

Biologicals Division

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Pel-Freez[®]

Analysis Certificate

PRODUCT: [REDACTED] Rabbit Plasma with EDTA, Sterile, Custom

CODE NO: 31164

LOT NO: 02236

PO#: [REDACTED]

STORAGE: -20 °C

DATE OF MANUFACTURE: January 22, 2014

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

PROCEDURE: Rabbit whole blood is collected from healthy young rabbits (New Zealand White, 8 12 weeks of age, either sex, and fasted) at the time of slaughter combined with 25 mL EDTA then QS to 250 mL with blood. The plasma is separated from the blood cellular components by centrifugation and pooled. The specified amount of Sodium Chloride is added and allowed to mix until dissolution is complete. The pH is adjusted and the plasma is then passed through a 0.22-micron filter, bottled and stored at -20 °C.

ASSAYS:

Total Protein: 5.31 g/dl

Hemoglobin: 13.20 mg/dl

Adjusted pH: 6.75 before sterile filtration

Final pH: 7.33 @ 50% Aqueous Solution

Bacterial Coagulase: 5 of 5 *S. aureus* strains +3 or greater at 6 hours. *S. epidermidis* & *E. aerogenes* were negative at 6 hours.

Optical Density: 0.337

Sterility: Pass, no growth at 14 days

QUALITY ASSURANCE

Quality Control Release Date: February 05, 2014

Amended on February 26, 2014 by B Crenshaw:
Corrected quality control release date



Sarah Graves
Quality Systems Technician

Meets or exceeds specifications ✓
Does not meet specifications

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES