

Biologicals Division

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Pel-Freez®

Analysis Certificate

PRODUCT: [REDACTED] Level 3 Modified Rabbit Plasma INR 2.2

CODE NO: 31162L3

LOT NO: 12235

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

**DATE OF
MANUFACTURE:** May 2, 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 31162L3 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: 405, lot: 211 327 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: 31162L3 INR 2.2				
Lot#: 12235	Testing Stage:	In-process	Final QC	Final QC
DOM: 5/2/2013	Testing Sample Identification:	Post-bulk 1 mL test sample	Replicate #1 5 mL QC sample	Replicate #2 5 mL QC sample
Test strip lot: 211 327 80	Ratio (%) Custom Rabbit Plasma:Adsorbed Rabbit Plasma	42:58	42:58	42:58
Product Tested in Quintuplicate	Meter 1: UP0106678	2.2	2.1	2.1
	Meter 2: UP0070515	2.2	2.1	2.1
	Meter 3: UP0101611	2.2	2.1	2.1
	Meter 4: UP0092011	2.2	2.2	2.1
	Meter 5: UP0085038	2.2	2.1	2.1
Summary Statistics	Mean	2.2	2.1	2.1
	Std Deviation	0.000	0.045	0.000
	%CV	0.00%	2.11%	0.00%

Target INR – 2.2 INR

QUALITY ASSURANCE

Quality Control Release Date: October 8, 2013



Sarah Graves
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SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE