

Pel-Freez®

Analysis Certificate

PRODUCT: [REDACTED] Rabbit Plasma Level 1 Test Batch INR 1.3

CODE NO: 60007 **LOT NO:** 28335

STORAGE: -10°C to -20°C for 15 days from DOM; -70°C or below for 12 months from DOM.

**DATE OF
MANUFACTURE:** October 10, 2013

APPEARANCE: Clear, amber fluid

EC 1069/2009: EU # AR-TEC-0007

**EU
REQUIREMENTS:** Product meets EU requirements for production of technical blood products.

PROCEDURE: Modified rabbit plasma is produced from custom rabbit plasma (Pel-Freez Part # 91162) and rat serum (Pel-Freez Part # 36125) using Pel-Freez SMP 31162L1 to a fixed INR value as part of an ongoing robust assurance trial.

Rabbit blood was collected and processed from New Zealand white rabbits (mixed gender, 8-12 weeks, US grown) at USDA plant #P-202 and were found to be free of contagious diseases.

Mature rat whole blood (Sprague-Dawley, averaging 7-8 weeks of age, either sex) is collected at the time of slaughter and refrigerated within 6 hours, and processed within 24 hours. The serum is then thawed, pooled, passed through a 0.22 micron filter, bottled and frozen at or below -10°C.

ASSAYS: INR obtained using [REDACTED] meter using test strips of code: 501, lot: 220 744 80. The QC Testin [REDACTED] page 2 of this certificate illustrates the ratios tested during production and final QC along with INR values.

QC Testing Data Table

Code: 60007 INR 1.3				
Lot#: 28335	Testing Stage:	In-process	Final QC	Final QC
DOM: 10/10/2013	Testing Sample Identification:	Post-bulk 1 mL test sample	Replicate #1 5 mL QC sample	Replicate #2 5 mL QC sample
Test strip lot: 220 744 80	Ratio (%) Custom Rabbit Plasma:Adsorbed Rabbit Plasma	99.98:0.1	99.98:0.1	99.98:0.1
Product Tested in Quintuplicate	Meter: UP0610760	1.3	1.2	1.2
	Meter: UP0734328	1.3	1.2	1.2
	Meter: UP0744403	1.3	1.2	1.2
	Meter: UP0570781	1.3	1.2	1.2
	Meter: UP0690781	1.3	1.2	1.2
Summary Statistics	Mean	1.3	1.2	1.2
	Std Deviation	0.000	0.000	0.000
	%CV	0.00%	0.00%	0.00%

Target INR– 1.3 INR

QUALITY ASSURANCE

Quality Control Release Date: October 11, 2013



Sarah Graves
Quality Systems Technician

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE