

Rate of HBS and HBC Repeat Reactive Rates in Maternal Samples vs. Whole Blood Donor Using the Abbott Prism

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Background: Maternal donor (MD) sample EIA repeat reactive (RR) rates have been previously studied and compared to whole blood donors¹. A new instrument, the Abbott Prism, was introduced in September, 2006. We looked at the RR rates using this instrument to determine any differences between the bead EIA system and Prism for MD versus WBD samples.

The following describes the Prism methodology:

HBS

- The assay is a two-step ChLIA assay. Microparticles coated with mouse monoclonal anti-HBs are incubated with sample (either plasma, serum, calibrator, or control) in the incubation well of the reaction tray. During incubation, HBsAg present in the sample binds to the antibody on the Microparticles.
- After this first incubation is complete, the reaction mixture is transferred to the glass fiber matrix of the reaction tray using the Transfer Wash. The Microparticles are captured by the matrix while the remaining mixture flows through to the absorbent blotter.
- The Acridinium-Labeled Goat Polyclonal Anti-HBs Conjugate is added to the Microparticles on the matrix and incubated. After this second incubation, the unbound Conjugate is washed into the blotter with the Conjugate Wash.
- The chemiluminescent signal is generated by addition of an alkaline hydrogen peroxide solution. The resultant photons are counted. The amount of light emitted is proportional to the amount of HBsAg in the sample.

Specificity based on assumed zero prevalence of HBsAg in whole blood and plasmapheresis donors was estimated in Abbot's clinical studies to be 99.99% (25,230/25,232) with a 95% confidence interval (CI) of 99.97% to 100.00%.

Anti-HB Core

The ABBOTT PRISM HBc assay is a two-step competitive/blocking ChLIA. Anti-HBc in serum/plasma blocks the binding of anti-HBc conjugate to the recombinant HBc antigen (rHBcAg) on the microparticles. A reduction in assay signal compared to control indicates presence of anti-HBc in a sample. The reactions occur in the following sequence:

- Microparticles coated with rHBcAg are incubated with either plasma, serum, calibrator or control in the incubation well of the reaction tray. During incubation, anti-HBc present in the sample binds to the rHBcAg on the Microparticles.
- After this first incubation is complete, the reaction mixture is transferred to the glass fiber matrix of the reaction tray using the Transfer Wash. The Microparticles are captured by the matrix while the remaining mixture flows through to the absorbent blotter.
- The Acridinium Labeled Human Anti-HBc Conjugate is added to the Microparticles on the matrix and incubated. The Conjugate will bind to rHBcAg which has not been blocked by Human Anti-HBc in the sample. After this second incubation, the unbound Conjugate is washed into the blotter with the Conjugate Wash.
- The chemiluminescent signal is generated by addition of an alkaline hydrogen peroxide solution. The resultant photons are counted. The amount of light emitted is inversely proportional to the amount of anti-HBc in the sample.

Of 6,873 donations presumed seronegative for anti-HBc, ABBOTT PRISM HBc had a estimated specificity of 99.81% (6,860/6,873) in Abbott's clinical trials.

¹ Rhamy, J and Dracker, R. Viral Marker Rates in Donors of Cord Blood. Transfusion, Sept. Suppl., 2005.

Methods: HBS antigen (HBS) and anti-HBC (HBC) Prism values were obtained for 5 months. Previously published RR rates¹ from the same lab for the same donor groups using the bead EIA were compared. Exact 95% binomial confidence intervals were computed for each percentage. Comparisons between the MD and WBD for differences in the percentages were performed using chi-square tests. Comparisons between the 2005 and 2007 for differences in the percentages were also performed using chi-square tests. P-values < 0.05 indicated statistically significant differences, and p-values between 0.05 and 0.10 were considered to be marginally significant.

Results: MD had significantly higher HBS and HBC % RR, % Conf Pos, and % Conf Pos/ RR than WBD for both 2005 and 2007. For WBD, 2007 had significantly higher HBS % Positive RR, marginally higher HBS % Conf Pos, and significantly lower HBC % RR than 2005. For MD, 2007 had marginally higher HBS % RR, significantly lower HBS % Conf Pos/ RR, and significantly lower HBC % RR.

Conclusions: For WBD, the Prism has significantly increased the rate of samples which test repeat reactive for HBS, has slightly increased the % which confirm positive, and has significantly decreased the %RR for HBC. MD had a slightly higher number of samples testing as repeat reactive for HBS, slightly fewer of the samples confirming, and fewer samples testing RR for HBC. However, all of these rates are significantly higher in MD with both bead and Prism than WBD. The Prism is an improvement for both populations of samples for testing HBC.

	2005						2007					
	Whole Blood Donors		Maternal Donors		Whole Blood Donors		Maternal Donors		Whole Blood Donors		Maternal Donors	
	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI
HBS % RR	0.02%	0.02%	0.03%	0.19%	0.13%	0.27%	0.04%	0.03%	0.05%	0.30%	0.22%	0.40%
% Conf Pos	0.01%	0.00%	0.02%	0.19%	0.13%	0.26%	0.02%	0.01%	0.03%	0.22%	0.14%	0.32%
% Conf Pos/RR	37.1%	21.5%	55.1%	96.9%	83.8%	99.9%	44.7%	30.2%	59.9%	78.1%	60.0%	90.7%
HBC % RR	0.50%	0.46%	0.53%	2.47%	2.24%	2.72%	0.25%	0.22%	0.28%	1.88%	1.66%	2.12%