

Certificate of Analysis

PRODUCT: [REDACTED] Level 2 Modified Rabbit Plasma**CODE NO:** 31162L2**LOT NO:** 23544**DATE OF****ORIGIN:** U.S.A.**MANUFACTURE:** August 23, 2022**STORAGE:** -10 °C to -20 °C for 15 days from DOM;
-70 °C or below for 12 months from DOM.**EU 142/2011:** AR-TEC-0007**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.

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 31162L2. Rabbit blood was collected and processed from New Zealand white rabbits (mixed gender, 8-12 weeks, US grown) at USDA plant P-202.**APPEARANCE:** Clear, amber fluid

ASSAYS:	Required Assays	Specification	Result
	INR	3.2 – 3.5	3.2

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP1248053	3.2	3.3	3.1	3.2
UP0479147	3.3	3.2	3.1	3.2
UP0413267	3.3	3.3	3.0	3.2
UP0973274	3.3	3.3	3.1	3.2
UP0870035		.3	3.1	3.2

INR obtained using [REDACTED] meter.
Test strips: code S- 3 935 80

QUALITY ASSURANCE

Quality Control Release Date: August 29, 2022



Quality Systems Technician

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