

Preservation of Plasma Anti/Coagulation Proteins Necessary for Use in the Clinic

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Background

Fresh frozen plasma (FFP) should be thawed before transfusing to patients but it must be monitored closely to avoid contamination, uncontrolled or prolonged thawing which may subsequently lead to plasma protein denaturation. In this study, we compared and evaluated the effect of two different thawing methods on clotting factor activities as well as factors such as throughput and turnaround time.

Current Industry Limitations

- Efficacy of temperature measurements (temperature of water bath versus temperature of actual substance used for transfer)
- Specimen Waste
- Labor/Time Risk of Contamination
- Data tracking

Scope of Study

- In Nov-Dec 2018, San Diego Blood engaged Band UC San Diego Health Laboratories on behalf of FreMon Scientific to perform specific plasma assays in support of the company's FDA 510(k) application for ZipThaw.
- Compare two plasma thawing methods: An FDA-approved standard water bath and the ZipThaw202.

Study Design

- Determination of plasma levels for selected plasma coagulation and anticoagulation proteins in 65 individual samples, each under three conditions:
 - Freshly collected, unfrozen plasma
 - Frozen then thawed plasma using the standard (FDA approved) method used at SDBB
 - Frozen then thawed plasma using the ZipThaw device.

- Three sets of samples (for a total of 197) were delivered to UCSD Lab 1,700+ assays were performed.

Assays Performed on each of 197 samples:

Prothrombin time (PT), International Normalized Ratios (INR), Activated Partial, Thromboplastin time (aPTT), Factor VIII activity, Factor V activity, Protein C activity, Protein S antigen, Von Willebrand activity, and Thrombin Antithrombin Complex.

ZipThaw™ 202 and ZipSleeve™

ZipThaw™ 202 is a Dual chamber, light weight, hand portable device that is easy to use in nearly any setting from blood/bio bank to point of care to laboratory, intended for thawing of FFP and other frozen or chilled bio product.



ZipSleeve™ is a disposable anti-contamination thawing pouch uniquely equipped with a RFID sensor to safely and accurately measure the actual bag temperature of the product being thawed.

Differentiating features in One Device



Total Weight 22 lbs./10 kg

- Dry - fully electronic
- Portable
- Rapid - under 15 minutes
- Low
 - ✓ Capital cost
 - ✓ Operating Cost
 - ✓ Maintenance
 - ✓ Energy consumption
- Easy to use
- Data recoding
- Data transfer
- Failsafe
- Reduced blood, plasma & tissue waste
- Cross-contamination reduced
- 3 year replacement warranty

Results

Fresh Plasma vs. Thawed Plasma (SDBB)

SUMMARY	Fresh Plasma		Thawed Plasma (SDBB)		Thawed Plasma vs Fresh Plasma	
	Mean	S.D.	Mean	S.D.	% change	t test p value
TESTS	n = 66		n = 66			
PT(sec)	12.2	1.0	12.1	0.8		
INR	1.1	0.1	1.1	0.1	1.1	% increase 0.404
aPTT(sec)	35.1	3.9	35.0	3.6		
PROTC (% NP)	99.6	21.4	101.1	20.5		
PROTS(% NP)	92.2	17.6	90.5	18.7		
FVIII(% NP)	89.0	32.1	84.1	30.6	5.6	% decrease 0.364
FV(% NP)	87.1	16.2	84.5	16.6	3.0	% decrease 0.369
VWACT (% NP)	92	36	93	36		
TAT (ng/ml)	3.3	1.6	4.3	2.5	31.3	% increase 0.005

Fresh Plasma vs. ZipThaw Plasma

SUMMARY	Fresh Plasma		ZipThaw Plasma		ZipThaw Plasma vs Fresh Plasma	
	Mean	S.D.	Mean	S.D.	% change	t test p value
TEST NAME	n = 66		n = 65			
PTI(s)	12.2	1.0	12.3	1.1		
INR	1.1	0.1	1.1	0.1	1.4	% increase 0.325
PTTO(s)	35.1	3.9	36.1	4.0	2.8	% increase 0.150
PROTC(%)	99.6	21.4	100.6	21.0		
PROTS(%)	92.2	17.6	89.0	18.0	3.5	% decrease 0.306
FVIII(%)	89.0	32.1	83.2	29.3	6.5	% decrease 0.280
FV(%)	87.1	16.2	85.1	15.5	2.2	% decrease 0.483
VWACT(%)	92.1	35.6	94.9	36.2		
TAT (ng/ml)	3.3	1.6	3.9	1.8	17.2	% increase 0.061

Thawed Plasma (SDBB) vs. ZipThaw Plasma

SUMMARY	Thawed Plasma SDBB		ZipThaw Plasma		ZipThaw Plasma vs Thawed Plasma SDBB	
	Mean	S.D.	Mean	S.D.	% change	t test p value
TESTS	n = 66		n = 65			
PT(sec)	12.2	0.8	12.3	1.1	1.0	% increase 0.466
INR	1.1	0.1	1.1	0.1		
aPTT(sec)	35.2	3.5	36.2	3.9	3.0	% increase 0.106
PROTC(% NP)	101.2	20.7	100.6	21.2		
PROTS(% NP)	90.5	18.8	88.8	18.0		
FVIII(% NP)	82.9	29.4	82.1	28.2		
FV(% NP)	84.7	16.6	85.3	15.6		
VWACT(% NP)	93.0	35.8	94.7	36.4		
TAT (ng/ml)	4.3	2.5	3.8	1.8	11.3	% decrease 0.211

Conclusions

No statistically significant differences among the parameters measured between the fresh plasma group and each of the two different frozen-thawed groups or between the two frozen-thaw groups

Slight increase in the mean TAT concentration, compared to fresh plasma, which is more significant with the standard method (33%, p=0.005) than the ZipThaw method (18%, 0.06) suggests lower likelihood of hypercoagulability with ZipThaw to enable homeostasis following therapy.