

Biologicals Division

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Pel-Freez®

Analysis Certificate

PRODUCT: Level 1 Modified Rabbit Plasma

CODE NO: 31162L1

LOT NO: 19934

STORAGE: 15 days at -10°C to -20°C or 12 months at -70°C or below.

MANUFACTURE: 17 July 2012

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
UP0076773	1.2	1.2	1.2
UP0035685	1.2	1.2	1.2
UP0036157	1.2	1.2	1.2
UP0078546	1.2	1.2	1.2
UP0070308	1.2	1.2	1.2

Target INR– 1.2 to 1.3

QUALITY ASSURANCE

Quality Control Release Date: July 20, 2012

Bruce Herbert