MTN-016 TRAINING
Infant HIV Testing

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An infant should be tested for HIV infection in MTN-016...

- If the infant’s mother:
  - Is known to be HIV-infected
  - Is newly diagnosed with HIV infection
  - Is HIV infected and breastfeeding
  - Requests it

- If there is suspected exposure to HIV
WHEN can an infant be tested for HIV infection in MTN-016?

- At a scheduled visit
  - Month 1
  - Month 6
  - Month 12

- At an interim visit
  - 6 weeks
  - 6 months + 2 weeks
  - 12 months + 2 weeks

Refer to the “Flow Chart for Testing HIV Exposed Infant within MTN-016”

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Testing HIV Exposed Infant within MTN-016

START
- Month 3 Visit
  - HIV DNA/RNA Negative
  - 5-6 weeks, initial visit in 2 weeks

Month 6 Visit: Exposed
- If infant has remained in hospital, repeat DNA/RNA PCR and schedule visit in 2 weeks

Month 6 Visit: Infected
- Collect specimen for RNA PCR and resistance
- Refer to local care and treatment program
- Schedule Month 12 visit

Month 12 Visit: Infected
- Collect specimen for RNA PCR and resistance
- Refer to local care and treatment program

Month 12 Visit: Exposed
- If infant has remained in hospital, repeat DNA/RNA PCR and schedule visit in 2 weeks

Month 12 + 2 Weeks
- If infant has not been transferred to hospital and is negative
- If infant has been transferred to hospital and is positive
- Schedule visit in 2 weeks

RNA >400 copies/ml HIV infection CONFIRMED
HOW should an infant be tested for HIV infection in MTN-016?

- DNA PCR
- RNA PCR

Do not use:
- HIV Rapid Test
- HIV Western Blot

Refer to the “Algorithmn for Infant HIV Testing”

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Algorithm for Infant HIV Testing

START
Sample 1 DNA PCR (cell pellet)

Negative

Positive

Sample 1 RNA PCR (plasma)

<400 copies

≥400 copies

Sample 2 RNA PCR
Confirmatory and resistance testing

<400 copies

≥400 copies

Infant is HIV infected. Schedule for counseling

STOP
If baby has continued exposure, redraw at a later date

Notify MTN NL

Notify MTN NL
Why are there different HIV tests for infants?

- **ANTIBODY TESTS**

  Rapid Tests and Western Blots
  - Used for HIV testing in children (over 18 months of age) and adults
  - Antibody based - tests look for the body’s reaction to the virus
  - Infants still have their mother’s antibodies
  - All HIV-exposed infants will be “positive” on antibody tests.
Why are there different HIV tests for infants?

- **NUCLEIC ACID TESTS**
  - DNA PCR and RNA PCR
    - For infants up to 18 months of age
    - Must look for the virus itself
    - **DNA PCR** – Tests for presence of HIV genetic sequence in cells
    - **RNA PCR** – measures how much virus is in the blood (viral load)
What other tests will be done for an HIV-positive infant?

- Standard genotypic resistance testing
- Sensitive resistance testing to identify any mutations that are not detected by standard testing

Why check for drug resistance?

Mother may have been exposed to ARV through study product or PMTCT when giving birth.
Coordinating mother and baby study visits if both are positive

If mother is...

- Not enrolled in MTN-015
  - If eligible → offer enrollment
  - If not eligible → test baby as scheduled

- Is enrolled in MTN-015
  - Try to schedule mother and baby at the same time if feasible
  - Will be helpful for monitoring drug resistance