

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

CODE NO: 31164

LOT NO: 35037

STORAGE: -20 °C

PO#: 6500214259

DATE OF MANUFACTURE: December 16, 2015

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 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 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:

Required Assays	Specification	Result
Total Protein Assay:	4.0 – 6.5 g/dL	5.24 g/dL
Hemoglobin Assay:	≤ 20 mg/dL	16.80 mg/dL
Adjusted pH:	6.6 – 6.8	6.7 before sterile filtration
Final pH:	FIO	7.12 @ 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.	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	0.469
Sterility*:	No growth at 14 days	1 L pack size and repeat 5 mL retention sample passed with no growth at 14 days in either thioglycollate and tryptic soy broth cultures.

*Growth noted in thioglycollate broth for 20 mL pack size sterility sample; no growth noted in tryptic soy broth for 20 mL pack size. Did not retest this sample size due to the need to consume an additional 20 mL sample. No growth noted in any tryptic soy broth culture for any pack size nor any growth observed in any of the plasma samples of any pack size incubated at 37°C for the duration of the 14 day sterility assay. Repeated sterility assay with 5 mL sample representative of the lot. No growth observed in either thioglycollate or tryptic soy broth for 5 mL sample. No growth observed in either thioglycollate or tryptic soy broth for 1 L pack size.



QUALITY ASSURANCE

Quality Control Release Date:

February 3, 2016

S. Graves

Sarah Graves

Quality Systems Technician

Meets or exceeds specifications ☒

Does not meet specifications ☐

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES