

HIV TESTING ALGORITHMS

A STATUS REPORT

KEY DATA NEEDS

<http://www.aphl.org/hiv/statusreport>

- Data for sequences of two or three different POC rapid tests performed prospectively in both high and low HIV prevalence settings
- False-negative result rates for different rapid tests used as the initial screening test in POC settings
- For discordant POC rapid test results (first test on oral fluid, second on blood), comparison data for repeating the first test on blood versus using a third (different) rapid test (see POC algorithm 3 and other algorithm schematics at <http://www.aphl.org/hiv/statusreport>)
- Data and/or modifications to Laboratory Algorithm 3 (Dual Immunoassay Algorithm) are needed to advance the “presumptive positive” interpretation of concordant results to a more definitive laboratory-based positive result. Will S/CO values for both the primary and secondary tests, if applicable, provide information to improve interpretation of Laboratory Algorithms 1-3?
- Data on the use of antigen-antibody detection (fourth generation) assays in Laboratory Algorithm 3 (Dual Immunoassay Algorithm)
- Number and percentage of primary test=repeat-reactive/secondary test=negative results in HIV-infected and uninfected patients using Laboratory Algorithm 3 (Dual Immunoassay Algorithm). Also, the number and percentage of primary test=positive/secondary test=positive results in HIV-uninfected patients
- Data to evaluate NAAT as a supplemental test including data comparing HIV-1 RNA or DNA tests (FDA licensed and unlicensed) with supplemental antibody tests, with follow-up for seroconversion
- Analytic and clinical sensitivity of pooled NAAT for various size pools, including threshold pool sizes for detection of HIV-1
- Performance of individual and pooled NAAT on serum vs. plasma specimens
- Number and percentage of specimens from persons truly infected with HIV-2 (diagnosed by medical evaluation and follow-up or by HIV-2 DNA sequence analysis) that are reactive on an HIV-1/2 antibody screening test, but false-negative on an HIV-1/2 discriminatory assay or HIV-2 only EIA