

Certificate of Analysis

PRODUCT: Rabbit Serum, Sterile, Trace-Hemolyzed, Heat Inactivated**CODE NO:** 31121**CUSTOMER PART NO:** 12309**LOT NO:** 35440**DATE OF
MANUFACTURE:** December 20, 2018**DATE OF EXPIRATION:** December 20, 2020**ORIGIN:** U.S.A.**STORAGE:** -10 °C or below**EU
REQUIREMENTS:** Product meets EU requirements for production of technical blood products.**HEALTHY
ANIMAL
STATEMENT:** This product is made from raw materials that were collected from animals found free from obvious signs of infectious and contagious disease.**PROCEDURE:** Whole blood from young healthy rabbits (New Zealand White and/or California White, 8–12 weeks of age, either sex, and fasted) is collected at the time of slaughter, processed within 6 hours and frozen. The serum is thawed, pooled, heat inactivated for 60 minutes at 56 °C, pre-filtered with a filter press, filtered with a 0.22µm filter, bottled, and frozen.**ASSAYS:**

Required Assays	Specification	Result
Total Protein	5.0 – 7.5 g/dL	5.8 g/dL
Hemoglobin	≤ 45 mg/dL	19 mg/dL
pH	Report result	8.1
Sterility	No growth at 14 days.	Passed. No growth at 14 days.
Bioburden	Report result	Heat tank: 0 cfu/plate Pressure tank: 0 cfu/plate
Endotoxin	≤ 200 EU/mL	5 EU/mL
Glucose	≥100 mg/dL	127 mg/dL

QUALITY ASSURANCE

Quality Control Release Date:

February 27, 2019

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