

Evaluating the Impact of the Revised HCV NAT Algorithm: Discontinuation of HCV RIBA on EIA Reactive NAT HCV Positive Donations

Background

The Gen Probe Nucleic Acid Testing (NAT) package insert allows for the discontinuation of the HCV RIBA confirmatory test if the donation is HCV EIA Repeat Reactive as well as NAT Positive HCV discriminated (dHCV). In October 2006, the NAT algorithm used by our laboratory was amended to discontinue the use of the HCV RIBA test when the above mentioned conditions were satisfied for our United Blood Services donor samples. This study was performed to assess the financial benefit and affect on the donor counseling effectiveness of the process change.

Methods

Donations from the United Blood Services sites from October 2005- September 2007 were evaluated. Donations that were HCV EIA RR and NAT Positive dHCV were evaluated for confirmatory testing using HCV RIBA through September 2006. In October 2006, if the donation was HCV EIA RR and NAT Positive dHCV, no further testing was performed. With the discontinuation of the HCV RIBA test, donor counseling amended the counseling message, notification letters and information sheets to reflect the two test results (dHCV and HCV EIA RR) instead of the previous three test results.

Results

The revised NAT algorithm resulted in a reduction of 452 RIBA HCV tests (33%) for a cost savings of \$52,076 (reagents, supplies and labor).

Results (cont.)

	October 2005 – September 2006	October 2006 – September 2007
Total number of donations	937,051	956,239
HCV RR EIA	1511	1378
HCV RIBA:		
▪ Positive	700	246
▪ Negative	456	369
▪ Indeterminate	313	293
▪ Untested (sample issue)	42	18
▪ Untested (revised NAT algorithm)	0	452
NAT dHCV Positive (EIA RR)	538	501
RIBA Pos / NAT dHCV Pos	512	48

Conclusion

The implementation of the revised NAT algorithm resulted in financial savings with minimal donor counseling impact. There were a few isolated questions from hospitals regarding the lack of HCV RIBA data that were easily answered with additional explanation and the notification/lookback processes can still be completed within the timeline required by FDA.

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