

### Certificate of Analysis

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

**CODE NO:** 31164

**LOT NO:** 30644

**STORAGE:** -20 °C

**PO#:** [REDACTED]

**DATE OF**

**MANUFACTURE:** November 2, 2022

**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% Na<sub>2</sub>EDTA 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.

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

**ASSAYS:**

| Required Assays                                | Specification                                                                                                                                                                                                | Result                                                                                                                                                                    |
|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Total Protein Assay:                           | 4.0 – 6.5 g/dL                                                                                                                                                                                               | 5.3 g/dL                                                                                                                                                                  |
| Hemoglobin Assay:                              | ≤ 20 mg/dL                                                                                                                                                                                                   | 20 mg/dL                                                                                                                                                                  |
| pH tested undiluted before sterile filtration: | 6.6 – 6.8                                                                                                                                                                                                    | 6.8 before sterile filtration                                                                                                                                             |
| pH at 1:2 dilution:                            | FIO                                                                                                                                                                                                          | 7.14 @ 50% aqueous solution                                                                                                                                               |
| 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 +3 or greater at 6 hours. <i>S. epidermidis</i> & <i>E. aerogenes</i> were negative at 6 hours. <i>S. pseudintermedius</i> +3 at 6 hours. |
| Optical Density at 1:2 dilution:               | 0.250 – 0.500                                                                                                                                                                                                | 0.398                                                                                                                                                                     |
| Sterility:                                     | No growth at 14 days                                                                                                                                                                                         | Pass                                                                                                                                                                      |

#### QUALITY ASSURANCE

Quality Control Release Date:

November 18, 2022



Sarah Graves  
 Quality Systems Technician

**Meets or exceeds specifications** ☒

**Does not meet specifications** ☐

**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**

