
   - ________ cells/ul CD4N
   - ________ % CD4P

6. Hemoglobin:
   - ________ g/dL HEMOG

7. ALT/SGPT:
   - ________ U/L ALT

8. Creatinine:
   - ________ 1. µmol/L CREAT
   - ________ 2. mg/dL

9. HIV-1 RNA: RNA
   - Circle One: < = > copies/mL
   - Not Detected NODETECT

10. Record the lowest CD4 cell count (NADIR) subject attained since HIV Diagnosis:
    CD4: ________ cells/ul

11. Record the CD4 cell count at the time of ART initiation:
    CD4: ________ cells/ul

12. Virologic monitoring: None VL_NONE
    - Record CD4 Count if within 30 Days of Viral Load Resistance Test CRF
    - VL_LGE_A-J mL
    - VLCD4_A-J/mm3
    - VLCD4P_A-J%
    - VLCOPY_A-J
    - RESDN_A-J

Form Completed by: FORMBY SIGNED.

Date: ________ FORMDT
### Subject ID:

| Visit Date: | |
| Visit Seq #: | |
| Page/Seq #: | |

### Medical Record Extraction

**Form Completed by:**
- FORMBY
- SIGNED.

**Data Entry:** 1st

| Data Entry: 1st | |
| 2nd | |

**Form MT:**

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**12. Viral Load Monitoring:**

- Viral Load Draw Date
- Available
- None

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<th>Viral Load Draw Date</th>
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**CD3+CD4+ count:**

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<th>CD3+CD4+ %</th>
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**Viral Load Copies/mL:**

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<th>Resistance Test</th>
<th>CFR</th>
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</table>

**All in:**

- vlcd4p
- vlcd4
- vl_lge vlcopy resdn vl_m vl_y

**nahrweg**
# WHO CLASSIFICATION

**Mark all that apply**

<table>
<thead>
<tr>
<th>WHO CLASSIFICATION</th>
<th># of episodes</th>
<th>Start Date (First Episode)</th>
<th>Stop Date (Last Episode)</th>
<th>Ongoing Mark if ongoing</th>
<th>DX Method</th>
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<tbody>
<tr>
<td>1. WHO Stage I</td>
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</tr>
<tr>
<td>a. Persistent Generalized Lymphadenopathy (W10.0)</td>
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<td>b. Herpes Zoster (within last 5 years) (W20.0)</td>
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<td>c. Minor Mucocutaneous Manifestations (W21.0)</td>
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<td>d. Recurrent Upper Respiratory Tract Infections (W22.0)</td>
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<td>d. Weight Loss ≤ 10% of Body Weight (W23.0)</td>
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<td>a. Severe Bacterial Infections (i.e. Pneumonia) (W30.0)</td>
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<td>b. Candidiasis–Oral (Thrush) (W31.0)</td>
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<td>c. Unexplained Chronic Diarrhea (&gt;1 month) (W32.0)</td>
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<td>d. Oral Hairy Leukoplaikia (W33.0)</td>
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<td>e. Unexplained Prolonged Fever (intermittent or constant, &gt;1 month) (W34.0)</td>
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<td>f. Weight loss &gt;10% of Body Weight (W35.0)</td>
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<td>g. Pulmonary Tuberculosis</td>
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<td>g1. Smear + (W36.1)</td>
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<td>g2. Smear − (W36.2)</td>
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<td>g6. Smear not done (W36.3)</td>
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*Refer to Diagnosis Method Code List*

QC/QA: ___________  Data Entry: 1st ___________  2nd ___________
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<th>WHO CLASSIFICATION</th>
<th># of episodes</th>
<th>Start Date (First Episode)</th>
<th>Stop Date (Last Episode)</th>
<th>Ongoing Mark if ongoing</th>
<th>DX Method¹</th>
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<td>4. WHO Stage IV</td>
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<td>a. Candidias</td>
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<td>□ a1. Esophageal (W40.1)</td>
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<td>□ a2. Lungs (W40.2)</td>
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<td>b. Extrapulmonary cryptococcal</td>
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<td>□ b1. CNS/Meningitis (W41.1)</td>
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<td>□ b2. Skin (W41.2)</td>
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<td>c. Cryptosporidiosis with Diarrhea (&gt;1 month) (W42.0)</td>
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<td>d. CMV Disease (other than spleen, liver, lymph nodes)</td>
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<td>□ d1. Esophagitis (W43.1)</td>
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<td>□ d2. Retinitis (W43.2)</td>
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<td>□ d3. Pneumonia (W43.3)</td>
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<td>□ d4. Colitis (W43.4)</td>
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<td>□ d5. CNS (W43.5)</td>
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<td>e. Herpes simplex</td>
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<td>□ e1. Mucocutaneous &gt;1month (W44.1)</td>
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<td>□ e2. Any visceral (W44.2)</td>
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<tr>
<td>f. HIV Encephalopathy (AIDS dementia complex) (W45.0)</td>
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<tr>
<td>g. HIV Wasting Syndrome (W46.0)</td>
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<tr>
<td>h. Kaposi's Sarcoma (KS)</td>
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<td>□ h1. Skin (W47.1)</td>
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<td>□ h2. Gastrointestinal (W47.2)</td>
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<td>□ h3. Pulmonary (W47.3)</td>
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<td>h90. Other (W47.9): Specify: _____________</td>
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¹Refer to Diagnosis Method Code List
<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Visit ID</th>
<th>Visit DT</th>
<th>Ongoing</th>
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<tbody>
<tr>
<td>WHOCLASS (Mark all that apply)</td>
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<tr>
<td>1. Lymphoma (W44.1)</td>
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<tr>
<td>2. Burkitts (W48.2)</td>
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<td>3. Diffuse Large B Cell (W48.3)</td>
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<tr>
<td>4. Other Non-Hodgkins (W48.4)</td>
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<tr>
<td>5. Hodgkins (W48.5)</td>
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</tbody>
</table>

| WHOCLASS SOURCE | CONFIDENTIAL | WHOCLASS PROTOCOL | RV339 (2013 VERSIN 1.0) | HENRY JACOBSON FOUNDAION |
## MEDICAL HISTORY

**Subject ID:** [__] [__] [__] [__] [__]  
**Visit Date:** [__] [__] [__] [__] [__]  
**Visit:** [__]

Mark if None (all 4 pages) **NONE**

Record General Medical History and Current Conditions. If Illness not listed, record Diagnosis on Medical History (page 4 of 4).

<table>
<thead>
<tr>
<th>Diagnosis (Mark all that apply)</th>
<th># of Episodes</th>
<th>Start Date (First Episode)</th>
<th>Stop Date (Last Episode)</th>
<th>Ongoing</th>
<th>DX Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Heart Disease DX1A_7E</td>
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<tr>
<td>a. Heart attack (myocardial infarction) (I21)</td>
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<tr>
<td>b. Heart Failure (I50)</td>
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<td>c. Angina (I20)</td>
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<tr>
<td>2. High blood pressure/ Essential HTN (I10)</td>
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<tr>
<td>3. Kidney Disease</td>
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<tr>
<td>a. Chronic kidney disease (N18)</td>
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<td>b. Kidney stones (N20)</td>
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<td>4. Diabetes</td>
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<tr>
<td>a. Type I (E10)</td>
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<tr>
<td>b. Type II (E11)</td>
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<td>5. Anemia</td>
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<tr>
<td>a. Related to medication (D61.1)</td>
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<tr>
<td>b. Related to pregnancy (O99.0)</td>
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<td>6. Mental health</td>
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<td>a. Depression (F33)</td>
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<td>b. Alcoholism (F10.2)</td>
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<td>7. Liver Problem</td>
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<tr>
<td>a. Acute hepatitis A (B15)</td>
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<tr>
<td>b. Chronic hepatitis B (B18.1)</td>
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<tr>
<td>c. Chronic Hepatitis C (B18.2)</td>
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<tr>
<td>d. Hepatitis, Alcoholic (K70.1)</td>
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<tr>
<td>e. Cirrhosis (K74)</td>
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</table>

^1Refer to Diagnosis Method Code List

QC/QA: [__]  
Data Entry: 1st [__] 2nd [__]
<table>
<thead>
<tr>
<th>Diagnosis (Mark all that apply)</th>
<th># of episodes</th>
<th>Start Date (First Episode)</th>
<th>Stop Date (Last Episode)</th>
<th>Ongoing Mark if ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Cancer <strong>DX8A_10F</strong></td>
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<tr>
<td>a. Multiple Myeloma (C90.0)</td>
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<tr>
<td>b. Lung (C34) <strong>DX8A_10F</strong></td>
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<tr>
<td>c. Breast (C50)</td>
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<tr>
<td>d. Cervix (invasive, not in situ) (C53)</td>
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<tr>
<td>e. Prostate (C61)</td>
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<tr>
<td>f. Skin Cancer, melanoma (C43)</td>
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<tr>
<td>9. Sexually transmitted infections</td>
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<tr>
<td>a. Syphilis, primary (A51.0)</td>
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<tr>
<td>b. Gonorrhea (A54)</td>
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<tr>
<td>c. Nongonococcal urethritis (N34.1)</td>
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<tr>
<td>d. Genital Herpes (A60)</td>
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<td>e. Chlamydia (A56.0)</td>
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<td>f. Genital or anal warts (A63.0)</td>
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<td>g. PID (Pelvic Inflammatory Disease) (N73.9)</td>
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<td>h. Trichomoniasis (A59)</td>
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<tr>
<td>10. Neurologic</td>
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<tr>
<td>a. Migraine (G43)</td>
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<td>b. Epilepsy/Seizures (G40)</td>
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<td>c. Drug–induced neuropathy (G62.0)</td>
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<td>d. Dementia (Non-AIDS) (F03)</td>
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<td>e. Traumatic brain injury (with loss of consciousness) (S06.2)</td>
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<tr>
<td>f. Stroke (I64)</td>
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</table>

1Refer to Diagnosis Method Code List
### MEDICAL HISTORY

#### Diagnosis

**Mark all that apply**

1. **Diarrhea over 4 weeks**
   - a. From medicine (R19.8)
   - b. From other reason not related to medicine (R19.4)

2. **Acute Pancreatitis (K85)**

3. **Lipodystrophy**
   - a. Buffalo hump (dorsocervical fat pad) (E65.0)
   - b. Loss of subcutaneous at in arms/legs (E88.1)
   - c. Accumulation of fat around the waist (E65.1)
   - d. Facial wasting appearance (M62.5)

4. **Osteoarthritis (M15.9)**

5. **Thyroid disease**
   - a. Low thyroid (E03.9)
   - b. High thyroid (E05)

6. **Bone density loss**
   - a. Osteoporosis without fracture (M81)
   - b. Hip fracture (S72.0)
   - c. Osteoporosis with fracture (M80)

7. **Malaria, severe (B50.8)**

---

1Refer to Diagnosis Method Code List

QC/QA:  
Data Entry: 1st  
2nd  

13
## Record other unlisted Medical History and Current Conditions

### Diagnosis
*(Refer to Diagnosis Code List)*

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<tr>
<th></th>
<th># of episodes</th>
<th>Start Date (First Episode)</th>
<th>Stop Date (Last Episode)</th>
<th>Ongoing</th>
<th>DX Method¹</th>
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<td>STARTDT</td>
<td>STOPDT</td>
<td>ONGO</td>
<td>DX_METH</td>
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<td>DX METHOD</td>
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**18. Other unlisted illness**

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<td>b. Name:</td>
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<td>c. Name:</td>
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<td>e. Name:</td>
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<td>f. Name:</td>
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<td>g. Name:</td>
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</table>

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¹Refer to Diagnosis Method Code List

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Form Completed by: **FORMBY** SIGNED. Date: __________ FORMDT

QC/QA: __________ Data Entry: 1st __________ 2nd __________
**MEDICATION RECORD** (page 1 of 3)

Subject ID: ____________

Visit Date: ____________

Mark if None (Never taken ARVs)

Enter fixed dose combinations on Medication Record Page 3, Other ARV Medication Use; refer to the Medication code list for the appropriate code.

<table>
<thead>
<tr>
<th>Medication (Mark all that apply)</th>
<th>Indication*</th>
<th>Start Date (STARTDT)</th>
<th>Stop Date (STOPDT)</th>
<th>Stop Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ 1. Abacavir (ABC) 300mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 2. Didanosine (ddl) 400mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
</tr>
<tr>
<td>□ 3. Lamivudine (3TC) 150mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 4. Lamivudine (3TC) 300mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 5. Stavudine (d4T) 30mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 6. Tenofovir (TDF) 300mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 7. Zidovudine (AZT) 300mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 8. Efavirenz (EFV) 600mg</td>
<td>a. PREP c. HIV Treatment</td>
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<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 9. Nevirapine (NVP) 200mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 10. Atazanavir (ATZ) 300mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 11. Atazanavir/ Ritonavir 300mg/100mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 12. Lopinavir/Ritonavir 400mg/100mg</td>
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<td>NºOngoing</td>
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<tr>
<td>□ 13. Ritonavir Boost 100mg</td>
<td>a. PREP c. HIV Treatment</td>
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<td>____________</td>
<td>NºOngoing</td>
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<tr>
<td>□ 14. Emtricitabine (FTC) 200mg</td>
<td>a. PREP c. HIV Treatment</td>
<td>____________</td>
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<td>NºOngoing</td>
</tr>
</tbody>
</table>

Does the pill count confirm adherence to ARVs?  ○ 1. Yes  ○ 0. No  ○ 7. Not Performed

PILL CT YESNONP.

QC/QA: ____________

Data Entry: 1st ____________ 2nd ____________

1Refer to Stop Code List; Enter Primary Stop Code only
## MEDICATION RECORD (page 2 of 3)

**Subject ID:** ____________ ____________  
**Visit Date:** ____________ ____________ ____________  
**Visit:** ____________

### Indication

#### 1. PCP Prophylaxis

<table>
<thead>
<tr>
<th>Medication (Mark all that apply)</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Ongoing</th>
<th>Stop Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Co-Trimoxazole (Septin)</td>
<td>____________ ____________</td>
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<tr>
<td>b. Dapsone</td>
<td>____________ ____________</td>
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<tr>
<td>c. Pentamidine</td>
<td>____________ ____________</td>
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<tr>
<td>z. Other, Specify: OTH_TXT1</td>
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#### 2. Treatment of latent TB (IPT)

<table>
<thead>
<tr>
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<th>Start Date</th>
<th>Stop Date</th>
<th>Ongoing</th>
<th>Stop Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Isoniazid</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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</tr>
<tr>
<td>b. Rifampicin</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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<tr>
<td>z. Other, Specify: OTH_TXT2</td>
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</table>

#### 3. TB Treatment (active)

<table>
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<tr>
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<th>Start Date</th>
<th>Stop Date</th>
<th>Ongoing</th>
<th>Stop Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Rifampicin</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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<td></td>
</tr>
<tr>
<td>b. Isoniazid</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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<td></td>
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<tr>
<td>c. Streptomycin</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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<tr>
<td>d. Ethambutol</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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<tr>
<td>e. Pyrazinamide</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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<tr>
<td>y. Other (1), Specify: OTH1TXT3</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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<td></td>
</tr>
<tr>
<td>z. Other (2), Specify: OTH2TXT3</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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</tbody>
</table>

#### 4. Cryptococcus Treatment

<table>
<thead>
<tr>
<th>Medication (Mark all that apply)</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Ongoing</th>
<th>Stop Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Fluconazole</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Amphotericin B</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>z. Other, Specify: OTH_TXT4</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
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</tr>
</tbody>
</table>

#### 5. Cryptococcus Prophylaxis

<table>
<thead>
<tr>
<th>Medication (Mark all that apply)</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Ongoing</th>
<th>Stop Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Fluconazole</td>
<td>____________ ____________</td>
<td>____________ ____________</td>
<td></td>
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</tr>
</tbody>
</table>

### Medication Allergies

- Mark all that apply

### 1Refer to Stop Code List; Enter Primary Stop Code only

Form Completed by: ____________  
**Date:** ____________ ____________ ____________

QC/QA: ____________  
Data Entry: 1st ____________ 2nd ____________  
16
### Other ARV Medication Use:

<table>
<thead>
<tr>
<th>Medication (CODE and NAME: refer to Medication Code List)</th>
<th>Indication*</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Ongoing Mark if ongoing</th>
<th>Stop Code¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEQUENCE</td>
<td>CODE</td>
<td>ARV_NAME</td>
<td>ARVIND_A</td>
<td>ASTARTDT</td>
<td>ARVONGO</td>
</tr>
<tr>
<td>SEQUENCE</td>
<td>CODE</td>
<td>ARV_NAME</td>
<td>ARVIND_C</td>
<td>ASTARTDT</td>
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</tr>
<tr>
<td>SEQUENCE</td>
<td>CODE</td>
<td>ARV_NAME</td>
<td>ARVIND_D</td>
<td>ASTARTDT</td>
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</table>

### Other Medication Use: (Please re-start sequencing)

<table>
<thead>
<tr>
<th>Medication (CODE and NAME: refer to Medication Code List)</th>
<th>Indication (refer to Diagnosis Code List)</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Ongoing Mark if ongoing</th>
<th>Stop Code¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEQUENCE</td>
<td>CODE</td>
<td>MD_CODE</td>
<td>MD_IND</td>
<td>MSTARTDT</td>
<td>MDONGO</td>
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<tr>
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<td>CODE</td>
<td>MD_CODE</td>
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</table>

¹Refer to Stop Code List; Enter Primary Stop Code only

Form Completed by: FORMBY SIGNED. Date: ____________

QC/QA: ____________ Data Entry: 1st ____________ 2nd ____________
## RECENT SYMPTOMS

Subject ID: ____________ | Visit Date: ____________ | Visit: ____________

Mark if All Normal (both pages)  Record symptoms the subject has had within the past week

<table>
<thead>
<tr>
<th>Body System</th>
<th>*If Abnormal, Mark all that apply</th>
<th>Comments</th>
</tr>
</thead>
</table>

### 1. General
- **GEN**
  - **0. Normal**
  - **1. Abnormal**
    - NORMAB.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Duration</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>&lt;1 week</td>
<td>GEN_A_D</td>
</tr>
<tr>
<td></td>
<td>1 wk-1 month</td>
<td>LGWKMON.</td>
</tr>
<tr>
<td></td>
<td>&gt;=1 month</td>
<td>GEN_ATXT</td>
</tr>
<tr>
<td>Sweats</td>
<td>&lt;1 month</td>
<td>GEN_B_D</td>
</tr>
<tr>
<td></td>
<td>&gt;=1 month</td>
<td>LGMON.</td>
</tr>
<tr>
<td></td>
<td>GEN_BTXT</td>
<td></td>
</tr>
<tr>
<td>Weight loss</td>
<td>&lt;10 kg</td>
<td>GEN_C_WT</td>
</tr>
<tr>
<td></td>
<td>10-20 kg</td>
<td>LGWEIGHT.</td>
</tr>
<tr>
<td></td>
<td>&gt;20 kg</td>
<td>GEN_CTXT</td>
</tr>
<tr>
<td>Fatigue</td>
<td>&lt;1 month</td>
<td>GEN_D_D</td>
</tr>
<tr>
<td></td>
<td>&gt;=1 month</td>
<td>LGMON.</td>
</tr>
<tr>
<td></td>
<td>GEN_DTXT</td>
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</tbody>
</table>

### 2. HEENT
- **HNT**
  - **0. Normal**
  - **1. Abnormal**
    - NORMAB.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Duration</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blurry vision</td>
<td></td>
<td>HNT_A</td>
</tr>
<tr>
<td>Eye pain</td>
<td></td>
<td>HNT_B</td>
</tr>
<tr>
<td>Swollen lymph nodes</td>
<td></td>
<td>HNT_C</td>
</tr>
<tr>
<td>Sore throat</td>
<td></td>
<td>HNT_D</td>
</tr>
<tr>
<td>Painful swallowing</td>
<td></td>
<td>HNT_E</td>
</tr>
<tr>
<td>Mouth lesions</td>
<td></td>
<td>HNT_F</td>
</tr>
</tbody>
</table>

### 3. Cardio Pulmonary
- **CP**
  - **0. Normal**
  - **1. Abnormal**
    - NORMAB.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Duration</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest pain</td>
<td>1. Exertional</td>
<td>CP_A_TYP</td>
</tr>
<tr>
<td></td>
<td>2. Pleuritic</td>
<td>EXPLEU.</td>
</tr>
<tr>
<td>Cough</td>
<td>Duration: [ ] Days</td>
<td>CP_B_DUR</td>
</tr>
<tr>
<td></td>
<td>Productive</td>
<td>CP_B_PRD</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td></td>
<td>CP_C</td>
</tr>
</tbody>
</table>

### 4. Gastrointestinal
- **GAS**
  - **0. Normal**
  - **1. Abnormal**
    - NORMAB.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Duration</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>Duration: [ ] Days</td>
<td>GAS_A</td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
<td>GAS_B</td>
</tr>
<tr>
<td>Anorexia</td>
<td></td>
<td>GAS_C</td>
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<tr>
<td>Vomiting</td>
<td></td>
<td>GAS_D</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td></td>
<td>GAS_E</td>
</tr>
<tr>
<td>Body System</td>
<td><strong>If Abnormal, mark all that apply</strong></td>
<td>Comments</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>5. Genitourinary</strong></td>
<td></td>
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<tr>
<td>0. Normal</td>
<td></td>
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<tr>
<td>1. Abnormal *</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>□ a. Vaginal or penile discharge</td>
<td>GTY_ATXT</td>
</tr>
<tr>
<td></td>
<td>□ b. Genital ulcer</td>
<td>GTY_BTXT</td>
</tr>
<tr>
<td></td>
<td>□ c. Blood in urine</td>
<td>GTY_CTXT</td>
</tr>
<tr>
<td></td>
<td>□ d. Burning/Painful urination</td>
<td>GTY_DTXT</td>
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<tr>
<td></td>
<td>□ e. Vaginal itching</td>
<td>GTY_ETXT</td>
</tr>
<tr>
<td></td>
<td>□ f. Painful intercourse</td>
<td>GTY_FTXT</td>
</tr>
<tr>
<td></td>
<td>□ g. Lower abdominal pain</td>
<td>GTY_GTXT</td>
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<tr>
<td></td>
<td>□ h. Swollen lymph nodes at groin</td>
<td>GTY_HTXT</td>
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<tr>
<td></td>
<td>□ i. Genital warts</td>
<td>GTY_ITXT</td>
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<tr>
<td><strong>6. Musculoskeletal</strong></td>
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<tr>
<td>0. Normal</td>
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<tr>
<td>1. Abnormal *</td>
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<td></td>
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<tr>
<td></td>
<td>□ a. Arthritis/Swollen joints</td>
<td>MUS_ATXT</td>
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<tr>
<td></td>
<td>□ b. Joint aches</td>
<td>MUS_BTXT</td>
</tr>
<tr>
<td></td>
<td>□ c. Muscle aches</td>
<td>MUS_CTXT</td>
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<tr>
<td><strong>7. Central Nervous System</strong></td>
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<td></td>
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<tr>
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<tr>
<td>1. Abnormal *</td>
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<tr>
<td></td>
<td>□ a. Headache</td>
<td>CNS_ATXT</td>
</tr>
<tr>
<td></td>
<td>□ b. Neck stiffness</td>
<td>CNS_BTXT</td>
</tr>
<tr>
<td></td>
<td>□ c. Confusion</td>
<td>CNS_CTXT</td>
</tr>
<tr>
<td></td>
<td>□ d. Numbness/loss of sensation</td>
<td>CNS_DTXT</td>
</tr>
<tr>
<td></td>
<td>□ e. Loss of balance</td>
<td>CNS_ETXT</td>
</tr>
<tr>
<td><strong>8. Skin</strong></td>
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<tr>
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<tr>
<td>1. Abnormal *</td>
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<tr>
<td></td>
<td>□ a. Jaundice</td>
<td>SKN_ATXT</td>
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<td></td>
<td>□ b. Rash</td>
<td>SKN_BTXT</td>
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<tr>
<td></td>
<td>□ Pruritic</td>
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<tr>
<td></td>
<td>□ Duration: ___ days</td>
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</table>

**Specify Symptom(s):**

<table>
<thead>
<tr>
<th>9. Other Body System (1):</th>
<th>OTBS1TXT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Other Body System (2):</td>
<td>OTBS2TXT</td>
<td></td>
</tr>
</tbody>
</table>

Form Completed by: FORMBY SIGNED. Date: ____________

QC/QA: ____________ Data Entry: 1st ____________ 2nd ____________
### 1. Vital Signs

<table>
<thead>
<tr>
<th>Height (cm)</th>
<th>Weight (kg)</th>
<th>Temperature °C</th>
<th>1. Oral</th>
<th>2. Axillary</th>
<th>Sitting Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>HT</td>
<td>WT</td>
<td>TEMP</td>
<td></td>
<td></td>
<td>Pulse (beats/min)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Respiration (breaths/min)</td>
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<td></td>
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<td></td>
<td>Systolic BP (mmHg)</td>
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<td></td>
<td></td>
<td>Diastolic BP (mmHg)</td>
</tr>
</tbody>
</table>

### 2. Physical Characteristics - Circumferences

2a. MUA (mid upper arm)  
2b. Waist  
2c. Hip

<table>
<thead>
<tr>
<th>MUA  cm</th>
<th>WAIST cm</th>
<th>HIP cm</th>
</tr>
</thead>
</table>

### 3. Chest X-ray performed?

- 0. Yes*  
- 0. No

*If Yes,  
3a. Chest X-ray result:  
3b. Why performed?

<table>
<thead>
<tr>
<th>NORMABND</th>
<th>WHYXRAY</th>
</tr>
</thead>
</table>

### 4. Physical Exam

- 0. Not Done

#### Body System

<table>
<thead>
<tr>
<th>General</th>
<th>Lymph Nodes</th>
<th>HEENT / HEENT Mucocutaneous</th>
<th>Chest</th>
<th>Abdomen</th>
<th>Urogenital</th>
<th>Extremities</th>
<th>Neurological</th>
<th>Other Body System: OTBODSYS OTBSYTXT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0. Normal</td>
<td>0. Normal</td>
<td>0. Normal</td>
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<td>0. Normal</td>
<td>0. Normal</td>
<td>0. Normal</td>
<td>0. Normal</td>
</tr>
</tbody>
</table>

#### Abnormal Findings (Mark all that apply)

- a. Generalized wasting
- b. Lipoatrophy
- c. Lipoaccumulation
- d. Generalized lymphadenopathy
- e. Cervical LAD
- f. Axillary LAD
- g. Inguinal LAD
- h. KS-like lesions
- i. Oral Hairy Leukoplakia
- j. Jaundice
- k. Thrush
- l. Decreased breath sounds
- m. Adventitial sounds (e.g. wheeze, rale)
- n. Hepatomegaly
- o. Splenomegaly
- p. Genital ulcer
- q. Joint swelling
- r. Edema
- s. Unstable gait
- t. Neuropathy
- u. Tremor
- Specify, Abnormal Finding(s):

#### Form Completed by:

FORMBY SIGNED.

Date: [_______]
### Specimen Collection

| Subject ID: __________-__________ | Visit Date: __________-__________-__________ | Visit: __________ |

1. **Clinical Blood Draw:**
   - **Date:** __________-__________-__________
   - **Time:** ____________ hrs (24 hour clock)

2. **When was the last time the subject had anything to eat or drink except water, plain tea, coffee or medication?**
   - **Date:** __________-__________-__________
   - **Time:** ____________ hrs (24 hour clock)

3. **Fasting Clinical Blood Draw** (Mark Yes if blood was drawn at least 8 hours after the time in Question 2):
   - YesNO.
   - 1. Yes
   - 0. No

4. **When was the last dose of ARV taken by the subject?**
   - **LSTDOS**
   - 5. NA (HIV Negative or not on ART)
     - **LSTDSDT**
     - **LSTDSTM**
     - Last dose date: __________-__________-__________
     - Time: ____________ Hrs (24 hour clock)

5. **Was this ARV regimen prescribed to be taken once or twice a day?**
   - 1. Once
   - 2. Twice
   - **DOSEPDAY**
   - **ONCETWIC.**

6. **List which ARVs were taken:** *(Refer to Medication Code List)*
   - **ARV_A**
   - **ARV_B**
   - **ARV_C**
   - a. __________
   - b. __________
   - c. __________

---

### Repository Blood Draw

- **Subject Refused (End Form)**
  - RBD_SUBR

7. **Was repository blood draw deferred or reduced?**
   - **DEFER**
   - YesNO.
   - 1. Yes
   - 0. No
   - **7a. If Yes,** why was the draw deferred or reduced?
     - *(Mark all that apply)*
     - **DEFER_A**
       - a. Pregnant
     - **DEFER_B**
       - b. Phlebotomy Failure
     - **DEFER_C**
       - c. Anemia

---

**Form Completed by: FORMBY SIGNED.**

**Date:** __________-__________-__________

**QC/QA:** __________

**Data Entry:** 1st __________ 2nd __________
<table>
<thead>
<tr>
<th>Lab Code</th>
<th>Draw Date</th>
<th>Lab Code</th>
<th>Draw Date</th>
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</thead>
<tbody>
<tr>
<td>SUBJID</td>
<td>VISITDT</td>
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<tr>
<td><strong>The Assays listed below are not part of the Schedule of Events, but results should be recorded if obtained as part of subject’s clinical care:</strong></td>
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<tr>
<td><strong>1. Glucose</strong></td>
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<tr>
<td>GLUCOSE</td>
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</tr>
</tbody>
</table>

**Form Completed by:** FORMBY SIGNED.  
**Date:** ____________

**QC/QA:** ____________  
**Data Entry:** 1st ____________  2nd ____________
### Automated (Machine Differential)

1. WBC Count: \[ \text{WBC} \] \( 10^3 \text{ cells/ul} \)
2. Hemoglobin: \[ \text{HEMOG} \] \( \text{g/dl} \)
3. Mean Corpuscular Volume: \[ \text{MCV} \] \( \text{fl} \)
4. Platelet Count: \[ \text{PLATELET} \] \( 10^3 \text{ cells/ul} \)
5. Neutrophil %: \[ \text{NEUTRO} \] \%
6. Lymphocyte %: \[ \text{LYMPH} \] \%
7. Monocyte %: \[ \text{MONOCYTE} \] \%
8. Eosinophil %: \[ \text{EOSINO} \] \%
9. Basophil %: \[ \text{BASOPHIL} \] \%

### Manual (Mark if so)
- NEUT_CK
- LYM_CK
- MONO_CK
- EOS_CK
- BASO_CK

The Assay listed below is not part of the Schedule of Events, but results should be recorded if obtained as part of subject’s clinical care.

10. Erythrocyte Sedimentation Rate (ESR): \[ \text{ESR} \] \( \text{mm/hr} \)
# Urinalysis

The Assays listed below are not part of the Schedule of Events, but results should be recorded if obtained as part of subject's clinical care.

<table>
<thead>
<tr>
<th>Lab Code</th>
<th>Draw Date</th>
<th>Lab Code</th>
<th>Draw Date</th>
</tr>
</thead>
</table>

### 1. Color
- **COLOR**
  - 0 (Yellow; 1 = other than Yellow)

### 2. Appearance
- **APPEAR**
  - 0 (Clear; 1 = other than Clear)

### 3. Glucose
- **GLUCOSE**
  - ZEROFOUR.
  - 0 (Neg or Normal; 1 = Trace, 1+ 100 or 250; 2 = 2+ or 500; 3 = 3+ or 1000; 4 = 4+ or ≥ 2000)

### 4. Bilirubin
- **BILIRUB**
  - ZEROFOUR.
  - 0 (Neg or Normal; 1 = Trace, 1+ or small; 2 = 2+ or moderate; 3 = 3+ or Large)

### 5. Ketones
- **KETONES**
  - ZEROFOUR.
  - 0 (Neg or Normal; 1 = Trace, 5, 1+, Small, 15; 2 = 2+, Moderate, 40; 3 = 3+, Large, 80; 4 = 4+, 160)

### 6. SPGR
- **SPGR**
  - LESEQGR.
  - <, =, or >
  - SPGR

### 7. Blood
- **BLOOD**
  - ZEROFOUR.
  - 0 (Neg or Normal; 1 = Trace, 1+ or small; 2 = 2+ or moderate; 3 = 3+ or Large)

### 8. pH
- **PH**
  - __.__

### 9. Protein
- **PROTEIN**
  - ZEROFOUR.
  - 0 (Neg or Normal; 1 = Trace, 1+ or 30; 2 = 2+ or 100; 3 = 3+ or 300; 4 = 4+ or >300)

### 10. Urobilinogen
- **UROB**
  - LESEQGR.
  - <, =, or >
  - UROB

### 11. Nitrite
- **NITRITE**
  - ZEROFOUR.
  - 0 (Neg or Normal; 1 = Positive)

### 12. Leukocyte Esterase
- **LEUKO**
  - ZEROFOUR.
  - 0 (Neg or Normal; 1 = Trace, 1+ or small; 2 = 2+ or moderate; 3 = 3+ or Large)

### 13. RBC UA
- **RBCUA**
  - ZEROFIVE.

### 14. WBC UA
- **WBCUA**
  - ZEROFIVE.

### 15. Micro-albumin
- **ALBUMIN**
  - ______mg/L

### 16. Protein-Creatinine Ratio
- **PCRATIO**
  - Note: For 13. & 14. use the following codes:
  - 0=Neg, 0, <1: 3=11-29
  - 1=1-4: 4=30-50
  - 2=5-10: 5=≤50, TNTC, PACKED/HPF

### 17. Protein
- **PROTEINC**
  - ______mg/dL

### 18. Creatinine
- **CREAT**
  - ______mg/dL

Form Completed by: ____________ Date: ____________
# Lymphocyte Subset Profile

**Seq. #:** [________]  
**Lab Code:** [________]  
**Draw Date:** [________]

<table>
<thead>
<tr>
<th>1. WBC</th>
<th>[________] /mm³</th>
<th>Lymph</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Lymphs</td>
<td>[________] /mm³</td>
<td>%</td>
</tr>
<tr>
<td>3. CD3+</td>
<td>[________] m³</td>
<td>%</td>
</tr>
<tr>
<td>4. CD3+CD4+</td>
<td>[________] /mm³</td>
<td>%</td>
</tr>
<tr>
<td>5. CD3+CD8+</td>
<td>[________] /mm³</td>
<td>%</td>
</tr>
<tr>
<td>6. % CD19+</td>
<td>[________] %</td>
<td>%</td>
</tr>
<tr>
<td>7. % CD3-CD56+</td>
<td>[________] %</td>
<td>%</td>
</tr>
</tbody>
</table>

**Draw Period:**  
- [ ] 1. At study visit  
- [ ] 2. Outside of study visit
ADDITIONAL MICROBIOLOGY

Subject ID: ______-______-______
Visit Date: ______-______-______
Visit: ______

1. TB Xpert: TBXPRTND
   - Lab Code: ______
   - Date: ______
   - Specimen Code: ______
   - Resis: YESNO.

   O 0. Negative
   O 1. Positive
   - If 1. Positive, drug resistance to Rifampin?
     O 1. Yes
     O 0. No

