The trouble with unreadables: IFA as a useful confirmatory test to resolve HIV EIA RR/WB Unreadable donor samples

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Background: The available licensed HIV-1 Western Blot (WB) for confirmatory donor testing has yielded increasing numbers of Unreadable (UNR) results. UNR results hinder interpretation and generate high levels of anxiety and confusion among blood donors and blood center consignees. This study evaluated repeat HIV-1 WB and HIV-1 immunofluorescence assay (IFA) on donor followup (F/U) samples for resolving HIV EIA repeat reactive (RR)/WB UNR cases.

Methods: Index donations were screened with Genetic Systems HIV-1/2 EIA and Chiron Procleix HIV-1/HCV NAT. EIA RR samples were confirmed with Genetic Systems HIV-1 WB. Donors of HIV-1/2 EIA RR/HIV-1 WB unreadable samples were contacted for F/U testing. F/U samples were again tested with HIV-1 WB; those repeatedly WB UNR were sent for HIV-1 IFA at a state reference laboratory. Donors were deferred permanently and consignee notification performed based on the HIV EIA RR index donation. Confirmatory and F/U results were incorporated into subsequent counseling.

Results: For HIV-1/2 EIA RR donor samples in 2004-2005, confirmatory HIV-1 WB testing was inconclusive in 52% of cases (Table 1). Secondly, the rate of WB UNR results has significantly increased, almost doubling in first quarter, 2005. All index donation UNR cases from 2004-2005 were negative for HIV-1 NAT. Donor F/U samples from 45% of UNR cases were available for repeat HIV-1 WB (Table 2). The majority of F/U samples yielded UNR results on repeat WB. 89% of these repeat WB UNR samples were negative by HIV-1 IFA, 11% were inconclusive, and none were positive.

Conclusions: The available licensed HIV-1 WB has yielded unacceptably high rates of UNR results. These donors are permanently deferred. WB on F/U samples was not useful due to repeat UNR results; however, IFA resolved as Negative most WB UNR cases. Due to low donor return rate, HIV-1 IFA on index donations would improve donor and consignee counseling and should be considered as an alternative HIV confirmatory method.

Table 1

HIV Result	2004 #	2004 %	2005 #	2005 %
EIA RR	805		328	
WB:				
Pos	66	8.3	18	5.5
Neg	310	38.8	139	42.4
IND	339	42.5	103	31.4
UNR	83	10.4	68	20.7
Total	798	100	328	100

Table 2

HIV Result	2004 #	2004 %
Index WB UNR	75	
Index NAT Pos	0	0
F/U WB	34/75	45.3
WB Pos	0	0
WB Neg	5	14.7
WB IND	2	5.9
WB UNR	27	79.4
F/U IFA	24/27	88.9
IFA Pos	0	0
IFA Neg	22	91.7
IFA IND	2	8.3