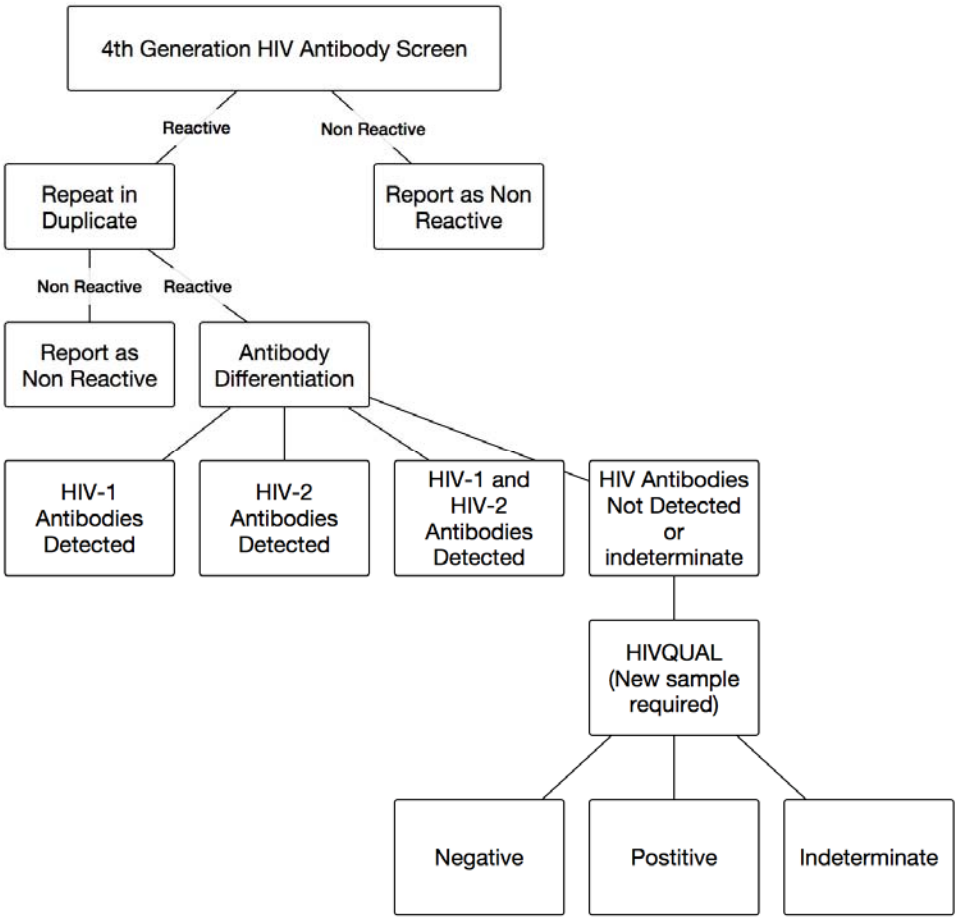
ProvLab HIV Diagnostic Algorithm:



New to the HIV Diagnostic Algorithm:

- Western blot confirmation will be replaced by the Geenius™ HIV-1/2 Antibody Differentiation Assay
- All indeterminate and negative Antibody Differentiation tests will be confirmed with **HIVQUAL**
  - ***A new EDTA sample is required for HIVQUAL assay***
- HIVQUAL has been validated by ProvLab for use in diagnostics of HIV, and will give a positive, negative or indeterminate result.
- Follow up EDTA samples for HIVQUAL:
  - ProvLab has implemented an active reminder to physicians that will be triggered when samples for HIVQUAL exceed 10 days.

Testing Guidelines:

- All first and second time positive samples will be confirmed by Antibody Differentiation
- Samples testing positive ≥3 times will not be reconfirmed
  - These patients should be monitored via HIV viral load testing

Special Populations:

1. ***Infants Born to HIV Positive Mothers:***
   a. Proviral DNA and HIVQUAL should be used for detection of active infection
   b. Antibody detection will represent maternal antibodies, and therefore serology cannot be used for HIV diagnosis in infants <18 months of age

2. ***Investigation of Elite Suppressor Status:***
   a. Patients who are repeatedly reactive by serology, but have never had a positive result by a molecular assay, and who are not on treatment, should be investigated as a possible elite suppressor.
   b. If the initial viral load is found to be <40 copies/ml, the viral load should be repeated before initiating any treatment, and a second viral load should be obtained within approximately 3 months of the first.
      i. If both viral loads are undetectable, this should trigger communication with a laboratory virologist to review the serologic results and initiate further laboratory testing, which would likely include Proviral DNA.
   c. The laboratory itself cannot reliably identify these patients, as treatment information is either unavailable, or incomplete. Therefore, the physician should trigger consultation with the laboratory for further follow-up of these patients.