   O 6. Not Done
      O 1. Stored
      O 2. No sputum produced

2. Stool Exams for ova and parasites: STOOLEXA
   - Code (1) ______
   - Code (2) ______
   - Code (3) ______

   O 0. Negative
   O 1. Positive

3. Stool Culture: STOOLCUL
   - Code (1) ______
   - Code (2) ______
   - Code (3) ______

   O 0. Negative
   O 1. Positive

4. Blood Culture: BLOODCUL
   - Code (1) ______
   - Code (2) ______
   - Code (3) ______

   O 0. Negative
   O 1. Positive

5. Other Body Fluid Culture: FLUIDCUL
   - Code (1) ______
   - Code (2) ______
   - Code (3) ______

   O 0. Negative
   O 1. Positive

6. Chlamydia: CHLAMYDI
   - Code (1) ______
   - Code (2) ______
   - Code (3) ______

   O 0. Negative
   O 1. Positive

7. Gonorrhea: GONORRHE
   - Code (1) ______
   - Code (2) ______
   - Code (3) ______

   O 0. Negative
   O 1. Positive

8. HPV (cervical specimen)
   - Subtype: ______

9. Mycobacterial specimen type:
   - MYCOBTP

9a. Mycobacterial smear
   - MYCOBSM

9b. Mycobacterial culture
   - MYCOBCUL

   O 0. Negative
   O 1. Positive, MTB*
   O 2. Positive, MAC*
   O 3. Positive, Other*

   *If Positive, MTB, MAC, or Other, Sensitivity Testing Results (Mark all resistance that applies):
   - Isoniazid
   - Pyrazinamide
   - Rifampin
   - Ethambutol
   - Other

1Refer to Specimen Code List; 2Refer to Organism Code List

Form Completed by: FORMBY SIGNED.
Date: ______-______-______

QC/QA: ______
Data Entry: 1st ______ 2nd ______
<table>
<thead>
<tr>
<th>Seq. #</th>
<th>LABCODE</th>
<th>DRAWDT</th>
<th>Draw Date:</th>
<th>Lab Code:</th>
<th>DRAWPER</th>
<th>Circle One:</th>
<th>VLCOPY</th>
<th>Not Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
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Form Completed by: FORMBY SIGNED. Date: ___-___-___-___-___-___-___-___

QC/QA: ___________ Data Entry: 1st ___________ 2nd ___________
<table>
<thead>
<tr>
<th>Sequence</th>
<th>Test Description</th>
<th>Code</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.</td>
<td>Hepatitis C virus AB (AntiHCV)</td>
<td>---</td>
<td>✅</td>
<td></td>
<td>material is not legible</td>
</tr>
<tr>
<td>B.</td>
<td>Syphilis screen:</td>
<td>---</td>
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</tr>
<tr>
<td>B.</td>
<td>Hepatitis C confirmatory test</td>
<td>---</td>
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<td></td>
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<tr>
<td>B.</td>
<td>FTA-ABS</td>
<td>---</td>
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<td></td>
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<tr>
<td>B.</td>
<td>MHA-TP/TP-PA</td>
<td>---</td>
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</tr>
<tr>
<td>B.</td>
<td>Hepatitis B surface Antigen</td>
<td>---</td>
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<tr>
<td>B.</td>
<td>Hepatitis B surface Antigen confirmatory test</td>
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<tr>
<td>B.</td>
<td>Hepatitis B e Antigen</td>
<td>---</td>
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</tr>
<tr>
<td>B.</td>
<td>Hepatitis B Core Antibody</td>
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</tr>
<tr>
<td>B.</td>
<td>Quantiferon TB ELISA</td>
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<tr>
<td>B.</td>
<td>Serum Cryptococcal Antigen</td>
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<tr>
<td>A.</td>
<td>Syphilis (Titer)</td>
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<tr>
<td>A.</td>
<td>FTA-ABS</td>
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<tr>
<td>A.</td>
<td>MHA-TP/TP-PA</td>
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<tr>
<td>B.</td>
<td>Hepatitis B surface Antigen</td>
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<tr>
<td>B.</td>
<td>Hepatitis B surface Antigen confirmatory test</td>
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</tr>
<tr>
<td>B.</td>
<td>Hepatitis B e Antigen</td>
<td>---</td>
<td></td>
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<tr>
<td>B.</td>
<td>Hepatitis B Core Antibody</td>
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<tr>
<td>B.</td>
<td>Quantiferon TB ELISA</td>
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<tr>
<td>B.</td>
<td>Serum Cryptococcal Antigen</td>
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<tr>
<td>A.</td>
<td>Syphilis (Titer)</td>
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<tr>
<td>A.</td>
<td>FTA-ABS</td>
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<tr>
<td>A.</td>
<td>MHA-TP/TP-PA</td>
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<td></td>
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<tr>
<td>B.</td>
<td>Hepatitis B surface Antigen</td>
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<tr>
<td>B.</td>
<td>Hepatitis B surface Antigen confirmatory test</td>
<td>---</td>
<td></td>
<td></td>
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<tr>
<td>B.</td>
<td>Hepatitis B e Antigen</td>
<td>---</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>B.</td>
<td>Hepatitis B Core Antibody</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.</td>
<td>Quantiferon TB ELISA</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.</td>
<td>Serum Cryptococcal Antigen</td>
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</tbody>
</table>

The Assays listed below are not part of the Schedule of Events, but results should be recorded if obtained as part of subject's clinical care.

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Test Description</th>
<th>Code</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.</td>
<td>Herpes Simplex Virus I</td>
<td>---</td>
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</tr>
<tr>
<td>14.</td>
<td>Herpes Simplex Virus II</td>
<td>---</td>
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</tr>
<tr>
<td>15.</td>
<td>Hepatitis A Antibody</td>
<td>---</td>
<td></td>
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</tr>
<tr>
<td>16.</td>
<td>CSF Cryptococcal Antigen</td>
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<td></td>
</tr>
<tr>
<td>17.</td>
<td>Toxoplasma Serology</td>
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</tr>
<tr>
<td>18.</td>
<td>Cytomegalovirus (CMV)</td>
<td>---</td>
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<td></td>
</tr>
</tbody>
</table>

Form Completed by: [FORMBY] SIGNED. Date: ____-____-____
### SEROLOGY (HIV Negative only)

#### Lab Code (for Rapid Diagnostic Test(s)):

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>HIV Positive</td>
</tr>
</tbody>
</table>

1. **HIV Rapid Diagnostic Test (1):**
   - **Type:** RDT1TYPE
   - **Date of Test:**
   - **Options:**
     - 0. Negative
     - 1. Positive
     - **HIV_1RDT NEGPOS.**

2. **HIV Rapid Diagnostic Test (2):**
   - **Type:** RDT2TYPE
   - **Date of Test:**
   - **Options:**
     - 0. Negative
     - 1. Positive
     - **HIV_2RDT NEGPOS.**

3. **HIV Rapid Diagnostic Test (3):**
   - **Type:** RDT3TYPE
   - **Date of Test:**
   - **Options:**
     - 0. Negative
     - 1. Positive
     - **HIV_3RDT NEGPOS.**

Lab Code (for ELISA & Western Blot Tests):

4. **HIV ELISA Test:**
   - **Type:** ELISRSLT
   - **Date of Test:**
   - **Options:**
     - 0. Nonreactive
     - 2. Indeterminate

5. **HIV Western Blot Test:**
   - **Type:** BLOTRESLT
   - **Date of Test:**
   - **Options:**
     - 0. Negative
     - 2. Indeterminate

Form Completed by: **FORMBY SIGNED.**

Date: **FORMDT**

QC/QA: ____________

Data Entry: 1st ____________ 2nd ____________
**Cognitive Evaluation** (page 1 of 2)

The following section is a summary of the clinical team's final impression of the subject’s level of function as it relates to cognition. It should be based on all available information and sources including the subject evaluation, information from friends and family members, and recent information from clinical encounters.

1. Please indicate the level of difficulty the subject currently experiences in facets of daily living, using a scale of: 0 = Normal, 1 = Mild, 2 = Moderate/Severe (Indicate only one level per facet on each row)

<table>
<thead>
<tr>
<th>Facet</th>
<th>Normal</th>
<th>Mild</th>
<th>Moderate/Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Memory</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Orientation</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Higher cognitive thinking</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Activities outside of the home</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Activities within the home</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. Personal care (Activities of Daily Living)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Sources of information used to rate functions: (Mark all that apply)

- [ ] a. Subject SOURCE_A
- [ ] b. Family member SOURCE_B
- [ ] c. Close friend/peer SOURCE_C
- [ ] d. Clinical history SOURCE_D
- [ ] e. Other, Specify: SOURCE_E OTH_1TXT

QC/QA: ___________________  Data Entry: 1st ___________  2nd ___________
### I. INTERNATIONAL HIV DEMENTIA SCALE

1. Registration - Words remembered:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial 1:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial 2:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Motor Speed - Number of taps in 5 seconds:

- NUMTAPS (number of taps)
- TAPSPTS points awarded (max of 4)

3. Psychomotor Speed - Number of sequences correctly performed in 10 seconds:

- NUMWORDS

4. Memory Recall - Points for words remembered:

- VALID_1T VALIDITY.

Valid: 1. Valid, Specify: VAL1_TXT

### II. WHO-UCLA AUDITORY VERBAL LEARNING TEST

#### List

- 1. Primary
- 2. Secondary

<table>
<thead>
<tr>
<th>Trial</th>
<th>Correct Responses</th>
<th>Intrusions</th>
<th>Repetitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.</td>
<td>T1_RESP</td>
<td>T1_INT</td>
<td>T1_REPET</td>
</tr>
<tr>
<td>II.</td>
<td>T2_RESP</td>
<td>T2_INT</td>
<td>T2_REPET</td>
</tr>
<tr>
<td>III.</td>
<td>T3_RESP</td>
<td>T3_INT</td>
<td>T3_REPET</td>
</tr>
<tr>
<td>IV.</td>
<td>T4_RESP</td>
<td>T4_INT</td>
<td>T4_REPET</td>
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<tr>
<td>V.</td>
<td>T5_RESP</td>
<td>T5_INT</td>
<td>T5_REPET</td>
</tr>
</tbody>
</table>

Valid: 2T VALIDITY.

Valid: 1. Valid, Specify: VAL2_TXT

### III. GROOVED PEGBOARD TEST

#### DOM Hand

- Right
- Left (Circle one)

| Time: [ ]' [ ]'' (max of 5’00'') |
| DOM_MIN | DOM_SEC |
| DOM_DROP | DOM_CORR |

Valid: 3T VALIDITY.

Valid: 1. Valid, Specify: VAL3_TXT

#### Non-dominant Hand

| Time: [ ]' [ ]'' (max of 5’00'') |
| NDM_MIN | NDM_SEC |
| NDM_DROP | NDM_CORR |

Valid: 4T VALIDITY.

Valid: 1. Valid, Specify: VAL4_TXT

### IV. ACTION FLUENCY TEST

Correct Responses: FT_CORR

Rule Violations: FT_VIOLA

Repetitions: FT_REPET

Valid: 4T VALIDITY.

Valid: 1. Valid, Specify: VAL5_TXT

### V. TRAILS A TEST

| Time: [ ]' [ ]'' (minutes’ seconds) |
| TT_MIN | TT_SEC |

Total Number of Correct Lines: TT_LINE

Errors: TT_ERROR

Prompts: TT_PROMPT

Valid: 5T VALIDITY.

Valid: 1. Valid, Specify: VAL5_TXT

Form Completed by: FORMBY SIGNED. FRMBYTXT

Date: [ ]-[-]---[-]---[-]---[-]---[-]---

QC/QA: [ ]

Data Entry: 1st [ ] 2nd [ ]
Update ongoing conditions from previous visit and add new medical conditions

<table>
<thead>
<tr>
<th>Seq. #</th>
<th>Codes</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Mark if Ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Diagnosis</strong></td>
<td><strong>Diagnosis Method</strong></td>
<td><strong>Treatment Outcome</strong></td>
<td>Data</td>
</tr>
<tr>
<td></td>
<td><strong>SEQUENCE</strong></td>
<td><strong>DX</strong></td>
<td><strong>DX_METHOD</strong></td>
<td><strong>OUT_TX</strong></td>
</tr>
<tr>
<td></td>
<td>___________</td>
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<td>___________</td>
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<td>___________</td>
</tr>
</tbody>
</table>

Comments

CMC_TXT1

---

1Refer to Diagnosis Code List; 2Refer to Diagnosis Method Code List; 3Refer to Treatment Outcome Code List

Form Completed by: FORMBY SIGNED.

Date: ___________
# ACUTE FEBRILE ILLNESS

**Subject ID:** [Blank]  **Visit Date:** [Blank]  **Visit:** [Blank]

**Date of Examination:** [Blank]  **EXAMDT**

1. **Temperature ≥ 99.5°F (37.5°C) or higher:** ☐ 1. Yes  ☐ 0. No  **ORALTEMP YESNO.**

2. **Any symptoms?** ☐ 1. Yes*  ☐ 0. No  **SYMPTOMS YESNO.**

   *If Yes, *(Mark all that apply)*

   - ☐ a. Feverishness
   - ☐ b. Headache
   - ☐ c. Malaise/Fatigue
   - ☐ d. Chills
   - ☐ e. Arthralgias
   - ☐ f. Myalgias
   - ☐ g. Nausea
   - ☐ h. Vomiting
   - ☐ i. Diarrhea
   - ☐ j. Abdominal pain
   - ☐ k. Anorexia
   - ☐ l. Chest Pain
   - ☐ m. Low back pain
   - ☐ n. Other, *Specify:*  **SYMP_Z OTH2_TXT**

3. **Do you sleep under a mosquito net?**  **MOSQUITO NSANR.**

   - ☐ 0. Not at all  ☐ 1. Sometimes  ☐ 2. Always  ☐ 8. No Response

4. **In the time since your last study visit, have you taken medicine to treat malaria?**  **MAL_TX YESNONR.**

   - ☐ 1. Yes  ☐ 0. No  ☐ 8. No Response

5. **Malaria Smear:** ☐ 0. Negative  ☐ 1. Positive*  ☐ 6. Not Done  **SMEAR NEGPOSND.**

   *If Positive,*

   - 5a. ☐ a. Malariae
   - 5b. ☐ a. Malarias
   - 6a. ☐ a. Rapid Diagnostic Test (RDT):
   - 6b. ☐ a. Inconclusive
   - 6c. ☐ a. Positive
   - 6d. ☐ a. Not Done
   - 6e. ☐ a. Thick
   - 6f. ☐ a. Thin

6. **Rapid Diagnostic Test (RDT):**  **RDT NPINCND.**

   - ☐ 0. Negative  ☐ 2. Inconclusive  ☐ 1. Positive  ☐ 6. Not Done

   - ☐ 1. SD Bioline Pf  ☐ 4. First Response
   - ☐ 2. SD Bioline Pan  ☐ 5. ICT
   - ☐ 3. Carestat  ☐ 90. Other, *Specify:*  **RDTNAME RDTNAME.**

7. **Diagnosis given to subject:** [Blank]  **DXGIVEN**

   *Refer to Diagnosis Code List; if Diagnosis is Malaria, use the following codes:*
   - *B50.0=Cerebral Malaria*
   - *B50.8=Severe Malaria, non-cerebral*
   - *B50.9=Uncomplicated Malaria*

8. **Treatment given *(Mark all that apply)***

   - ☐ a. Oral Artemesinin combination
   - ☐ b. Oral Quinine
   - ☐ c. Oral Chloroquine
   - ☐ d. Oral Fansidar
   - ☐ e. Oral Primaquine
   - ☐ f. Oral Clindamycin
   - ☐ g. Oral Doxycycline or Tetracycline
   - ☐ h. IV/IM Artemether
   - ☐ i. IV/IM Quinine
   - ☐ j. IV/IM Artesunate
   - ☐ n. Other, *Specify:*  **TX_Z OTH8_TXT**

9. **DBS for PCR obtained?** ☐ 1. Yes  ☐ 0. No  **DBS_PCR YESNO.**

**Form Completed by:**  **FORMBY SIGNED.**  **Date:** [Blank]  **FORMDT**

**QC/QA:** [Blank]  **Data Entry:** 1st [Blank]  2nd [Blank]
**SEQUENCED HOSPITALIZATION / SERIOUS/ACUTE VISIT**

<table>
<thead>
<tr>
<th>Sequence #</th>
<th>Date of hospital visit:</th>
<th>Date of discharge, if hospitalized:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HOSPVDT</td>
<td>NOTHOSP</td>
</tr>
<tr>
<td></td>
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<td>DISDT</td>
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</table>

<table>
<thead>
<tr>
<th>Diagnosis†</th>
<th>Dx Method²</th>
<th>Treatment³</th>
<th>TX Outcome⁴</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>DX_A</td>
<td>DXMETH_A</td>
<td>TX_1A-TX_4A</td>
<td>TX_OUT_A</td>
<td>A_TXT</td>
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<tr>
<td>DX_B</td>
<td>DXMETH_B</td>
<td>TX_1B-TX_4B</td>
<td>TX_OUT_B</td>
<td>B_TXT</td>
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<td>DX_C</td>
<td>DXMETH_C</td>
<td>TX_1C-TX_4C</td>
<td>TX_OUT_C</td>
<td>C_TXT</td>
</tr>
</tbody>
</table>

**Hospital Name:** HOSPNAME

**Location:** HOSPLOC

---

*Refer to Diagnosis Code List; †Refer to Diagnosis Method Code List; ‡Refer to Treatment Code List; ††Refer to Treatment Outcome Code List*

Form Completed by: FORMBY SIGNED.

