

## Certificate of Analysis

**PRODUCT:** [REDACTED] Rabbit Plasma with EDTA, Sterile, Custom**CODE NO:** 31164**LOT NO:** 01437**PO#:** [REDACTED]**DATE OF  
MANUFACTURE:** January 14, 2015**Origin:** U.S.A.**STORAGE:** -20 °C**EU  
REQUIREMENTS:** Product meets European Union requirements for production of technical blood products.

**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 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.

**ASSAYS:**

| Required Assays      | Specification                                                                                                                        | Result                                                                                                                          |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| Total Protein Assay: | 4.0 – 6.5 g/dL                                                                                                                       | 5.25 g/dL                                                                                                                       |
| Hemoglobin Assay:    | ≤ 20 mg/dL                                                                                                                           | 13.20 mg/dL                                                                                                                     |
| Adjusted pH:         | FIO                                                                                                                                  | 6.75 before sterile filtration                                                                                                  |
| Final pH:            | FIO                                                                                                                                  | 7.03 @ 50% aqueous solution                                                                                                     |
| 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:     | 0.250 – 0.500                                                                                                                        | 0.301                                                                                                                           |
| Sterility:           | No growth at 14 days                                                                                                                 | Pass, no growth at 14 days.                                                                                                     |

**QUALITY ASSURANCE**

Quality Control Release Date: January 28, 2015

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