

Certificate of Analysis**PRODUCT:** Modified Rabbit Plasma I.N.R. 1.1**CODE NO:** 60018**LOT NO:** 05537**DATE OF MANUFACTURE:** February 24, 2015**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 31162L1.03.

Rat serum used in the manufacture of this plasma was sourced from the U.S.A.

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

ASSAYS:	Required Assays	Specification	Result
	INR	1.1	1.2

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0101611	1.1	1.2	1.2	1.2
UP0092011	1.1	1.2	1.2	1.2
UP0071015	1.1	1.2	1.2	1.2
UP0085038	1.1	1.2	1.2	1.2
UP0106678		.2	1.2	1.2

INR obtained using [REDACTED] meter. Test strips: code 086 lot 230 734 80

QUALITY ASSURANCE

Quality Control Release Date: March 16, 2015

Brenda Crenshaw

Quality Systems Manager

Meets or exceeds specifications ☐

N/A – Plasma bulked to INR level per PO

Does not meet specifications ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**