

Certificate of Analysis
PRODUCT: [REDACTED] Level 3 Modified Rabbit Plasma I.N.R. 2.1 – 2.3

CODE NO: 31173

LOT NO: 26339

DATE OF MANUFACTURE: September 20, 2017

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	2.2

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0065813	2.2	2.1	2.2	2.2
UP0079221	2.2	2.1	2.2	2.2
UP73423	2.2	2.1	2.1	2.1
UP0040309	2.2	2.1	2.2	2.2
UP0040599	2.2		2.2	2.2

 INR obtained using [REDACTED] meter. Key code: 250
 Test strips: code X 10

QUALITY ASSURANCE

Quality Control Release Date: October 26, 2017


 Sarah Graves
 Quality Systems Technician

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