Date: ____________

QC/QA: ____________ 

Data Entry: 1st ____________ 2nd ____________
WOMEN’S HEALTH

Subject ID: [___-___-___] Visit Date: [___-___-___-___] Visit: [___]

1. Date of last menstrual period: [___-___-___-___] LASTMDT

2. Gravida: [___] Para: [___]
   GRAVIDA PARA

3. Are you sexually active? SEX_ACT
   ○ 1. Yes* ○ 0. No (if No, end form)

4. Are you currently pregnant? CURRPEG
   ○ 1. Yes* ○ 0. No
   *If Yes, record pregnancy test result on the Blood Chemistry CRF and end form

5. Do you use a method of family planning?
   ○ 1. Yes* ○ 0. No
   FAMPLAN YESNO.

*If Yes, (Mark all that apply)

- □ a. Abstinence FPLAN_YA
- □ b. Lactation Amenorrhea FPLAN_YB
- □ c. Condoms (Male or Female) FPLAN_YC
- □ d. Birth control pills FPLAN_YD
- □ e. Birth control injections FPLAN_YE
- □ f. Birth control implant FPLAN_YF
- □ g. Intrauterine device FPLAN_YG
- □ h. Natural family planning FPLAN_YH
- □ i. Female surgery (tubal ligation) FPLAN_YI
- □ j. Male surgery (vasectomy) FPLAN_YJ
- □ z. Other, Specify: FPLAN_YZ OTHY_TXT

**If No, (Mark all that apply)

- □ a. Trying to conceive FPLAN_NA
- □ b. No partner currently FPLAN_NB
- □ c. Partner uses condoms FPLAN_NC
- □ d. Can’t afford FPLAN_ND
- □ e. Desired method not available FPLAN_NE
- □ f. Side effects FPLAN_NF
- □ g. Interactions with ART FPLAN_NG
- □ z. Other, Specify: FPLAN_NZ OTHN_TXT

Form Completed by: FORMBY SIGNED. Date: [___-___-___]

QC/QA: ___________ Data Entry: 1st ___________ 2nd ___________
PAST/CURRENT OBSTETRIC HISTORY

<table>
<thead>
<tr>
<th>Subject ID:</th>
<th>Visit Date:</th>
<th>Visit:</th>
</tr>
</thead>
</table>

### 1. Pregnancy Outcome:
- 1. Live birth
- 2. Abortion
- 3. Stillbirth
- 4. Ongoing

*Note: Subject is excluded from study if pregnant at Visit 1*

If Result is 2. Abortion or 3. Stillbirth for Q1: only respond to Q2.- Q8. for corresponding pregnancy.

### 2. Age at delivery/end of pregnancy:
- [___] years

### 3. Was Mother diagnosed with HIV during this pregnancy?
- 1. Yes*
- 0. No
- 5. NA

*If Yes, when?*
- 1. 1st Trimester (weeks 1-12)
- 2. 2nd Trimester (weeks 13-27)
- 3. 3rd Trimester (week 27+)
- 4. At Delivery

### 4. PMTCT services accessed?
- 1. Yes*
- 0. No

*If Yes, when? (Mark all that apply)*
- a. Before delivery
- b. At time of delivery
- c. Postpartum

### 5. Was ART eligibility evaluation done?
- 1. Yes*
- 0. No
- 7. Unknown

*If Yes, method: (Mark all that apply)*
- a. Clinical (WHO)
- b. Immunological (CD4)
- c. Unknown

### 6. ARV prescribed to mother? (Mark all that apply)
- 0. None
- 5. NA

*Dates of ARTs should be included on Medication Record CRF*
- a. Antepartum AZT
- b. Antepartum Triple ARV prophylaxis
- c. Antepartum HAART
- d. Intrapartum SD NVP
- e. Intrapartum AZT
- f. Intrapartum 3TC

### 7. Was ARV taken by mother as prescribed?
- 0. No, never taken
- 1. Sometimes taken
- 2. Yes, always taken
- NA

### 8. Gestational age at delivery/end of pregnancy:
- [___] weeks

### 9. Delivered by skilled birth attendant?
- 1. Yes
- 0. No

### 10. Place of delivery:
- 1. Home
- 2. Hospital

### 11. Method of delivery:
- 1. Vaginal
- 2. C Section

### 12. Was mother offered ART postpartum?
- 1. Yes*
- 0. No

*If Yes, Duration of post-partum ART?*
- 1. Days
- 2. Weeks
- 3. Months

*If Yes, Was post-partum ART taken as prescribed?*
- 0. No, never taken
- 1. Sometimes taken
- 2. Yes, always taken

### 13. ARV prescribed to child? (Mark all that apply)
- 0. None
- 5. NA

*Specify: OTH13TXT*
- a. SD NVP
- b. Continuous NVP
- c. 3TC
- d. AZT
- e. Triple ARV
- f. Unknown

QC/QA: 
Data Entry: 1st 
2nd 
37
Subject ID: | Visit Date: | Visit:
--- | --- | ---

14. Duration ARV prescribed to child postpartum:  
- 0. Ongoing  
- 1. Days  
- 2. Weeks  
- 3. Months  

15. Was ARV given to child as prescribed?  
- 0. No, never given  
- 1. Sometimes given  
- 2. Yes, always given

16. Was mother counseled on infant/young child feeding?  
- 1. Yes*  
- 0. No

16a. *If Yes, which method was used?  
- 1. Exclusive breastfeeding  
- 2. Exclusive replacement feeding  
- 3. Mixed

17. Duration of breastfeeding?  
- 1. Days  
- 2. Weeks  
- 3. Months  
- 5. NA

18. Current health status of child?  
- 1. Alive and well  
- 2. Alive and chronically ill  
- 3. Deceased  
- 4. Other

19. Result of Child’s HIV tests:

<table>
<thead>
<tr>
<th>Test #1</th>
<th>Test #2</th>
<th>Test #3</th>
<th>Test #4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draw Date</td>
<td>T1_DT</td>
<td>T2_DT</td>
<td>T3_DT</td>
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<tr>
<td>Age</td>
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<td>T2_AGE</td>
<td>T3_AGE</td>
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<tr>
<td>DNA PCR</td>
<td>Results*</td>
<td>Results*</td>
<td>Results*</td>
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<tr>
<td>RDT</td>
<td>Results*</td>
<td>Results*</td>
<td>Results*</td>
</tr>
<tr>
<td>EIA/WB</td>
<td>Results*</td>
<td>Results*</td>
<td>Results*</td>
</tr>
<tr>
<td>Viral Load (RNA PCR)</td>
<td>Results*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

20. Definitive HIV status of child:  
- 0. Negative  
- 1. Positive

20a. *If Positive*, is child on ART?  
- 1. Yes*  

20a1. *If Yes, duration:  
- 1. Weeks  
- 2. Months  
- 3. Years

20a2. **If No, (Mark All that Apply):  
- a. Non-Adherence
- b. Prior ART Toxicity
- z. Other, Specify: OTH20TXT

Form Completed by: FORMBY Signed.

QC/QA: | Data Entry: 1st | 2nd |
--- | --- | ---
### Cervical Cancer Screening

**Subject ID:** | | | | | | | |  
**Visit Date:** | | | | | | | |  
**Visit:** | | | | | | | |  
**Date of Exam:** | | | | | | | |  

1. Abnormal vaginal discharge: **AB_VAGIN**  
   - 1. Yes  
   - 0. No  
2. Heavy menstrual bleeding (more than one pad/hour): **HM_B**  
   - 1. Yes  
   - 0. No  
3. Intermenstrual bleeding: **INTER_B**  
   - 1. Yes  
   - 0. No  
4. Post-coital bleeding: **POST_B**  
   - 1. Yes  
   - 0. No  
5. Pain during sexual intercourse: **PAIN**  
   - 1. Yes  
   - 0. No  
6. Lower abdominal pain not related to menstruation: **LOWPAIN**  
   - 1. Yes  
   - 0. No  
7. External Genitalia: **EXTERG**  
   - 0. Normal  
   - 1. Abnormal  
8. Vagina Wall: **VAGINA**  
   - 0. Normal  
   - 1. Abnormal  
9. Bimanual exam:  
   - 0. Normal  
   - 1. Abnormal*  
   - 6. Not Done  

9a. *If Abnormal, (Mark all that apply)*  
   - a. Adnexal mass: **B_EXAMA**  
   - b. Enlarged uterus: **B_EXAMB**  
   - z. Other abnormality, Specify: **B_EXAMZ OTH_9TXT**  

10. Cervical Exam (VIA/VILI):  
   - 0. Normal  
   - 1. Abnormal*  
   - 6. Not Done  

10a. *If Abnormal, (Mark all that apply)*  
   - a. Acetowhite/yellow lesion  
   - b. Cryotherapy performed: **C_EXAMB**  
   - z. Other abnormality, Specify: **OTH10TXT**  

11. Was the subject referred?  
   - 1. Yes*  
   - 0. No  

11a. *If Yes, why?:  
   - a. Acetowhite/yellow lesion not amenable to cryotherapy  
   - b. Cryotherapy not available: **REF_WHYA - REFWHYC**  
   - c. Findings suspicious of cancer  
   - z. Other, Specify: **REF_WHYZ OT11ATXT**  

11b. *If Yes, outcome of referral:*  
   - Did not see consultant: **REF_NOCON**  
   -  
   - a. LEEP  
   - b. Hysterectomy  
   - c. Observation  
   - d. Biopsy  
   - e. Radiotherapy  
   - f. Cryotherapy  

---

**Form Completed by:** **FORMBY SIGNED.**  
**Date:** | | | | | | | |  
**QC/QA:** | | | | | | | |  
**Data Entry:** 1st | 2nd |
MISSED VISIT

Form to be completed when the allotted visit window has closed.
Use the scheduled visit number for this form.

