

Biologicals Division

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Pel-Freez®

Analysis Certificate

PRODUCT: [REDACTED] Level 3 Modified Rabbit Plasma

CODE NO: 31162L3

LOT NO: 11435

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

**DATE OF
MANUFACTURE:** April 24, 2013

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 31162L3.

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 1069/2011: EU # AR-TEC-0007

APPEARANCE: Clear, amber fluid

ASSAYS: INR obtained using [REDACTED] meter.

Meter	1	2	Average
UP0101611	2.4	2.3	2.4
UP0089865	2.4	2.3	2.4
UP0092011	2.3	2.3	2.3
UP0106678	2.3	2.4	2.4
UP0085038	2.4	2.4	2.4

Target INR - **2.2 to 2.5** 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