MTN-016 TRAINING Infant HIV Testing

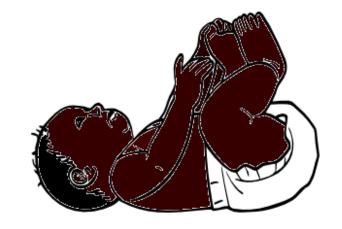
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An infant should be tested for HIV infection in MTN-016...

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?

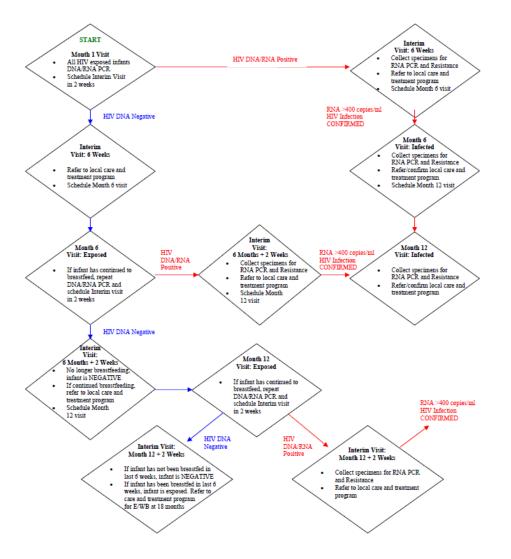
At a scheduled visit

- 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"

> MTN-016 SSP Appendix 12-3 Page 12-12

Testing HIV Exposed Infant within MTN-016



HOW should an infant be tested for HIV infection in MTN-016?

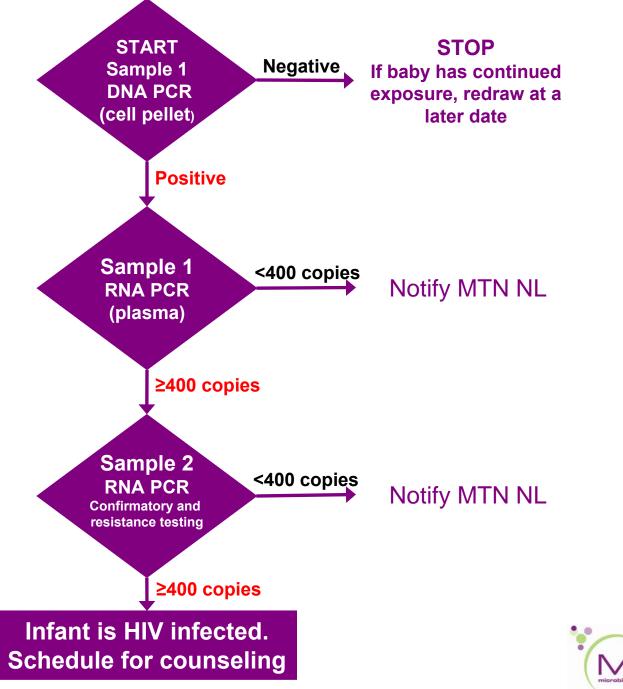
DNA PCRRNA PCR

Do not use:HIV Rapid TestHIV Western Blot

Refer to the "Algorithmn for Infant HIV Testing"

> MTN-016 SSP Appendix 12-2 Page 12-11

Algorithm for Infant HIV Testing



Why are there different HIV tests for infants?

ANTIBODY TESTS

Rapid Tests and Western Blots

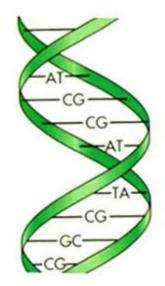
- Used for HIV testing in children (over 18 months of age) and adults
- Antibody based tests look for the body's reaction to the virus
- Infants still have their mother's antibodies
- All HIV-exposed infants will be "positive" on antibody tests.



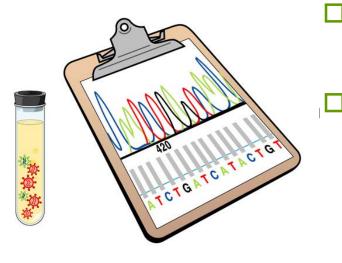
Why are there different HIV tests for infants?

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 \rightarrow offer enrollment
- If not eligible \rightarrow 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