

Certificate of Analysis
PRODUCT: [REDACTED] Level 3 Modified Rabbit Plasma

CODE NO: 31162L3

LOT NO: 18338

DATE OF MANUFACTURE: July 1, 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.

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.

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	2.3

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0018528	2.3	2.3	2.3	2.3
UP0010646	2.3	2.2	2.2	2.2
UP0030163	2.3	2.3	2.2	2.3
UP0024176	2.3	2.3	2.2	2.3
UP0083793		.3	2.2	2.3

 INR obtained using [REDACTED] meter.
 Test strips: code R 0

QUALITY ASSURANCE

Quality Control Release Date: July 6, 2016



 Sarah Graves
 Quality Systems Technician

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