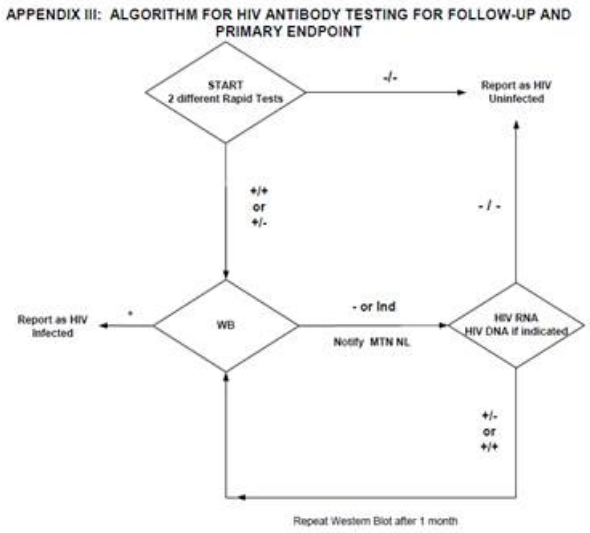
Scenario 4

An MTN-020 participant came in for her month 14 visit and had the following results:

Visit 14.0
Rapid Test 1: NEGATIVE
Rapid Test 2: POSITIVE (very faint band)
Western Blot: NEGATIVE
HIV RNA: 85 copies/mL

The participant came back in 1 month for her repeat Western blot. The site went through the algorithm again and got the following results:



Visit 15.0
Rapid Test 1: NEGATIVE
Rapid Test 2: NEGATIVE
Western blot: NEGATIVE
HIV RNA: Target Not Detected

The site used stored plasma from visit 14.0 and repeated the viral load. The new result for visit 14.0 was "target not detected". When they went back and investigated the run sheet from the original viral load, they found that the negative control had failed.

Focused Questions

- **What is the consequence of the false positive viral load result at visit 14.0?**
- **What are all of the errors that occurred in this situation?**
- **How can these errors be prevented in the future?**

Talking Points

- The participant was misdiagnosed as HIV infected.
- The diagnosis was based on a detectable viral load result that could not be reproduced.
- Areas of investigation:
  Failed negative control and false positive sample result
  - Examine possible sources of contamination (for example, by performing an environmental scan where various areas of the lab are swabbed and run on the Abbott m2000)
  - Examine lab practices (changing gloves between work areas, maintaining PCR "clean" and "dirty" spaces)
  - Rule out sample mix-ups
  - Make sure machine maintenance is up to date

  Reporting out a result from a failed run
  - Examine result review practices