

Evaluation of an alternate HIV confirmatory testing algorithm

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Background: The current algorithm for anti-HIV-1/2 repeat reactive (RR) samples requires reflex to HIV-1 western blot (WB) and HIV-2 EIA. For HIV-1, less than 10% of the current anti-HIV RR donations confirm positive using this algorithm. An alternate algorithm was evaluated in which a second manufacturer's (mfg) EIA is run and only concordant RRs are further evaluated by WB. The inclusion of HIV nucleic acid testing (NAT) in routine screening allows the algorithm to be evaluated against RNA results (considered the gold standard).

Methods: Two subsets of HIV-1/2 RR samples were evaluated from two blood centers (BC1 and BC2) from 1/1/00-3/31/02. BC1 screened with Genetic Systems' pEIA (mfg1) with 1657 HIV RR; in this study these samples were evaluated with the Abbott rDNA EIA (mfg2). BC2 screened with mfg2 with 6227 HIV RR samples; in this study these samples were evaluated with mfg1. The 1657 RR on mfg1 had been tested by WB (Bio-Rad); the 6227 RR on mfg 2 had been tested by WB (Calypte). The results of WB and primary/alternate EIA results were compared to the NAT screening results. Both BCs used Chiron Procleix HIV-1/HCV NAT in pools of 16 for NAT screening; NAT-reactive pools were resolved to individual donation.

Results:

BC1 (mfg1)	No. mfg2 RR	No. NAT Pos
No. WB Pos 80 (5%)	80 (100%)	79
WB Ind 544 (33%)	31 (6%)	0
WB Neg 1033 (62%)	49 (5%)	0
BC2 (mfg2)	No. mfg1 RR	No. NAT Pos
No. WB Pos 266 (4%)	250 (94%)	237
WB Ind 2890 (46%)	16 (0.6%)	1
WB Neg 3071 (49%)	13 (0.4%)	0

The 1/80 NAT neg sample from BC1 was strongly RR on both EIAs and strongly WB pos. Of the 266 WB pos from BC2, the 16 mfg1 neg samples were all NAT neg, and with the exception of two, had weak mfg2 EIA signals and weak WB results. The two remaining samples of the 16 were retested by NAT individually by two different mfg's tests and were NAT neg on both. Therefore, all 16 WB pos, EIA discordants appear to be WB false pos donations. An additional 13 EIA concordant RR samples (WB pos) at BC2 were NAT neg in pools and when tested individually. Of the total 266 WB pos samples at BC2, 29 (16+13) were NAT neg.

Conclusions: Using NAT as the gold standard, the sensitivity of the HIV dual EIA algorithm is 100% (317/317), (95% CI 98.84-100%) and specificity is 98.4% (7447/7567), (95% CI 98.11-98.68%). The number and percentage of blots eliminated was 98.4% (7764/7884). Therefore, this algorithm is sensitive, specific and will reduce the use of a subjective assay that yields high indeterminate and false positive rates.