

Certificate of Analysis

PRODUCT: [REDACTED] Level 2 Modified Rabbit Plasma**CODE NO:** 31162L2**LOT NO:** 17638**DATE OF
MANUFACTURE:** June 24, 2016**ORIGIN:** U.S.A.**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.**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 and were found to be free of contagious diseases.

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

Required Assays	Specification	Result
INR	3.1 – 3.3	3.2

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0092785	3.2	3.2	3.2	3.2
UP0018528	3.3	3.3	3.3	3.3
UP0083793	3.3	3.2	3.3	3.3
UP0024176	3.2	3.2	3.2	3.2
UP0030163		.2	3.3	3.3

INR obtained using [REDACTED] meter.
Test strips: code 23 1**QUALITY ASSURANCE**

Quality Control Release Date: June 29, 2016


Sarah Graves
Quality Systems Technician**Meets or exceeds specifications** ☒**Does not meet specifications** ☐

Amended by S. Graves on July 14, 2016: Corrected Date of Manufacture

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES