

Certificate of Analysis

PRODUCT: [REDACTED] Level 1 Modified Rabbit Plasma

CODE NO: 31162L1

LOT NO: 20738

DATE OF MANUFACTURE: July 25, 2016

ORIGIN: U.S.A.

STORAGE: -10 °C to -20 °C for 15 days from DOM; -70 °C or below for 12 months from DOM.

EC 1069/2011: AR-TEC-0007 **REQUIREMENTS:** **EU** Product meets EU requirements for production of technical blood products.

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

ASSAYS:

Required Assays	Specification	Result
INR	1.1 – 1.2	1.2

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP0018528	1.2	1.2	1.2	1.2
UP0010646	1.1	1.1	1.2	1.2
UP0083793	1.1	1.2	1.2	1.2
UP0092785	1.1	1.2	1.2	1.2
UP0024176		1.2	1.2	1.2

INR obtained using [REDACTED] meter.
 Test strips: code R 80

Meter	QC Testing (sample 1)	QC Testing (sample 2)	QC Testing (sample 3)	Average QC Testing
UP0018528	1.0	1.0	1.0	1.0
UP0010646	1.0	1.0	1.0	1.0
UP0083793	1.0	1.0	1.0	1.0
UP0092785	1.0	1.0	1.0	1.0
UP0024176		1.0	1.0	1.0

INR obtained using [REDACTED] meter.
 Test strips: code 21

QUALITY ASSURANCE

Quality Control Release Date:

August 1, 2016



Sarah Graves

Quality Systems Technician

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

Lot meets specifications based on INR results using code Ro41 lot 230 734 80. Customer is accepting lot based on these results.

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES