

rtificate of Analysis**PRODUCT:** [REDACTED] Level 1 Modified Rabbit Plasma**CODE NO:** 31162L1**LOT NO:** 12338**DATE OF
MANUFACTURE:** May 2, 2016**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 31162L1.

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	1.1 – 1.2	1.1

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0030163	1.1	1.1	1.1	1.1
UP0018528	1.1	1.2	1.2	1.2
UP0010646	1.1	N/A	N/A	N/A
UP0092785	1.2	1.1	1.1	1.1
UP0024176	1.1	1.1	1.2	1.2
UP0083793		.1	1.1	1.1

INR obtained using [REDACTED] meter.
Test strips: code R 734 80

QUALITY ASSURANCE

Quality Control Release Date: May 4, 2016


Sarah Graves

Quality Systems Technician

Meets or exceeds specifications ☒**Does not meet specifications** ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**