

Certificate of Analysis

PRODUCT: [REDACTED] Rabbit Plasma with EDTA, Sterile, Custom**CODE NO:** 31164**LOT NO:** 03339-PILOT**STORAGE:** -20 °C**PO#:** N/A**DATE OF
MANUFACTURE:** February 2, 2017**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.

ASSAYS:	Required Assays	Specification	Result
	Total Protein Assay:	4.0 – 6.5 g/dL	5.3 g/dL
	Hemoglobin Assay:	≤ 20 mg/dL	17 mg/dL
	Adjusted pH:	6.6 – 6.8	6.7 before sterile filtration
	Final pH:	FIO	7.0 @ 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	0.377
	Sterility:	No growth at 14 days	Passed. No growth at 14 days.

QUALITY ASSURANCE

Quality Control Release Date: February 16, 2017

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