

rtificate of Analysis**PRODUCT:** [REDACTED] Level 2 Modified Rabbit Plasma I.N.R. 3.2 – 3.4¹**CODE NO:** 31172**LOT NO:** 21241**DATE OF
MANUFACTURE:** July 31, 2019**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		3.2 – 3.4 ¹				3.2
Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	QC Testing (sample 3)	QC Testing (sample 4)	Average QC Testing
UP0497782	3.3	3.0	3.2	3.2	3.2	3.2
UP0870087	3.4	3.1	3.1	3.2	3.2	3.2
UP0087106	3.3	3.1	3.2	3.2	3.2	3.2
UP0852706	3.3	3.2	3.0	3.2	3.2	3.2
UP0908631	3.3		3.2	3.3	3.2	3.2

INR obtained using [REDACTED] meter. Key code: S_307 ML
Test strips: lot 286**QUALITY ASSURANCE**

Quality Control Release Date: August 14, 2019



Sarah Graves

Quality Systems Technician

Meets or exceeds specifications ☒Does not meet specifications ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**¹ Specification revised per customer memo. PFB deviation # DR19-011.