

Certificate of Analysis

PRODUCT: [REDACTED] Level 3 Modified Rabbit Plasma**CODE NO:** 31162L3**LOT NO:** 32341**DATE OF****MANUFACTURE:** November 19, 2019**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** This product is made from raw materials that were collected from animals found free from obvious signs of infectious and contagious disease.**STATEMENT:** 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 **EC 1069/2011:** AR-TEC-0007

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 obvious signs of contagious diseases.

APPEARANCE: Clear, amber fluid**ASSAYS:**

Required Assays	Specification	Result
INR	2.1 – 2.4	2.4

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP1132877	2.4	2.4	2.4	2.4
UP0076807	2.4	2.4	2.4	2.4
UP1010535	2.4	2.3	2.4	2.4
UP01459131	2.4	2.4	2.4	2.4
UP0870035		.4	2.4	2.4

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

QUALITY ASSURANCE

Quality Control Release Date:

December 2, 2019

Doug Stocker
Quality Systems Technician**Meets or exceeds specifications** ☒**Does not meet specifications** ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**