

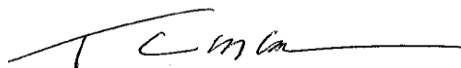
Certificate of Analysis**PRODUCT:** [REDACTED] Rabbit Plasma with EDTA, Sterile, Custom**CODE NO:** 31164**LOT NO:** 05642**STORAGE:** -20 °C**PO#:** [REDACTED]**DATE OF
MANUFACTURE:** February 25, 2020**Origin:** U.S.A.**EU
REQUIREMENTS:** Product meets European Union
requirements for production of
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% Na₂EDTA 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	5.5 g/dL
Hemoglobin Assay:	≤ 20 mg/dL	16 mg/dL
Adjusted pH:	6.6 – 6.8	6.8 before sterile filtration
Final pH:	FIO	7.1 @ 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. <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.</i> <i>aerogenes</i> were negative at 6 hours. <i>S. pseudintermedius</i> +4 at 24 hours.
Optical Density:	0.250 – 0.500	0.357
Sterility:	No growth at 14 days	Pass

QUALITY ASSURANCE

Quality Control Release Date:

March 17, 2020

Theresa Kwasny
Quality Systems Manager**Meets or exceeds specifications** ☒**Does not meet specifications** ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**