PRISM HBsAg Performance Relative to HBV NAT

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PRISM HBsAg
HBsAg Sensitivity

Calculated Mean Assay Sensitivity	**PRISM HBsAg**	**AUSZYME Monoclonal (Procedure C)**
ng/ml (ad)	0.09	0.63
ng/ml (ay)	0.08	0.42

Reactive Rates and Specificity for Volunteer Whole Blood and Plasmapheresis Donors PRISM HBsAg vs Test of Record N = 25, 238

	PRISM HBsAg	Test of Record
Initial Reactive Rate	0.06%	0.36%
Repeat Reactive Rate	0.03%	0.03%
%RR Confirmed or Supplemental Test Positive	75.0%	50.0%
% Specificity	99.99%	99.98%

5 Stage Markov Model Analysis of 25 HBV Seroconverters

- In all cases PRISM HBsAg exhibited improved detection of seroconversion compared to AUSZYME Monoclonal (Procedure C)
- PRISM HBsAg detected HBsAg an average of **6.8** days earlier than AUSZYME Monoclonal (Procedure C)
  - (4.3 – 10.9 days, 95% Confidence Interval)
- PRISM HBsAg detected HBsAg an average of **12.6** days longer than AUSZYME Monoclonal (Procedure C)
  - (5.6 – 28.7 days, 95% Confidence Interval)

HBV DNA Detection Relative to HBsAg(-) Early Window Period

- Samples from 15 HBV seroconversion series were tested undiluted in a research HBV DNA PCR assay.
- Early window period samples that were PCR positive when tested undiluted were then tested by PCR at a 1:16 dilution.

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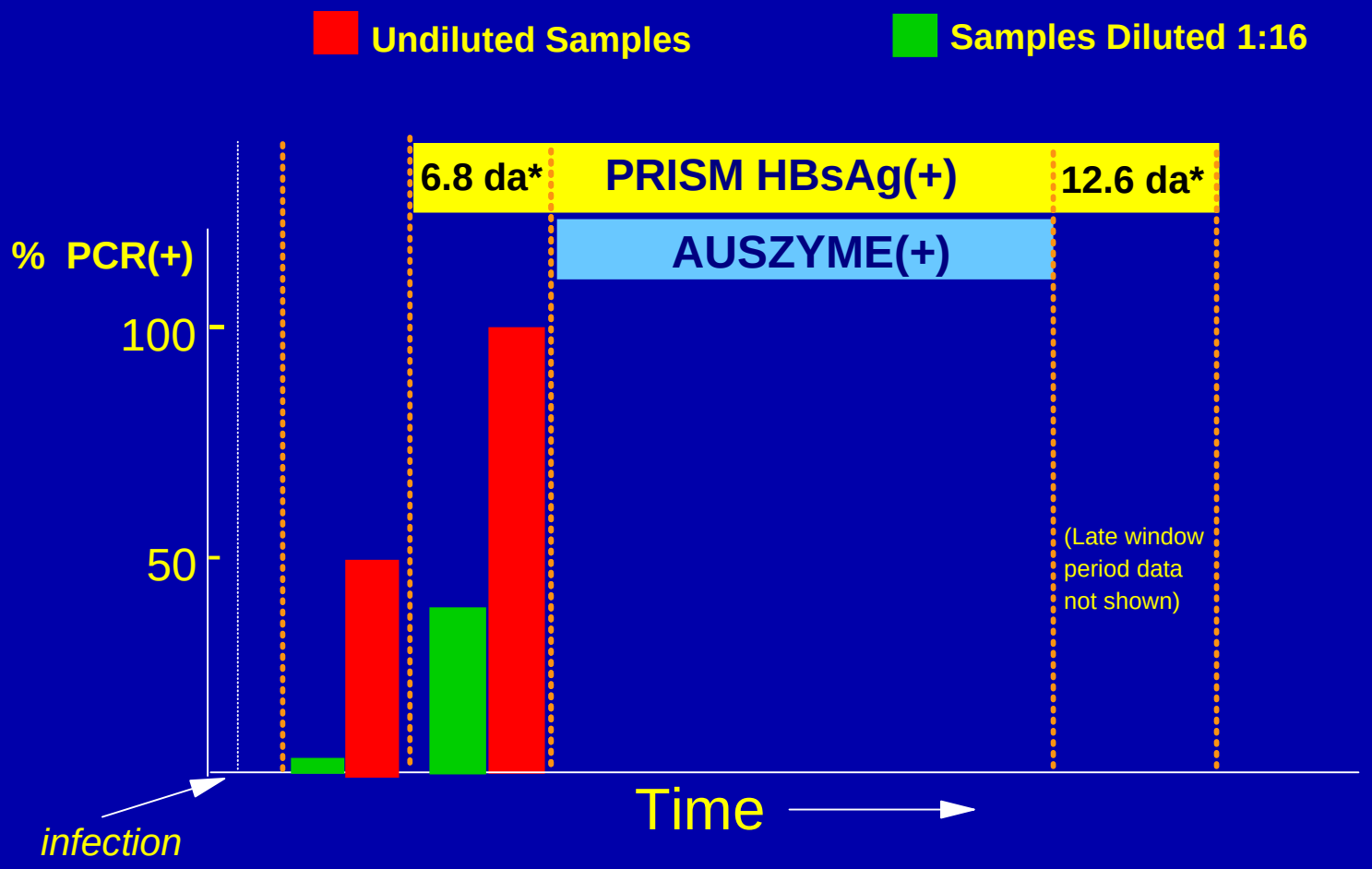
Detection of HBV DNA Relative to HBsAg(-) Early Window Period



*Mean value based on Markov Model Analysis.

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