

Certificate of Analysis

PRODUCT: [REDACTED] Level 3 Modified Rabbit Plasma**CODE NO:** 31162L3**LOT NO:** 09037**DATE OF
MANUFACTURE:** March 31, 2015**ORIGIN:** U.S.A.**STORAGE:** -10 °C to -20 °C for 15 days from DOM; -70 °C or below for 12 months from DOM.**EC 1069/2011:** 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.

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.

APPEARANCE: Clear, amber fluid

ASSAYS:	Required Assays	Specification	Result
	INR	2.1 – 2.4	2.2

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0708430	2.2	2.2	2.2	2.2
UP0036175	2.2	2.2	2.2	2.2
UP0078546	2.3	2.2	2.1	2.2
UP0069818	2.2	2.2	2.2	2.2
UP0040457		2	2.2.	2.2
INR obtained using [REDACTED] meter. Test strips: code 08				

QUALITY ASSURANCE

Quality Control Release Date: April 8, 2015

Sarah Graves
Quality Systems Technician**Meets or exceeds specifications** ☒**Does not meet specifications** ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**