

Certificate of Analysis

PRODUCT: [REDACTED], Custom Rabbit Plasma with Sodium Citrate,

CODE NO: 31163 **LOT NO:** [REDACTED]
STORAGE: -20 °C **PO#:** [REDACTED]
DATE OF MANUFACTURE: September 13, 2022 **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 (albino, 8–12 weeks of age, either sex, and fasted) at the time of slaughter, combined with 50 mL of 8.5% sodium citrate, and 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. Then the plasma is pre-filtered, passed through a 0.22-micron filter, bottled, and stored at -20 °C.

APPEARANCE: Tan to tan-yellow with a trace pink color; free of excessive hemolysis

ASSAYS:

Required Assays	Specification	Result
Total Protein Assay:	3.9 – 6.5 g/dL	4.1 g/dL
Hemoglobin Assay:	≤ 20 mg/dL	12 mg/dL
pH at 1:2 dilution:	6.5 – 8.5	7.78
Bacterial Coagulase at 1:2 dilution:	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. <i>S. pseudintermedius</i> greater than or equal to 1+ within 24 hours.	5 of 5 <i>S. aureus</i> strains +4 at 6 hours. <i>S. epidermidis</i> & <i>E. aerogenes</i> were negative at 6 hours. <i>S. pseudintermedius</i> +4 at 6 hours.
Optical Density at 1:2 dilution:	0.200 – 1.300	0.268
Sterility:	No growth at 14 days	Pass

QUALITY ASSURANCE

Quality Control Release Date:

September 29, 2022



Doug Stocker
 Quality Systems Technician

Meets or exceeds specifications ☒

Does not meet specifications ☐

Updated by T.Kwasny on 27Jan2023 to include PO#.

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES