



MTN HIV TESTING ALGORITHMS

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Outline

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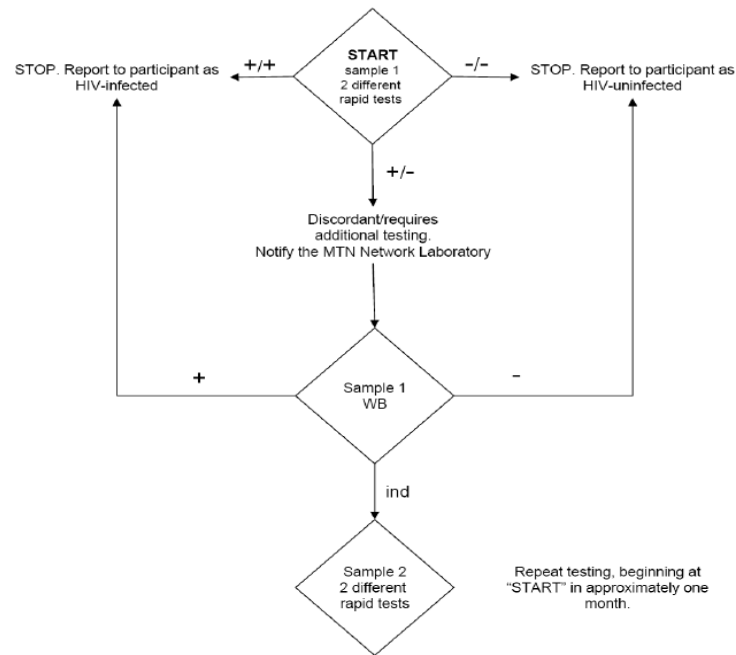
Definition: HIV Algorithm

- Steps followed to come up with a laboratory HIV diagnosis

HIV Testing Methods

- Antibody Methods
 - Rapids (*MTN*)
 - Western* Blot (WB) (*MTN*)
 - ELISA
- Antigen Method
 - P24
- HIV PCR
 - Viral Load (HIV RNA) (*MTN*)
 - HIV DNA (*MTN*)

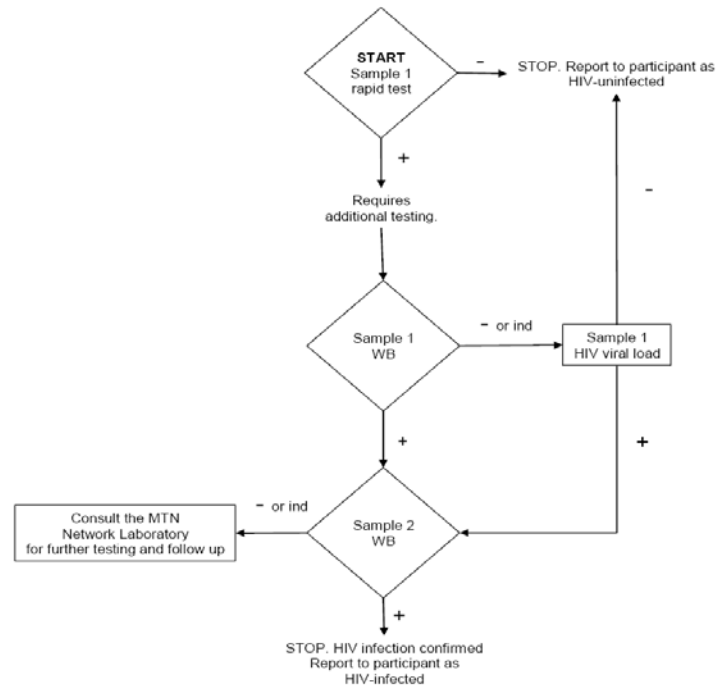
MTN 003 : Screening



Interpretation

- Starts with 2 different rapids
 - Both negative: HIV Uninfected/Eligible
 - Both positive: HIV infected/Excluded
 - Discordant: Proceed to WB/Notify NL
- Further tests done on indeterminate results with NL notification
- Process re-started after a month if WB is inconclusive

Follow Up and Primary Endpoint



Interpretation

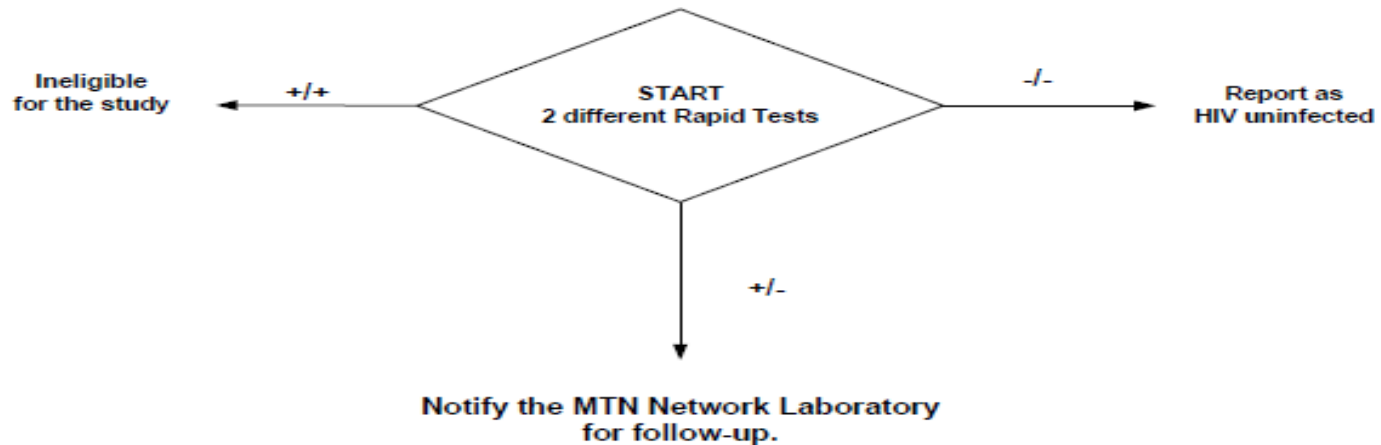
- Starts with 1 rapid (2 if required by local regulations)
 - Negative result :HIV uninfected
 - Positive: Proceed to WB (Sample 1)
- WB is negative or indeterminate:
 - Consult NL
 - Perform VL
 - VL negative: restart algorithm next visit
 - VL positive: Continue to sample 2

Interpretation

- Sample 2 WB:
 - Positive: Algorithm complete at site level. Plasma sent to NL for third confirmatory WB
 - Negative or Indeterminate (Rare): Consult the NL
- Don't forget to collect CD4, VL and Plasma Archive with Sample 2 WB draw

