

Certificate of Analysis

PRODUCT: [REDACTED], Custom Rabbit Plasma with Sodium Citrate,**CODE NO:** 31163**LOT NO:** 14738**STORAGE:** -20 °C**PO#:** [REDACTED]**DATE OF
MANUFACTURE:** May 26, 2016**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 8.5% Sodium Citrate and processed per customer specifications. 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:	4.0 – 6.5 g/dL	4.1 g/dL
Hemoglobin Assay:	≤ 20 mg/dL	11 mg/dL
Final pH:	6.5 – 8.5 at 1:2 aqueous dilution	7.8 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	0.260
Sterility:	No growth at 14 days	Passed. No growth at 14 days.

QUALITY ASSURANCE

Quality Control Release Date: June 10, 2016



Sarah Graves

Quality Systems Technician

Meets or exceeds specifications ☒**Does not meet specifications** ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**