

Biologicals Division

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Pel-Freez®

Analysis Certificate

PRODUCT: Level 1 Modified Rabbit Plasma

CODE NO: 31162L1

LOT NO: 11635

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

**DATE OF
MANUFACTURE:** April 26, 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

APPEARANCE: Clear, amber fluid

ASSAYS: INR obtained using [REDACTED] meter.

Meter	1	2	Average
UP0101611	1.2	1.2	1.2
UP0089865	1.2	1.1	1.2
UP0092011	1.2	1.2	1.2
UP0106678	1.2	1.2	1.2
UP0085038	1.2	1.2	1.2

Target INR– 1.2 to 1.3 INR

QUALITY ASSURANCE

Quality Control Release Date: April 29, 2013



Stephanie Whitmore
Quality Systems Technician

Meets or exceeds specifications: ✓

Does not meet specifications

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE