

Biologicals Division

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Pel-Freez®

Analysis Certificate

PRODUCT: [REDACTED] Rabbit Plasma Level 2 Test Batch INR 3.4

CODE NO: 60009 **LOT NO:** 26835

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

**DATE OF
MANUFACTURE:** September 25, 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 adsorbed rabbit plasma (Pel-Freez Part # 81162), using Pel-Freez SMP 31162L2 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.

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: 60009 INR 3.4				
Lot#: 26835	Testing Stage:	In-process	Final QC	Final QC
DOM: 9/25/2013	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	10.7:89.3	10.7:89.3	10.7:89.3
Product Tested in Quintuplicate	Meter 1: UP0610760	3.4	3.3	3.4
	Meter 2: UP0734328	3.4	3.3	3.3
	Meter 3: UP0744403	3.4	3.3	3.3
	Meter 4: UP0570781	3.4	3.3	3.3
	Meter 5: UP0690781	3.4	3.3	3.3
Summary Statistics	Mean	3.4	3.3	3.3
	Std Deviation	0.000	0.000	0.045
	%CV	0.00%	0.00%	1.35%

Target INR– 3.4 INR

QUALITY ASSURANCE

Quality Control Release Date: October 2, 2013



Stephanie Whitmore
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SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE