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Oral Presentation

AN EVALUATION OF HEPATITIS B NAT ON US BLOOD DONORS (S27-030F)*R R Gammon (rgammon@floridasbloodcenters.org), P Simmonds-Brown, A Prichard, M Soto, C Williams, A Barr, BloodNet USA, Lakeland, FL***Background:**

Detection of hepatitis B virus (HBV) in the US is based upon EIA screening for core antibody (anti-HBc) and surface antigen (HBsAg). A multi-site study was conducted to evaluate a multiplexed HIV/HCV/HBV nucleic acid test (NAT) for viral detection in volunteer blood donations over a 4.5-month period. Our results are reported here.

Methods:

9 collection sites participated. Plasma samples were tested in pools (MP) of 1:16 donations or individually (IDT) using a Transcription-Medicated Amplification (TMA) triplex NAT assay. Reactive pools were retested as individual donations with discriminatory assays to detect the presence of specific viruses. Standard NAT and serological testing were concurrently performed on all donations. Reactive HBV NAT results were confirmed with an alternate sample by an alternate NAT-real time polymerase chain reaction (PCR). HBV seronegative results were confirmed by repeating the anti-HBc and HBsAg using an alternate sample. Confirmed HBV TMA and PCR reactive as well as seronegative donors (HBsAg-, anti-HBc-) were entered into a substudy and upon return were tested for HBV by NAT (TMA and PCR) and serology (HBsAg and anti-HBc). Turnaround-times of licensed NAT vs. the investigational triplex assay were compared.

Results:

	Tested	Tests	Invalid samples	Reactive	Discriminated Positive HBV	HBsAg+	Anti-HBc +
MP	114,720	7,170	2	176	28	33	777
IDT	5,247	5,247	0	213	27	23	109

Five potential window period yield cases were eligible for the substudy. 2/5 donors returned for one follow-up bleed at 21 and 56 days post-index donation and were HBV NAT nonreactive by TMA & PCR but had not seroconverted. The other substudy participants were lost to follow-up. Incidence of HBV NAT+ seronegative donations tested was 1 in 23,993. Turnaround-time for licensed and investigational NAT and serology was 12 hours.

Conclusions:

Adding HBV NAT to the menu of blood testing successfully interdicted HBV NAT reactive blood donations that tested seronegative from a volunteer blood donor population. The investigational triplex assay performed concurrently with licensed NAT did not affect turnaround-time.