

## Certificate of Analysis

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

**CODE NO:** 31163 **LOT NO:** 26344

**STORAGE:** -20 °C **PO#:** 6501119759

**DATE OF MANUFACTURE:** September 20, 2022 **Origin:** U.S.A.

**EU REQUIREMENTS:** Product meets European Union requirements for production of technical blood products.

**HEALTHY ANIMAL STATEMENT:**

**PROCEDURE:** This product is made from raw materials that were collected from animals and found free from obvious signs of infectious and contagious disease.

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                                                                                                                                                                                                     | 3.9 g/dL                                                                                                                                                                                                           |
| Hemoglobin Assay:                    | ≤ 20 mg/dL                                                                                                                                                                                                         | 10 mg/dL                                                                                                                                                                                                           |
| pH at 1:2 dilution:                  | 6.5 – 8.5                                                                                                                                                                                                          | 7.7                                                                                                                                                                                                                |
| Bacterial Coagulase at 1:2 dilution: | 5 of 5 <i>S. aureus</i> strains +3 or greater at 6 - 24 hours.<br><i>S. epidermidis</i> & <i>E. aerogenes</i> negative at 6 - 24 hours.<br><i>S. pseudintermedius</i> greater than or equal to 1+ within 24 hours. | 5 of 5 <i>S. aureus</i> strains +3 or greater at 6 - 24 hours.<br><i>S. epidermidis</i> & <i>E. aerogenes</i> negative at 6 - 24 hours.<br><i>S. pseudintermedius</i> greater than or equal to 1+ within 24 hours. |
| Optical Density at 1:2 dilution:     | 0.200 – 1.300                                                                                                                                                                                                      | 0.284                                                                                                                                                                                                              |
| Sterility:                           | No growth at 14 days                                                                                                                                                                                               | No growth at 14 days                                                                                                                                                                                               |

### QUALITY ASSURANCE

Quality Control Release Date: October 6, 2022



Avery Donson  
Quality Systems Clerk/Tech

**Meets or exceeds specifications** ☒

**Does not meet specifications** ☐

Amended to include customer PO# T. Kwasny 04Oct2023

**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**