ASPIRE Lab Highlights

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Terminology: the term “archive” will now refer only to plasma storage at enrollment for endpoint determination.

Plasma aliquots must now be 1 mL. In VOICE, they had flexibility on aliquot size.

We will now be tracking the purpose of the stored plasma on the CRF and in LDMS. This is to facilitate shipping.
HIV algorithm

- WB bands on CRF
- No more Sample 2
APPENDIX III: ALGORITHM FOR HIV ANTIBODY TESTING FOR FOLLOW-UP AND PRIMARY ENDPOINT

START
2 different Rapid Tests

+/+
OR
+/-

Report as HIV Infected

-/-

WB

- or Ind

- / -

HIV RNA
HIV DNA if indicated

+/-
OR
+/+

Notify MTN NL

Repeat Western Blot after 1 month

Ind: indeterminate test results
Pelvic Tests

- No BV Blue Test
- Back to Standard Wet Mount
- Possibly 2 ways to ID trich-will be accounted for on CRF
- Order of collection of pelvic swabs to be a point of emphasis in training.
Random

- Herpes lesion testing
- Pap Smears
- Fingerstick testing
  - Not a study requirement but may be advantageous for monthly visits-home based testing.
  - Do I need a validation study?
Thank You - Questions?

What the heck was he saying????