

AABB 56th Annual Meeting, 2003

NAT IMPLEMENTATION FROM A TO Z

Steve Negin, Central California Blood Bank

Introduction

Our blood center operates as an independent, non-profit blood donor center that tests approximately 100,000 donations per year. Prior to 9/11, donor blood was sent to a larger facility for nucleic acid testing (NAT). The 9/11 tragedy caused immediate transportation problems that disrupted our blood services. So after FDA approved and licensed Procleix[®] HIV-1/HCV Assay for blood testing in 2002, we explored NAT implementation to prevent future disruption of our blood services.

Planning

Task	Timing	Cost
Building new lab	8 weeks	\$58,000
Capital Equipment	2 weeks	\$345,000
SOP writing	2 weeks	\$500
Installation	1 week	\$1,400
Training	5 people, 1 week each	NA
Validation	3 weeks	NA
Proficiency	3 people, 1 week each	\$1,250
Parallel testing	2 people, 2 weeks	\$13,800

Results

Routine NAT in our blood center began in September 2002. Since then, only five invalid runs occurred due to explainable errors (i.e., $\geq 4\%$ invalid run rate). No invalid samples were the cause of invalid runs. 18 donor samples tested positive for HCV using NAT and all were HCV antibody reactive. There were no positives for HIV-1.

Conclusions

NAT implementation using the Procleix HIV-1/HCV Assay was both smooth and efficient due to proper planning and technical support provided by the vendor. We conclude that NAT in our facility is more cost effective, excluding implementation costs, than sending donor samples to a larger testing facility. We expect to recover capital costs within five years from implementation. Thus, NAT provides advantages to our blood center and customers by reducing long-term costs, increasing turnaround time, and eliminating risk of potential disruption to blood services.