

Alternative Confirmatory Testing Strategy Using Rapid HIV Assays

<i>Abstract Category:</i>	Point of Care Algorithms Using Combinations of Rapid Tests
<i>Primary Author:</i>	Niel Constantine
<i>Affiliation:</i>	Institute of Human Virology, University of Maryland School of Medicine, Baltimore, MD
<i>Co-Authors:</i>	T. Croxton, M. Charurat, P. Villalba-Diebold, A. Abimiku, WA. Blattner

OBJECTIVE

Because alternative HIV testing strategies can offer advantages, particularly for point of care testing, there is a need (1) to determine the confirmatory rate of samples testing positive by two rapid tests, and (2) to determine the concordance of results and ability of a 3-test rapid testing algorithm to confirm results.

METHODS

To determine the confirmatory rate for samples testing positive by both the Determine and Stat-Pak rapid HIV tests used in a parallel algorithm, 151 samples from the Recruiting Acute Cases of HIV study (REACH) in Nigeria were further tested by the Genetic Systems HIV-1/HIV-2 Plus EIA and the BioRad HIV-1 Western blot (WB). For evaluating the concordance of results using a 3 rapid test strategy, 9,176 samples from the REACH study were tested by the Determine (D) and Stat-Pak (S), but if discordant results were obtained, the Genie II (G) rapid HIV test was used (a small percent were tested by a different 3-rapid test algorithm); all samples producing discordant results between the tests were tested by WB for resolution. Concordance of the results was calculated using percent agreement between paired results.

RESULTS

For the confirmatory rate determination of the 2 test algorithm, all 151 samples that were positive by both rapid tests were positive by the EIA and were confirmed as positive by WB, yielding a confirmatory rate of 100%. In the 3-test strategy, 1,539 samples were positive by the first two tests, yielding a concordant prevalence rate of 16.8%. The percent agreement between the Determine and Stat-Pak was 96.5%. There were 323 (3.5%) samples that produced discordant results (319 D+/S- and 4 D-/S+), with 12 of 229 (5.2%) being positive by the 3rd rapid test (G). Testing by Western blot on the discordant samples indicated a false positive rate of 90.0% and 20.0% for the Determine and Stat-Pak, respectively. Of the 12 discordant samples that were positive by the 3rd rapid test (positive by 2/3 rapid tests), 10 (83.3%) were confirmed by WB.

CONCLUSIONS

The Determine and Stat-Pak HIV parallel rapid test alternative algorithm produced no false positives when both tests produced positive results, indicating a specificity of 100%. In a 3-test alternative testing strategy, there was a high concordance of results with the first two tests, and when results were discordant, a positive result by the third test was most often found to be confirmed positive.