

Biologicals Division

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Pel-Freez®

Analysis Certificate

PRODUCT: Level 2 Modified Rabbit Plasma

CODE NO: 31162L2

LOT NO: 31736-B

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

**DATE OF
MANUFACTURE:** November 13, 2014

PROCEDURE: Modified rabbit plasma is produced from custom rabbit plasma (Pel-Freez Part # 91162 lot 28936) and adsorbed rabbit plasma (Pel-Freez Part # 81162), using Pel-Freez SMP 31162L2. The raw material used to manufacture this lot is independent from the raw material used to manufacture 31162L2 lot 31736-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.

EC 1069/2009:
EU 142/2011: EU # AR-TEC-0007

EU REQUIREMENTS: Product meets EU requirements for production of technical blood products.

APPEARANCE: Clear, amber fluid

ASSAYS: INR obtained using [REDACTED] meter.
Test strips: code 2

Meter	1	2	Average
UP0751548	3.1	3.0	3.1
UP0570781	3.1	3.0	3.1
UP1014649	3.1	3.0	3.1
UP0690781	3.0	3.0	3.0
UP0610760	3.0	3.0	3.0

Target INR – **3.0 to 3.2** INR

QUALITY ASSURANCE

Quality Control Release Date: November 19, 2014



Sarah Graves
Quality Systems Technician

Meets or exceeds specifications ✓
Does not meet specifications

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE