

ASPIRE Lab Highlights

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Plasma storage

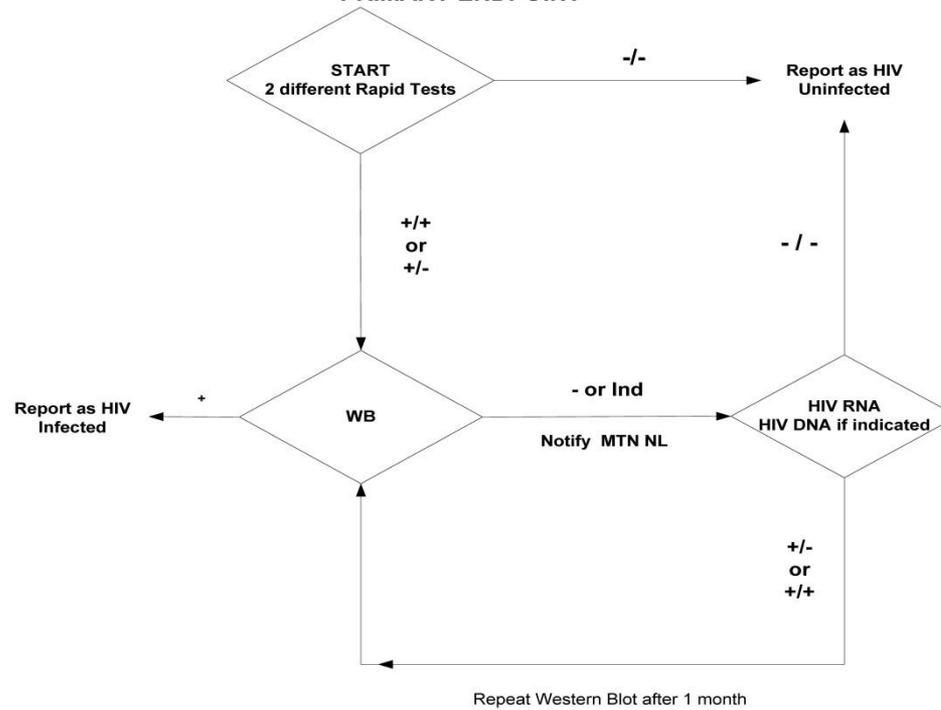
- Terminology: the term “archive” will now refer only to plasma storage at enrollment for endpoint determination.
- Plasma aliquots must now be 1 mL. In VOICE, they had flexibility on aliquot size.
- We will now be tracking the purpose of the stored plasma on the CRF and in LDMS. This is to facilitate shipping.

HIV algorithm

- WB bands on CRF
- No more Sample 2

HIV algorithm

APPENDIX III: ALGORITHM FOR HIV ANTIBODY TESTING FOR FOLLOW-UP AND PRIMARY ENDPOINT



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????