MTN 018

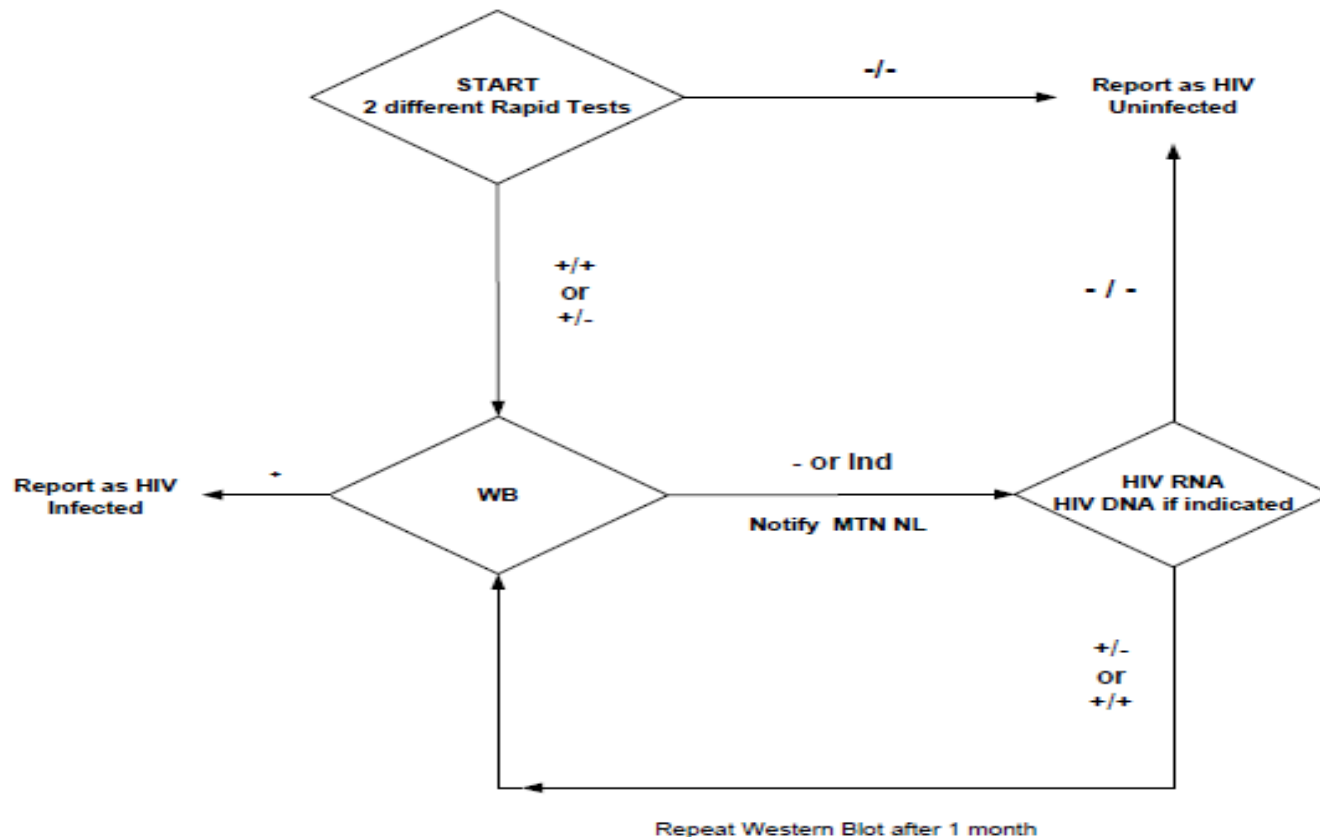
Screening & Enrolment



Interpretation

- Starts with 2 different rapids
 - Two positives: infected/excluded
 - Two Negatives: not infected/eligible
 - Discordant: notify NL/excluded

MTN 018: Follow-Up and Primary Endpoint Determination



Interpretation

- Starts with 2 rapids (All sites)
 - Both Negative: Uninfected
 - Both Positive: Proceed to WB, (CD4, VL, Archive)
 - Discordant: Proceed to WB, (CD4, VL, Archive)
- WB:
 - Positive: Site testing complete
 - Negative or indeterminate: HIV RNA testing and DNA if indicated. Notify NL

Interpretation

- RNA (and DNA if indicated) negative: Restart algorithm
- RNA (or DNA if indicated) positive: Repeat WB in one month

Advantages

- Advantages
 - Easier counselling messages
 - Less visits and blood draws for participants
 - Less burden on site staff/ less need for communications with NL
 - Better capture of endpoints for protocol purposes
 - Collects sample closer to seroconversion for resistance testing

Disadvantages

- Disadvantages
 - Does not have second confirmation sample drawn on different day to check for potential labelling errors. Rapid HIV tests and WB samples must be from separate collections on the same day.
 - May have few CD4/plasma archive samples processed that are not needed

Conclusion

- Important to differentiate these two: 'consult' VS 'notify'
- Captures all possible outcomes from rapids