

rtificate of Analysis**PRODUCT:** [REDACTED] Level 1 Modified Rabbit Plasma**CODE NO:** 31162L1**LOT NO:** 21945**DATE OF****MANUFACTURE:** 07Aug2023**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
UP1229542	1.1	1.2	1.2	1.2
UP01570790	1.1	1.2	1.2	1.2
UP01668059	1.1	1.2	1.2	1.2
UP01670440	1.1	1.2	1.2	1.2
UP01732892		.2	1.2	1.2

INR obtained using [REDACTED] meter.
Test strips: code S 0 993 80

QUALITY ASSURANCE

Quality Control Release Date: August 10, 2023



Kendra Graham

Quality Systems Technician / Clerk

Meets or exceeds specifications ☒**Does not meet specifications** ☐

Revised to add DOM. TKwasny 17Aug2023

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES