

Pel-Freez®

Analysis Certificate

PRODUCT: Level 4 Modified Rabbit Plasma INR 3.8

CODE NO: 60015

LOT: 00336

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

**DATE OF
MANUFACTURE:** January 3, 2014

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

PROCEDURE: Rabbit blood was collected at USDA plant P-202 from New Zealand White rabbits (mixed gender, 8-12 weeks, US grown) that were found to be free of contagious diseases. Custom Rabbit Plasma was produced by mixing blood with custom anticoagulant solution according to Pel-Freez SMP 91162, chilled for 2 hours on wet ice and frozen at -70 °C. Adsorbed Rabbit Plasma was produced by mixing Custom Rabbit Plasma with barium sulfate, centrifuged, chilled and frozen at -70 °C in the same manner.

Custom Rabbit Plasma and Adsorbed Rabbit Plasma were thawed, mixed with 9.972 g/L HEPES hemisodium salt, and blended together in proportions to yield a INR value of 3.8.

After mixing thoroughly, the product was chilled for 2 hours on wet ice and frozen at -70 °C.

The QC Testing Data Table on page 2 of this certificate illustrates the ratios tested during production and final QC.

EC 1069/2009:

EU 142/2011: EU # AR-TEC-0007

APPEARANCE: Clear, amber fluid

Biologicals Division

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ASSAYS: INR obtained using [REDACTED] meter.
Test strips: code 5

QC Testing Data Table

Meter	1	2	Average
UP0751548	3.7	3.7	3.7
UP0570781	3.7	3.7	3.7
UP0734328	3.7	3.7	3.7
UP0610760	3.7	3.7	3.7
UP0744403	3.7	3.7	3.7

Target INR – **3.7** INR

QUALITY ASSURANCE

Quality Control Release Date: **January 20, 2014**



Stephanie Whitmore
Quality Systems Technician

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSE