MTN-020 Algorithm

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MTN Network Lab

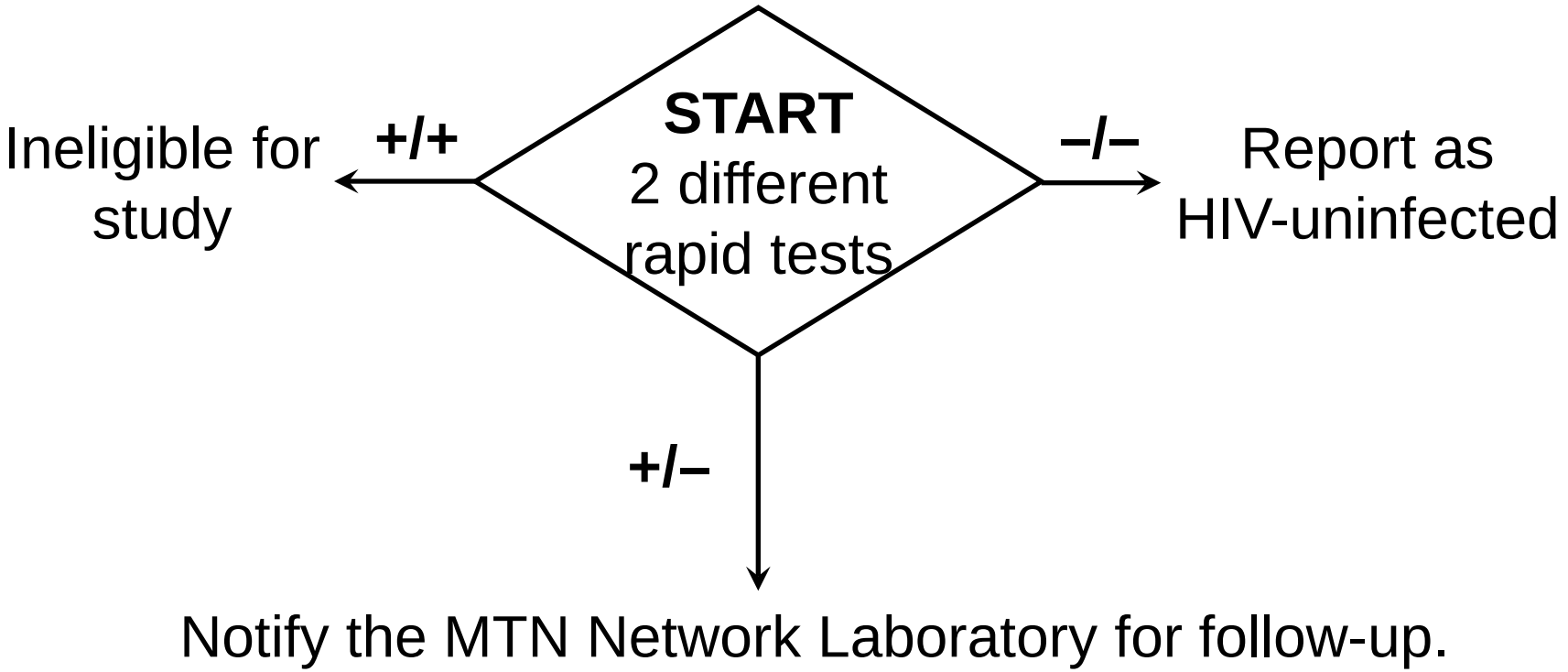
Regional Meeting 2012

Cape Town

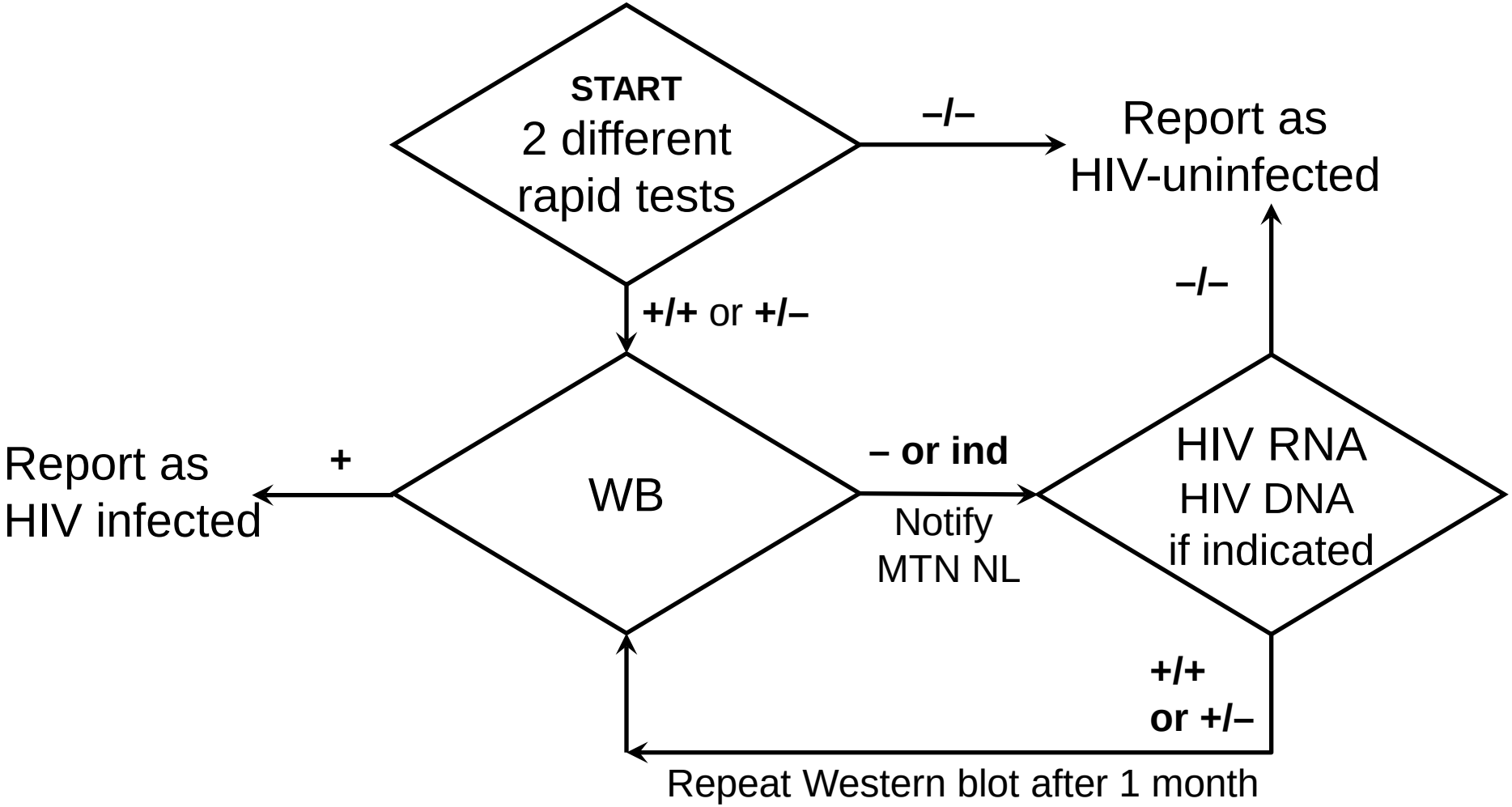
MTN-020

- Review of MTN-020 Algorithm
- Case Scenarios
  - Discordant Rapids at Screening
  - Unusual Result Pattern at Follow-Up
  - HIV Positive at Quarterly Visit
- Lessons Learned from VOICE

MTN-020 Screening



MTN-020 Follow-Up/Endpoint



Case 1

- A screening participant has these results:

- **What is her HIV status?**
- **Should she be enrolled?**
- **What should be done next?**

Case 2

- Participant B had the following test results at visit 7.0:
  - Two positive rapid tests
  - Indeterminate WB
  - Undetectable HIV RNA

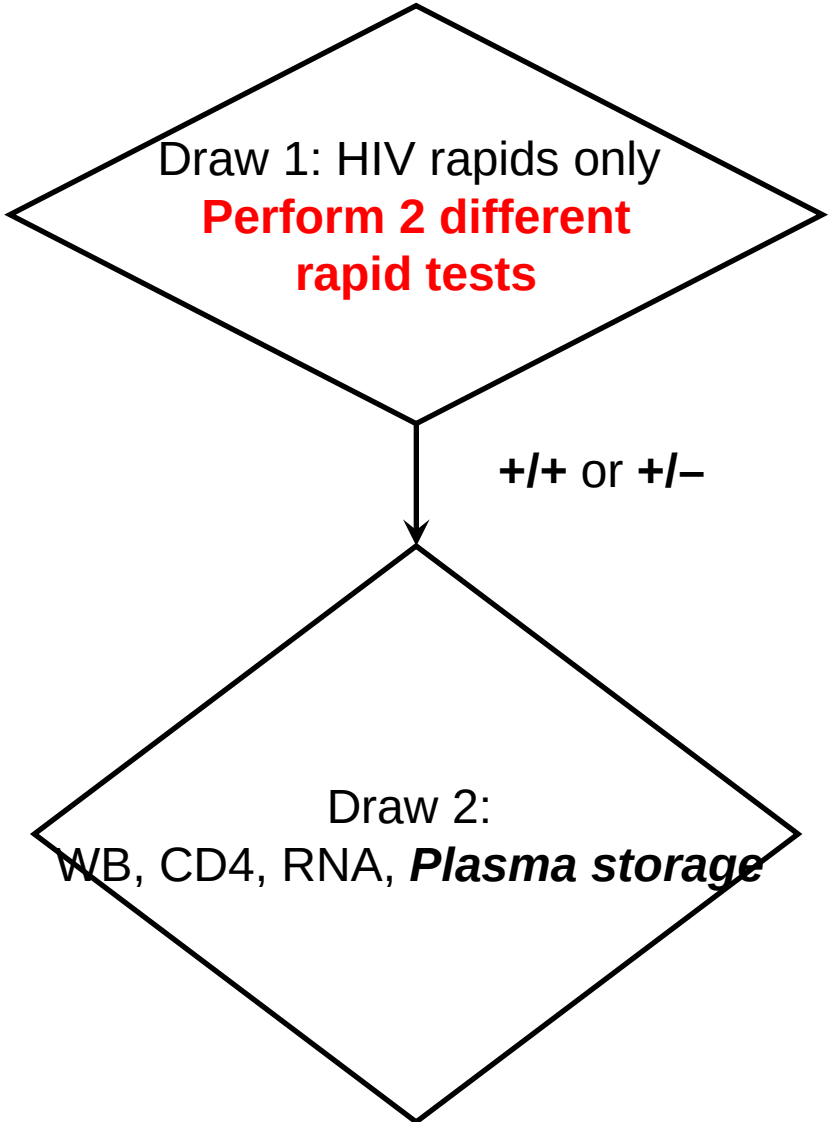
What is her HIV status?
What should be done next?
What results are needed to resume study product?

Case 3

- Participant C had two positive rapids at visit 6.0 (quarterly visit).
  - **Scenario 1:** The rapids were done by fingerstick.
  - **Scenario 2:** The rapids were done by venipuncture.

How much blood should be drawn next?
What will the blood be used for?

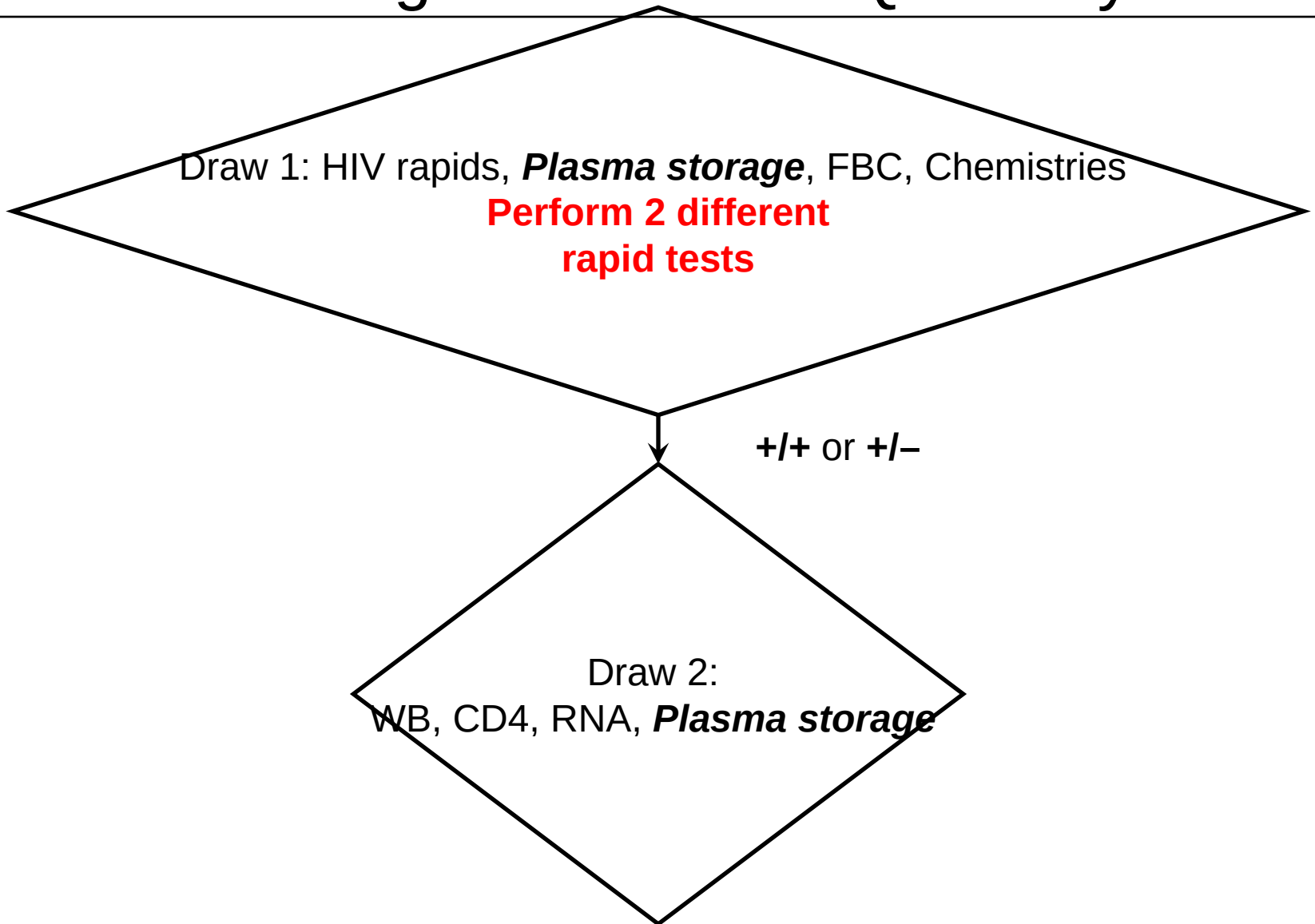
Plasma Storage Scenario 1: Monthly Visit



Plasma Storage Scenario 1: Monthly Visit

- Simple Situation logistically
- Draw enough whole blood with second draw to store 6 mL of plasma
- Plasma is marked with code “CON” in LDMS

Plasma Storage Scenario 2: Quarterly Visit



Plasma Storage Scenario 2: Quarterly Visit

- Situation less simple
- Routine plasma storage minimum is 4 mL
- HIV algorithm confirmation plasma storage minimum is 6 mL
- Routine plasma is marked with code “RPS” in LDMS
- Confirmation Plasma is marked with code “CON” in LDMS

Plasma Storage Scenario 2: Quarterly Visit

- Current Guidance
  - SSP states that no more than 6 mL plasma needs to be stored at a visit
  - NL had told MRC they can collect enough additional plasma with second draw to meet 6 mL minimum
  - No specifications about handling plasma storage codes (RPS/CON) when routine and confirmation plasma storage needed at same visit

Plasma Storage Scenario 2: Quarterly Visit

- Proposed operational improvements:
  - Change guidance so that when routine and confirmation plasma storage needed at same visit, 6 additional mL of plasma are stored from the second draw
  - Minimum 4 mL would be stored from the first draw and marked as “RPS” in LDMS
  - Minimum 6 mL would be stored from the second draw and marked as “CON” in LDMS
  - Total minimum stored would be 10 mL

Plasma Storage Scenario 2: Quarterly Visit

- Proposed operational improvements:
  - Benefits
    - Plasma tested at NL would be same plasma used for WB at the site.
    - Would standardize and simplify HIV algorithm plasma storage draws between visit types.
    - There would be additional plasma available at visits where there are positive rapids which are of greater scientific interest.
    - Reduces chances that plasma storage would be completely missed at a visit with positive rapids.

Plasma Storage Scenario 2: Quarterly Visit

- Questions for sites
  - Would this present challenges for sites to track two plasma storages separately from the same visit (CRF, specimen labeling, requisition forms/LDMS tracking sheets/ LDMS storage)?
  - Informed consent blood volumes?
  - Any additional concerns for sites performing fingerstick HIV rapids?

Lessons Learned from VOICE

- Lesson 1: Staff collecting specimens must review frequently the algorithm, related sample collections and procedures.

Lessons Learned from VOICE

- Lesson 2: Have reference materials available where specimens are collected. **SOP's** Cheat sheets, checklists etc…

Lessons Learned from VOICE

- Lesson 3 : Labs need to closely oversee kit inventories.

Lessons Learned from VOICE

- Lesson 4: Communications are key. Sites clinics and labs should meet periodically and speak frequently. The NL will strive to improve communications with the sites.

Lessons Learned from VOICE

- Lesson 5: Rapid HIV tests. Simple? Not so simple!
  - Do not become complacent with the little details.
    - Timers
    - Supply set up
    - Weak bands
  - Documentation requirements are challenging.
  - Provide frequent and comprehensive oversight