

Certificate of Analysis
PRODUCT: [REDACTED] Level 1 Modified Rabbit Plasma

CODE NO: 31162L1

LOT NO: 05839

ORIGIN: U.S.A.

DATE OF MANUFACTURE: February 27, 2017

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

HEALTHY ANIMAL STATEMENT: This product is made from raw materials that were collected from animals found free from obvious signs of infectious and contagious disease.

All specimens that contain materials of animal origin were procured using the latest animal testing guidelines, laws or regulations and materials were obtained from US Department of Agriculture ("USDA") approved facilities.

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
UP0755158	1.1	1.1	1.1	1.1
UP0010644	1.1	1.1	1.1	1.1
UP0069500	1.1	1.1	1.1	1.1
UP0030300	1.1	1.1	1.1	1.1
UP0605047		.1	1.1	1.1

INR obtained using [REDACTED] meter.

Test strips: code 25

QUALITY ASSURANCE

Quality Control Release Date: February 28, 2017



 Sarah Graves
 Quality Systems Technician

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