

Certificate of Analysis

PRODUCT: [REDACTED], Custom Rabbit Plasma with Sodium Citrate,**CODE NO:** 31163**LOT NO:** 08739**STORAGE:** -20 °C**PO#:** [REDACTED]**DATE OF
MANUFACTURE:** March 28, 2017**Origin:** U.S.A.**EU REQUIREMENTS:** Product meets European Union requirements for production of technical blood products.**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 50ml of 8.5% Sodium Citrate 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 plasma is then pre-filtered and passed through a 0.22-micron filter, bottled and stored at -20 °C.**ASSAYS:**

Required Assays	Specification	Result
Total Protein Assay:	3.9 – 6.5 g/dL	3.9 g/dL
Hemoglobin Assay:	≤ 20 mg/dL	10 mg/dL
Final pH:	6.5 – 8.5	7.6 at 1:2 aqueous dilution
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:	0.200 – 1.300	0.244
Sterility:	No growth at 14 days	Passed. No growth at 14 days.

QUALITY ASSURANCE

Quality Control Release Date: April 13, 2017

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