

Evaluation of the Effect of Freeze/Thaw Cycles on Chagas EIA Repeat Reactive/RIPA Positive Donations

Background

In 2007, a large regional blood donor testing laboratory implemented T.cruzi (Chagas) antibody testing.

- There is limited knowledge or experience with sample stability.
- A study was performed to investigate the effect of freeze/thaw cycles on positive donations received at this facility.

Methods

Donations identified as anti-T.cruzi (Chagas) EIA repeat reactive and RIPA positive were used for the study.

- 10 citrated plasma units were identified.
- Two frozen aliquots from each unit were used for this study. Nine of the ten units had been previously frozen and then thawed prior to receipt.
- At the time of testing, one aliquot from each unit was thawed. The second aliquot was thawed and refrozen twice prior to being thawed for testing.
- Thawed aliquots were split into 3 tubes and all were tested in the same EIA run to avoid run-to-run variance.
- A logistic regression was performed with 3 ordinal categories for the number of freeze/thaw cycles and the mean S/CO of the triplicate tests as the explanatory variable.

Donation	# Thaws	S/CO 1	S/CO 2	S/CO 3	Mean S/CO	Difference from original S/CO	Sample Type	Donation	# Thaws	S/CO 1	S/CO 2	S/CO 3	Mean S/CO	Difference from original S/CO	Sample Type
A	0	1.273	1.218	1.486	1.326		Serum	F	0	5.273	5.984	5.389	5.549		Serum
	2	0.997	0.915	0.958	0.957	-0.369	CPD		2	5.960	5.595	5.771	5.775	+0.226	CPD
	5	0.907	0.935	1.099	0.980	-0.346	CPD		5	5.572	5.255	5.652	5.493	-0.056	CPD
B	0	1.413	1.426	1.439	1.426		Serum	G*	0	3.305	3.157	3.072	3.178		Serum
	2	1.839	1.986	1.941	1.922	+0.496	CPD		1	3.184	3.371	3.261	3.272	+0.094	CPD
	5	1.776	1.802	1.827	1.802	+0.376	CPD		4	3.448	3.300	3.161	3.303	+0.125	CPD
C	0	6.881	6.356	6.707	6.641		Serum	H	0	1.078	1.100	1.123	1.100		Serum
	2	5.790	5.992	6.385	6.056	-0.585	CPD		2	1.110	1.037	1.059	1.069	-0.031	CPD
	5	6.142	6.028	6.082	6.084	-0.557	CPD		5	1.195	1.093	1.099	1.129	+0.029	CPD
D	0	4.841	5.446	6.132	5.473		Serum	I	0	2.144	1.728	1.896	1.923		Serum
	2	5.391	5.544	4.890	5.275	-0.198	CPD		2	2.082	2.062	1.881	2.008	+0.085	CPD
	5	5.476	5.258	5.159	5.298	-0.175	CPD		5	1.952	2.059	2.261	2.091	+0.168	CPD
E	0	3.869	4.362	4.184	4.138		Serum	J	0	6.165	6.416	7.129	6.570		Serum
	2	4.235	4.229	4.153	4.206	+0.068	CPD		2	6.598	6.272	6.292	6.387	-0.183	CPDA-1
	5	4.062	4.195	4.371	4.209	+0.071	CPD		5	5.824	6.303	6.496	6.208	-0.362	CPDA-1

*This plasma unit was not frozen prior to shipment.

Results

The mean EIA S/CO results from the plasma aliquots were averaged and compared to the original serum mean S/CO.

- Units E and G had index S/CO ratios between 3 and 5 while units C,D,F and J had index S/CO ratios > 5.
- Conversely, the index S/CO of units A,B,H and I were <2.0 and unit A became negative after two freeze/thaw cycles (Table).

Conclusion

The mean S/CO differences of the thawed plasma were not statistically significant.

- However, the impact of freeze/thaw reduced the S/CO ratio below the cutoff for positivity in 1 (25%) of 4 units with an index S/CO ratio of < 2.00.
- Subsequent to this study, the cutoff calculation for a positive result was lowered by the manufacturer to the equivalent of 0.92 S/CO thus changing the interpretation of the one negative unit to positive.
- Using the modified cutoff calculation, all results for all thawed plasma samples would have remained positive.

Poster ID: SP231

Session #: I

Transfusion Transmitted Diseases: Parasites

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