

Certificate of Analysis

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

CODE NO: 31164

LOT NO: 29540

STORAGE: -20 °C

PO#: [REDACTED]

DATE OF MANUFACTURE: October 22, 2018

Origin: U.S.A.

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

EU 142/2011: AR TEC 0007

HEALTHY ANIMAL STATEMENT: This product is made from raw materials that were collected from animals and found free from obvious signs of infectious and contagious disease.

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 2.5% Na₂EDTA 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.

APPEARANCE: Tan to tan-yellow with a trace pink color; free of excessive hemolysis

ASSAYS:

Required Assays	Specification	Result
Total Protein Assay:	4.0 – 6.5 g/dL	5.1 g/dL
Hemoglobin Assay:	≤ 20 mg/dL	17 mg/dL
Adjusted pH:	6.6 – 6.8	6.7 before sterile filtration
Final pH:	FIO	6.9 @ 50% aqueous solution
Bacterial Coagulase:	5 of 5 <i>S. aureus</i> strains +3 or greater at 6 - 24 hours. <i>S. epidermidis</i> & <i>E. aerogenes</i> negative at 6 - 24 hours. <i>S. pseudintermedius</i> greater than or equal to 1+ within 24 hours.	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. <i>S. pseudintermedius</i> +1 at 24 hours.
Optical Density:	0.250 – 0.500	0.377
Sterility:	No growth at 14 days	Passed. No growth at 14 days.

QUALITY ASSURANCE

Quality Control Release Date:

November 12, 2018



Sarah Graves
 Quality Systems Technician

Meets or exceeds specifications ☒

Does not meet specifications ☐

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES