

Certificate of Analysis
PRODUCT: [REDACTED] Level 1 Modified Rabbit Plasma I.N.R. 1.1 – 1.3

CODE NO: 31171

LOT NO: 02639

DATE OF MANUFACTURE: January 26, 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 31162L1.

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

Required Assays	Specification	Result
INR	1.1 – 1.3	1.2

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0085038	1.2	1.2	1.2	1.2
UP0092348	1.2	1.2	1.2	1.2
UP0870054	1.2	1.2	1.2	1.2
UP0092011	1.2	1.2	1.2	1.2
UP0095112	1.2		1.2	1.2

 INR obtained using [REDACTED] meter.
 Test strips: code 25

QUALITY ASSURANCE

Quality Control Release Date: January 31, 2017



 Sarah Graves
 Quality Systems Technician

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