

Certificate of Analysis**PRODUCT:** [REDACTED] Level 3 Modified Rabbit Plasma I.N.R. 2.1 – 2.3**CODE NO:** 31173**LOT NO:** 31037**DATE OF
MANUFACTURE:** November 6, 2015**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 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 contagious diseases.

APPEARANCE: Clear, amber fluid

ASSAYS:	Required Assays	Specification	Result
	INR	2.1 – 2.3	2.3

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0079221	2.3	2.3	2.3	2.3
UP0040599	2.3	2.3	2.3	2.3
UP0036193	2.3	N/A	N/A	N/A
UP0073423	2.3	2.3	2.3	2.3
UP0065813	2.3	2.3	2.3	2.3
UP0040309	N/		2.3	2.3

INR obtained using [REDACTED] meter.

Test strips: code 08

QUALITY ASSURANCE

Quality Control Release Date: November 11, 2015


Sarah Graves

Quality Systems Technician

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