

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

CODE NO: 31162L1

LOT NO: 01143

DATE OF MANUFACTURE: January 11, 2021

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.

APPEARANCE: Clear, amber fluid

ASSAYS:	Required Assays	Specification	Result
	INR	1.1 – 1.2	1.2

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0086894	1.2	1.2	1.2	1.2
UP0973274	1.2	1.2	1.2	1.2
UP1248053	1.2	1.2	1.2	1.2
UP0413267	1.2	1.2	1.2	1.2
UP0870035		1.2	1.2	1.2

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

QUALITY ASSURANCE

Quality Control Release Date: January 13, 2021



 Sarah Graves
 Quality Systems Technician

Meets or exceeds specifications ☒
Does not meet specifications ☐

Amended to repair typo on DOM. T. Kwasny 04Feb2021

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES