

Reinventing blood safety

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Oral Presentation*

Performance of the Procleix HIV-1/HCV Assay was not Adversely Affected by the Sudden Increase in Testing Volume after the N.Y. World Trade Center Disaster.

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Objective:

The Procleix™ HIV-1/HCV Assay, a nucleic acid test for the simultaneous detection of HIV-1 and HCV RNA in plasma developed by Gen-Probe, has been used to screen over 70% of the U.S. blood supply since March 1999, and was approved by the FDA in February 2002. The World Trade Center disaster (WTCD) on September 11, 2001 resulted in exceptionally high numbers of donations. This study examined the effect of this increased testing volume on the performance of the Procleix HIV-1/HCV Assay.

Design/Methods:

All samples from voluntary blood donations were routinely screened in pools of 16 by the Procleix Assay before and after the WTCD at four testing sites. Two time periods were examined -- August 11, 2001 to September 11, 2001 (pre-WTCD) and September 12, 2001 to October 11, 2001 (post-WTCD). The numbers of donations tested, numbers of runs, numbers of samples per run, invalid run rates, and invalid sample rates were examined.

Results:

The number of donations screened by the Procleix HIV-1/HCV Assay at the four sites increased by 42.4% post-WTCD. The sites screened 264,908 donations in 502 assay runs before the WTCD compared to 377,152 donations in 549 runs after the WTCD. The number of samples tested per run increased from an average of 60 to 69. Invalid run rates decreased slightly from 2.2% to 2.0%. The rate of invalid samples within valid runs increased from an average of 0.33% to 0.44%.

Conclusions:

The 42.4% increase in donations after the WTCD did not significantly affect the ability of the blood testing centers to screen each donation for HIV-1 and HCV RNA using the Procleix HIV-1/HCV Assay. Invalid run rates or invalid sample rates remained low after the disaster. The data indicate the flexibility of the sites using the Procleix HIV-1/HCV Assay to adapt to sudden large increases in donations.