

rtificate of Analysis
PRODUCT: [REDACTED] Level 2 Modified Rabbit Plasma I.N.R. 3.0 – 3.2

CODE NO: 31172

LOT NO: 34040

DATE OF MANUFACTURE: December 6, 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 obvious signs of 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 31172.

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	3.0 – 3.2	3.0

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP1123192	3.1	3.0	3.0	3.0
UP01536906	3.1	3.0	3.0	3.0
UP01514593	3.1	3.0	3.0	3.0
UP1128368	3.1	3.0	3.0	3.0
UP01544233	3.0	†N/A	†N/A	†N/A

†meter malfunction

I.N.R. obtained using [REDACTED] meter. Key code: S_334

Test strips: lot 32264

QUALITY ASSURANCE

Quality Control Release Date: December 10, 2018



Sarah Graves

Quality Systems Technician

Meets or exceeds specifications ☒

Does not meet specifications ☐

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES