

Certificate of Analysis**PRODUCT:** [REDACTED] Rabbit Plasma with EDTA, Sterile,**CODE NO:** 31164**PO#:** [REDACTED]**LOT NO:** 35136**DATE OF MANUFACTURE:** December 17, 2014**STORAGE:** -20 °C**ORIGIN:** U.S.A.**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 to 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.

ANALYSIS		
Required Assays	Specification	Result
Appearance:	Tan to tan yellow in color with trace pink. No indication of high lipid concentration.	Tan to tan yellow in color with trace pink. No indication of high lipid concentration.
Total Protein Assay:	4.0 – 6.5 g/dL	5.19 g/dL
Hemoglobin Assay:	≤ 20 mg/dL	10.00 mg/dL
Adjusted pH:	FIO	6.74 before sterile filtration
Final pH:	FIO	6.98 @ 50% aqueous solution
Bacterial Coagulase:	Four of the five <i>S. aureus</i> strains ≥ 3 at 4 – 6 hours. All <i>S. aureus</i> strains ≥ 3 at 24 hours. <i>S. epidermis</i> and <i>E. aerogenes</i> negative.	5 of 5 <i>S. aureus</i> strains +3 or greater at 6 hours. <i>S. epidermidis</i> & <i>E. aerogenes</i> were negative at 6 hours.
Optical Density	0.250 – 0.500	0.301
Sterility	No growth at 14 days	Passed. No growth at 14 days.

QUALITY ASSURANCE

Quality Control Release Date: January 16, 2015



Sarah Graves

Quality Systems Technician

Meets or exceeds specifications ✓**Does not meet specifications****SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**