Visit Window:

Follow the schedule of 180-day study visit windows based on the subject’s enrollment date. Within the visit windows, the range to complete the study visit is 90 days before the scheduled visit date, or within 90 days after. A Missed Visit form must be completed after the visit window has closed. A visit must never be completed less than 90 days since the previous completed study visit. A visit date must be scheduled no less than 90 days, and no more than 180 days, after the previous completed visit.

1. Last Completed Study Visit #: __________  LAST_VIS

2. Date of Last Completed Study Visit :
   __________  LAST_DT

3. Date of most recent subject contact (any contact):
   __________  CONTACDT

4. Reason for missed visit: *(Mark all that apply)*
   - ( ) a. Unknown/Unable to contact  REAS_A
   - ( ) b. Work schedule/conflict  REAS_B
   - ( ) c. Hospitalized or ill  REAS_C
   - ( ) d. Moved out of area  REAS_D  DEATHDT
   - ( ) e. Deceased, Date of Death: __________
   - ( ) f. No longer wishes to participate in study  REAS_F
   - ( ) z. Other, Specify:  REAS_Z  OTH_ZTXT

Form Completed by: ________________  FORMBY  SIGNED.  Date: __________

QC/QA: __________  Data Entry: 1st __________  2nd __________
### Status Change

<table>
<thead>
<tr>
<th>Date of Status Change:</th>
<th>SCDT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Last Protocol Visit:</td>
<td>LASTDT</td>
</tr>
<tr>
<td>Is the subject being terminated from the study?</td>
<td>1. Yes</td>
</tr>
</tbody>
</table>

**Status Change: SCHANGE, SCHANGE.**

1. Transfer to Site - Enter Site Code:
   - [ ] SC_TO
   - [ ] Status Change = 1, 2, or 3

2. Reactivated
   - [ ] RECONDT

3. New HIV Infection → *(If enrolled as HIV Negative, re-enroll subject as HIV Positive)*

4. Subject withdrew consent
5. Lost to Follow-up (no contact attained for 360 days since initial missed visit)
6. Moved out of area - no research contact available
7. Became incarcerated
8. Protocol violation, Specify: ____________
9. Concurrent Illness precludes participation
10. Other, Specify: ____________

**Date of Death:**
- [ ] DEATHDT
- [ ] 10a. Was an autopsy performed? | 1. Yes | 0. No |
- [ ] 10b. Primary cause of death:
  - [ ] 7. Unknown
  - [ ] 1. Known, code: ____________
  - [ ] 2. Known, Other, Specify: ____________
- [ ] 10c. Secondary if any:
  - [ ] 1. Known, code: ____________
  - [ ] 2. Known, Other, Specify: ____________

*Refer to Site Code List; Refer to Diagnosis Code List*

All information entered onto this Case Report Form by myself or my designee for this subject is correct to the best of my knowledge.

**PI Signature:** ____________

**Form Completed by:** ____________

**Date:** ____________
PATHOLOGY

Other Pathology Results (Male and Female)

Date: [___/___/___]  
Specimen Code (refer to Specimen Code List): [___/___]  or, if no code, Other, Specify:  
Diagnosis Code (refer to Diagnosis Code List): [___/___/___]  or, if no code, Other, Specify:  
Results (path report summary): 

PAP Smear Results (Female only)

Date: [___/___/___]  
1. Specimen satisfactory for evaluation?  
   - 1. Yes*  
   - 0. No  
   If No, End Form.  

1a. *If Yes, Negative for intraepithelial lesion or malignancy?  
   - 1. Yes  
   - 0. No**  

1a1. Mark all that apply:  
   - a. Trichomonas vaginalis  
   - b. Fungal organisms consistent with Candida  
   - c. Shift in flora suggestive of bacterial vaginosis  
   - None  

1a2. **If No (Mark a. Squamous Cell, b. Glandular Cell, and/or c. Other abnormalities as applicable):  

   a. Squamous Cell: SQUAMCEL SQUAMCEL.  
      - 1. Atypical squamous cells of undetermined significance (ASCUS)  
      - 2. Atypical squamous cells cannot exclude HSIL (ASCH)  
      - 3. Low grade squamous intraepithelial lesion (LSIL) – encompassing HPV/mild dysplasia/ cervical intraepithelial neoplasia (CIN 1)  
      - 4. High grade squamous intraepithelial lesion (HSIL) – encompassing moderate and severe dysplasia, carcinoma in situ (CIN 2 and CIN 3)  
      - 5. Squamous cell carcinoma  
      - 0. No squamous cell abnormality  

   b. Glandular Cell: GLANDCEL GLANDCEL.  
      - 1. Atypical glandular cells (AGC)  
      - 2. Atypical glandular cells, favor neoplastic  
      - 3. Endocervical adenocarcinoma in situ (AIS)  
      - 4. Adenocarcinoma  
      - 0. No glandular cell abnormality  

   c. Other abnormality (Mark all that apply):  
      - a. Endometrial cells in a woman ≥40 years of age  
      - z. Other, Specify:  
      - OTHABN_A  
      - OTHABN_Z  
      - 0. No other abnormality NOOTHAB  

Form Completed by: FORMBY SIGNED.  
Date: [___/___/___]  
QC/QA: __________  
Data Entry: 1st __________  2nd __________
RV329 - AFRICOS CRFs

ANNOTATION KEY

SAS VARIABLE/SAS DATA SET LABELS IN BLUE
IE – SUBJID/R_SYMPT

CLINPLUS FORMAT LABELS/CLINPLUS SCREEN LABELS IN RED
IE – YESNO/R_SYMPT2. IF HIGHLIGHTED IN PURPLE, REFERS TO STUDY CODE LIST
WHICH HAS BEEN INTEGRATED INTO CLINPLUS AS A FORMAT.
CHECKBOX VARIABLES, IE, IND_A, HAVE THE DEFAULT CHECKBOX.
FORMAT AND THEREFORE ARE NOT INDIVIDUALLY ANNOTATED.
FORMS ANNOTATED AS “SEQUENCED” IN RED INDICATE ONE FORM
ACCOMMODATES MULTIPLE RECORDS IN CLINPLUS, IE, WHO CLASS.

CLINPLUS/SAS VARIABLES ASSOCIATED STUDY CODES WHICH ARE NOT
CLINPLUS-FORMATTED ARE NOTED WITH *

REFER TO CLINPLUS DATA STRUCTURE DOCUMENTATION FOR DETAILS ON
CLINPLUS/SAS VARIABLES

REFER TO THE FORMAT SAS SCRIPT FOR DETAILS ON FORMATS

REFER TO THE STUDY CODES DOCUMENT FOR DETAILS ON STUDY CODE LISTS
Version History

Changes made in version 1.7
Q2 Creatinine – added CRET_LGE (< = >) and format LESEQGR.
Q12 Total Bilirubin – added format LESEQGR.

Changes made in version 1.6
CRF OBX_HX1
Q7 – Added option NA to format NSY in field TAKE_PRE (9/23/2013)

Changes made in version 1.5 (30OCT2013)
CRF OBX_HX1
Q5a – Added METH_TXT comment field for ART eligibility evaluation method comment
Q6 – Added PRES_TXT free text field for prescribed ARV comment

Changes made in version 1.4 (13SEP2013)

OBS_HX1
Q12a changed format from DWM to ODWM for added option ONGOING

Changes made in version 1.3 (12Aug2013)

Extract
Added following variable to Q12_VLDT_E-J/VLCD4_E-J/VLCD4P_E-J/
VL_LGE_E-J/VLCOPY_E-J/RESDN_E-J

Blood Chemistry
Added-Labcd2-7,Labcd8-13,Labcd14-17,Tbil_lge,Labcd20-27

Serology
Added-LABCD1-18

HIV Status
Q2e – added variable ELIG_D for option d. Plan B+

Changes made in version 1.2 (18Jul2013)

OBS_HX2
Q20 – changed format from NEGPOSNK to NEGPOSNU for added option NA
Changes made in version 1.1 (01Jul2013)

OBS_HX1:
Q3 – changed format from YESNONA to YNONANK for added option UNKNOWN
Q4 – changed format from YESNONA to YNONANK for added options NA, UNKNOWN
Q5 – changed format from YESNONK to YNONANK for added options NA
Q6 – added option UNKNOWN to format NONENA
Q12 – changed format from YESNO to YNONANK for added options NA, UNKNOWN,
Q13 - added UNKNOWN to format CHD_ARV

OBS_HX2:
Q16 – changed format from YESNO to YNONANK for added options NA, UNKNOWN
Q17 - added option ONGOING to format DWMNA
Q18 - added option UNKNOWN to format CHD_STAT
Q20a – changed format from YESNO to YNONANK for added option UNKNOWN,

EXTRACT:
Q12a, b, c, d – (VLCOPY_A, VLCOPY_B, VLCOPY_C, VLCOPY_D) added format FIELD_DA for none numerical responses.