

Segregation and Verification of NAT Tissue Donor Sample Testing (AP32)

T Glanzer (tgross@bloodsystems.org), L Patterson, R Russell, J Dunn Williams, G Robertson, Blood Systems Laboratories, Tempe, AZ; D Houghton, Blood Systems Laboratories, Bedford, TX; S Caglioti, Blood Systems Laboratories, Tempe, AZ

Background: The American Association of Tissue Banks (AATB), the National Marrow Donor Program (NMDP) and American Association of Blood Banks (AABB) recently published information regarding the requirement to perform individual donor sample (IDS) NAT human immunodeficiency virus (HIV-1) and hepatitis C virus (HCV) testing on samples from all Human Cells, Tissues, Cellular and Tissue-Based Products (HCTP). Based upon this requirement and the Procleix HIV-1/HCV (MX) assay package insert information, a system was developed to ensure HCTP samples were not tested in mini-pools (MP), which is the method used for routine blood donor screening. Manual verification of all HCTP samples at a high volume testing facility was deemed too cumbersome and risky. Therefore, electronic verification was required to develop a quick and accurate check of all HCTP samples to ensure they were appropriately IDS tested.

Study: The process utilized two production databases, LifeTrak Lab (LTL) and NAT Tracker (Tracker), which contained information about IDS requirements and test processes used, respectively. In addition, a new HCTP database was developed using Access to verify IDS processing for each HCTP sample. Each batch containing HCTP samples was checked into LTL and a quarantine hold was applied to prevent result release until final IDS verification was performed. The samples were routed with an HCTP/IDS batch tag for NAT MX testing. Upon completion of testing, a report was generated by the HCTP database that displayed 'Investigate' when a sample requiring IDS in LTL was not present within Tracker. Reports that contained samples labeled 'Investigate' (absence of IDS results) were then sent to the NAT laboratory for IDS testing. The HCTP verification process was performed between January 1, 2006 and March 31, 2006. A total of 9,714 were identified as HCTP samples requiring IDS testing. Of these 99.98% (9,712/9,714) were tested appropriately. There were 0.02% (2 of 9,714) HCTP samples tested inappropriately as MP samples. However, these samples were detected by the HCTP database as investigate. Both samples were IDS tested before result reporting.

Conclusions: An electronic verification process was needed to assure IDS compliance with HCTP samples in a high volume testing laboratory. The routing and segregation process for IDS HCTP testing proved highly effective 99.98% of the time. For those two occasions where the segregation process failed, the HCTP database proved effective in detecting these samples. Therefore, providing the extra measure of safety to comply with regulatory requirements.