

Implementation of Bio-Rad HIV-1/HIV-2 Plus O EIA

Background:

Blood Systems Laboratories (BSL), a Division of Blood Systems Incorporated, implemented the Bio-Rad HIV-1/HIV-2 Plus O EIA assay in April of 2007. Prior to implementation, the laboratory used the Genetic Systems HIV-1/ HIV-2 Peptide EIA assay for over six years. Whenever a new version of an assay is implemented, there is always uncertainty as to the impact on the donor deferral rates. It is normal to encounter some culling with a new assay and the hope is that reactive rates will stabilize within a few months to at least previous levels. This study reports the performance of the HIV-1/HIV Plus O assay in a routine blood donor population previously screened with the HIV-1/HIV-2 Peptide EIA.

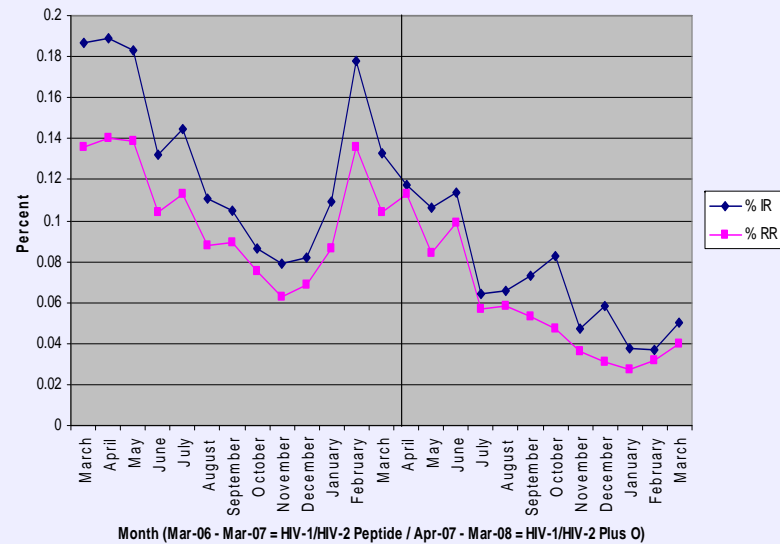
Methods:

Data for the HIV-1/HIV-2 Peptide assay from March 2006 to March 2007 were evaluated, which included a total of 1,923,459 samples tested. This was compared to data for the HIV-1/HIV-2 Plus O assay from April 2007 to March 2008, which included a total of 2,049,671 samples tested. Correlation to confirmatory testing was also evaluated. The confirmatory method used during the study period for the HIV-1/HIV-2 Peptide assay was the HIV-1 Western blot and HIV-1 IFA for the HIV-1/HIV-2 Plus O assay.

Results:

The samples tested with the HIV-1/HIV-2 Peptide assay resulted in an average IR rate of 0.123 % and RR rate of 0.096 %. Data for the HIV-1/HIV-2 Plus O assay from April 2007 to March 2008 were evaluated, resulting in an average IR rate of 0.069 % and RR rate of 0.052 %. Upon implementation of the Bio-Rad HIV-1/HIV-2 Plus O repeat reactive rates averaged at 0.093 % for about three months, which is attributed to some culling during this time period. Repeat reactive rates started dropping four months after implementation and have remained at an average rate of 0.038 %. The repeat reactive rate is nearly 60% lower with the Plus O assay compared to the Peptide assay. There was no significant change noted in the confirmatory rate between the two screening assays, which indicates no loss of sensitivity.

Anti-HIV-1/HIV-2 Reactive Rate Comparison



Conclusion:

The implementation of Bio-Rad HIV-1/HIV-2 Plus O was a significant benefit for Blood Systems Laboratories and the blood center customers we serve due to the reduced repeat reactive rate. There are 60 % fewer donors deferred because of a false positive HIV-1/2 test result using the new assay, with no indicated decrease in sensitivity.

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