

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

CODE NO: 31162L1

LOT NO: 25439

DATE OF MANUFACTURE: September 11, 2017

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.

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 **REQUIREMENTS:** EU 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	1.2	1.1

 INR obtained using [REDACTED] meter.
 Test strips: code X 10

Meter	Final Bulk
UP0124142	1.1
UP0095119	1.1
UP0084011	1.1
UP0077741	1.1
UP0083793	1.1

Meter	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0479147	1.1	1.1	1.1
UP0790030	1.1	1.1	1.1
UP0076807	1.1	1.1	1.1
UP0758412	1.1	1.1	1.1
UP0752340	1.1	1.1	1.1

QUALITY ASSURANCE

Quality Control Release Date: September 18, 2017



Sarah Graves

Quality Systems Technician

 Meets or exceeds specifications ☒

 Does not meet specifications ☐
SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES