

State of Analysis

PRODUCT: [REDACTED] Level 1 Modified Rabbit Plasma I.N.R. 1.0 – 1.2

CODE NO: 31171

LOT NO: 29645

DATE OF MANUFACTURE: October 23, 2023

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 obvious signs 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 31171.

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	1.0 – 1.2	1.1

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP01570790	1.1	1.1	1.1	1.1
UP01656560	1.1	1.1	1.1	1.1
UP01732892	1.1	1.1	1.1	1.1
UP01583599	1.1	1.1	1.1	1.1
UP01668059	1.1	1.1	1.1	1.1

INR obtained using [REDACTED] meter. Key code: S_486 XSPT 80
Test strips: code S

QUALITY ASSURANCE

Quality Control Release Date: October 24, 2023



Kendra Graham

Quality Systems Technician / Clerk

Meets or exceeds specifications ☒

Does not meet specifications ☐

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES