

Certificate of Analysis

PRODUCT: Rabbit Plasma Sterile Custom- [REDACTED]**CODE NO:** 31154**LOT NO:** 05537**DATE OF
MANUFACTURE:** February 24, 2015**ORIGIN:** U.S.A.**STORAGE:** 2-8 °C**EU
REQUIREMENTS:** Product meets EU 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, mixed sex) at time of slaughter. The blood is combined at 25 ml 3.5% EDTA then QS to 250 ml with blood. The plasma is separated from the blood cellular components by centrifugation. The plasma is pooled, passed through a 0.22 micron filter, bottled, and stored at 2-8 °C prior to shipment on wet ice.

ASSAYS:

Required Assays	Specification	Result
Total Protein:	4.0 – 6.5 g/dL	4.90 g/dL
Hemoglobin:	≤ 20 mg/dL	11.60 mg/dL
pH:	7.0 – 8.5	7.71
Coagulation:	Clot formation	No clot formed after 10 minute incubation with Milli-Q water and thromboplastin D. However, a clot formed after 10 minute incubation in reaction supplemented with 10 mM calcium chloride (final concentration).
Sterility:	No growth at 14 days	<i>Passed. No growth at 14 days.</i>

QUALITY ASSURANCE

Quality Control Release Date: February 24, 2015

Amended by S.Graves on February 25, 2015: Total Protein concentration amended and clarification regarding coagulation testing added



Quality Systems Technician

Meets or exceeds specifications ☐**Does not meet specifications** ☒*Clotting reaction requires supplementation of 10 mM Calcium Chloride (final concentration)***SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**