

Certificate of Analysis**PRODUCT:** [REDACTED] Level 2 Modified Rabbit Plasma INR 3.0 – 3.2**CODE NO:** 31172**LOT NO:** 08040**DATE OF
MANUFACTURE:** March 21, 2018**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 and found free from infectious and contagious disease.

**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 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	3.0 – 3.2	3.1

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0040599	3.0	3.0	3.1	3.1
UP0065813	3.1	3.1	3.1	3.1
UP0079221	3.1	3.0	3.1	3.1
UP0040309	3.1	3.1	3.1	3.1
UP0073423	3.1	3.1	3.0	3.1

INR obtained using [REDACTED] meter. Key code: 250
Test strips: lot XSP**QUALITY ASSURANCE**

Quality Control Release Date: March 28, 2018



Sarah Graves

Quality Systems Technician

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