

Biologicals Division

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Pel-Freez®

Analysis Certificate

PRODUCT: Level 1 Modified Rabbit Plasma

CODE NO: 31162L1

LOT NO: 31636-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 12, 2014

PROCEDURE: Modified rabbit plasma is produced from custom rabbit plasma (Pel-Freez Part # 91162 lot 31036) and rat serum (Pel-Freez Part # 36125) using Pel-Freez SMP 31162L1. The rabbit plasma used to manufacture this lot is independent from the rabbit plasma used to manufacture 31162L1 lot 31636-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.

Mature rat whole blood (Sprague-Dawley, averaging 7-8 weeks of age, either sex) is collected at the time of slaughter and refrigerated within 6 hours, and processed within 24 hours. The serum is then thawed, pooled, passed through a 0.22 micron filter, bottled and frozen at or below -10 °C.

EC 1069/2009: 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 06

Meter	1	2	Average
UP0570781	1.2	1.2	1.2
UP0751548	1.2	1.2	1.2
UP1014649	1.2	1.2	1.2
UP0610760	1.2	1.2	1.2
UP0690781	1.2	1.2	1.2

Target INR– **1.1 to 1.3** INR

QUALITY ASSURANCE

Quality Control Release Date: November 18, 2014



Sarah Graves
Quality Systems Technician

Meets or exceeds specifications ✓
Does not meet specifications

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE