

Biologicals Division

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Pel-Freez®

Analysis Certificate

PRODUCT: Level 1 Modified Rabbit Plasma

CODE NO: 31162L1

LOT NO: 32435

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

**DATE OF
MANUFACTURE:** November 20, 2013

PROCEDURE: Modified rabbit plasma is produced from custom rabbit plasma (Pel-Freez Part # 91162) and rat serum (Pel-Freez Part # 36125) 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.

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 50

Meter	1	2	Average
UP0690781	1.2	1.2	1.2
UP0570781	1.1	1.1	1.1
UP0610760	1.1	1.2	1.2
UP0744403	1.2	1.2	1.2
UP0751548	1.1	1.2	1.2

Target INR– 1.2 to 1.3 INR

QUALITY ASSURANCE

Quality Control Release Date: November 22, 2013



Sarah Graves
Quality Systems Technician

Meets or exceeds specifications: ✓
Does not meet specifications

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE