

# Evaluation of HBsAg Positive/HBc Negative Donations with PCR Assay

## Background

In 2006, a large regional blood donor testing laboratory implemented HBV Polymerase Chain Reaction (PCR) testing on HBsAg Confirmed Positive/anti-HBc negative samples to provide additional information for donor counseling.

## Methods

Donations from January 2006 through December 2007 were used for the study.

- Donations collected during 2006 were screened using enzyme immunoassay (EIA) methods.
- Donations collected during 2007 were screened using chemiluminescent (ChLIA) methods.
- Samples that were HBsAg confirmed positive and anti-HBc negative were tested using HBV PCR.
- The most sensitive sample preparation method was used if sufficient volume (1mL) was available to enhance detection.
- An alternate method using only 200µL of sample was required for only 2 (0.81%) samples tested.

### Year 2006 - Using Ortho HBsAg and HBc EIA

Total Number of Donations 2,599,648

	Number Routed for HBV PCR	PCR Positive	PCR Negative	Samples QNS, USS or USA
	93	13	65	15
Percent	0.004%	14.00%	69.90%	16.10%

### Year 2007 - Using Abbott Prism HBsAg and HBc

Total Number of Donations 2,735,988

	Number Routed for HBV PCR	PCR Positive	PCR Negative	Samples QNS, USS or USA
	155	23	125	7
Percent	0.006%	14.80%	80.60%	4.60%

## Results

From January to December 2006 there were 2,599,648 donations tested by the EIA methods.

- Of these, 93 samples were routed for the HBV PCR testing.
- There were 65 PCR negative, 13 PCR positive, and 15 samples that were either quantity not sufficient (QNS) or sample age/storage not acceptable (USA/USS) for testing.
- An average of 8 samples were routed for testing each month with an average of 1 reactive sample per month during 2006.

From January to December 2007 there were 2,735,988 donations tested by the ChLIA methods.

- Of these, 155 samples were routed for the HBV PCR testing.
- There were 125 PCR negative, 23 PCR positive and 7 samples that were either QNS or USA/USS for testing.
- An average of 13 samples were routed for testing each month with an average of 2 reactive samples per month during 2007.

## Conclusions

Based on the rate of HBV DNA positive samples detected in these populations, there is good correlation between the HBsAg and anti-HBc EIA and ChLIA methodologies.

- There was a slightly higher percentage of negative samples in 2007 but no significant change in the percentage of PCR positive samples.
- This is most likely due to the decrease of samples that were QNS or USA/USS during 2007.
- An improved process of identifying and freezing samples that met certain criteria prior to confirmatory testing was identified which allowed more complete data for 2007.

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Transfusion Transmitted Diseases: Testing Issues (Virology)

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