

Performance of a “Rapid Results” 4th Generation Immunoassay Algorithm

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Objective: Several automated analysers can deliver 4th generation HIV immunoassay (4GIA) results within a few hours of specimen draw. We report a prospective trial of rapid testing for acute and chronic HIV infection using an all rapid results algorithm.

Methods: AMPLIAR Protocol 010 was a cross sectional study of HIV diagnostic testing, with a longitudinal component to follow patients with discrepant results to confirm HIV seroconversion and HIV status. Between 2007 and 2010, clients requesting HIV tests at 4 voluntary testing centers in South Brazil were enrolled. Site laboratories each performed 4GIA screening with confirmation by 3GIA and IFA/WB. Blood samples were obtained for pooled RNA (bDNA, 1:20), confirmatory testing as needed and BED-CEIA analysis. Beginning in 2009, samples were immediately tested using the VIDAS Duo Ultra 4GIA, Determine HIV 1/2 Ab rapid test and DPP HIV-1/2 Confirmatory Immunoblot rapid test. We evaluated performance of a serial rapid results algorithm (rapid 4GIA reflexed to Ab rapid test +/- confirmatory assay if 4GIA result is positive); a parallel algorithm (rapid 4GIA and Ab rapid test performed simultaneously, reflexed to confirmatory assay if either is positive); and standard batched 4GIA and pooled RNA-based algorithms.

Results: 3,617 subjects were studied; of those 521 were confirmed HIV+ (HIV prevalence: 14.4%). A subset of 1,829 (296 HIV+) subjects were tested with the all-rapid-results algorithm. With a pooled RNA/Ab algorithm as a reference standard we observed the following performance characteristics: 1. Algorithm: 4GIA-rapid (parallel,) Turnaround: 2.5 hours, Se of algorithm: 100.0 (98.8,100), Sp of initial screening test(s): 99.0 (98.4,99.4) 2. Algorithm: 4GIA-rapid (serial), Turnaround: 3.5 hours, Se of algorithm: 98.9 (97.1,99.6), Sp of initial screening test(s): 99.3 (98.8,99.6) 3. Algorithm: 4GIA-standard (serial), Turnaround: 1-3 weeks, Se of algorithm: 99.0 (97.8,99.6), Sp of initial screening test(s): 99.3 (98.9,99.5) 4. Algorithm: Rapid Ab only, Turnaround: 1.0 hour, Se of algorithm: 98.4 (97.0, 99.2), Se of initial screening test(s): 99.8 (99.6,99.9)

Conclusions: Rapid results from an automated 4G assay analyser provided similar sensitivity and specificity to batched 4G testing. We found furthermore that an algorithm with parallel rapid 4G/rapid Ab screening as the first step in the algorithm significantly reduced the time to final result, when compared to an algorithm with sequential rapid 4G screening and rapid Ab testing as the first steps. Parallel rapid 4G/rapid Ab testing also increased sensitivity. The parallel rapid test approach may be preferred when turnaround time is critical.