

rtificate of Analysis**PRODUCT:** [REDACTED] Level 2 Modified Rabbit Plasma I.N.R. 6.9-7.4**CODE NO:** 31185**LOT NO:** 16745**DATE OF
MANUFACTURE:** July 16, 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 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	6.9 – 7.4	7.1

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP01656560	7.1	7.1	7.0	7.1
UP01570790	7.1	7.1	7.0	7.1
UP1229542	7.2	7.1	6.8	7.0
UP01732892	7.1	7.2	6.9	7.1
UP01668059	7.1	7.2	6.9	7.1

INR obtained using [REDACTED] meter. Key code: S_486 XSPT
Test strips: lot 5609**QUALITY ASSURANCE**

Quality Control Release Date: June 22, 2023



Sarah Graves

Quality Systems Bio Lab Supervisor

Meets or exceeds specifications ☒**Does not meet specifications** ☐

Revised to harmonize product description with specification. T. Kwasny 21Jul2023

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES