

Certificate of Analysis

PRODUCT: [REDACTED] Rabbit Plasma with EDTA, Sterile, Custom**CODE NO:** 31164**LOT NO:** 10438**PO#:** [REDACTED]**STORAGE:** -20 °C**DATE OF
MANUFACTURE:** April 13, 2016**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	5.4 g/dL
Hemoglobin Assay:	≤ 20 mg/dL	20 mg/dL
Adjusted pH:	6.6 – 6.8	6.8 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.	5 of 5 <i>S. aureus</i> strains +3 or greater at 6 hours. <i>S. epidermidis</i> & <i>E.</i> <i>aerogenes</i> were negative at 6 hours.
Optical Density:	0.250 – 0.500	0.347
Sterility:	No growth at 14 days	Passed. No growth at 14 days.

QUALITY ASSURANCE

Quality Control Release Date: April 29, 2016

Sarah Graves
Quality Systems Technician**Meets or exceeds specifications** ☒**Does not meet specifications** ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**