

Certificate of Analysis

PRODUCT: Rabbit Serum, Non-Hemolyzed, Sterile, Young, Heat Inactivated**CODE NO:** 31129**LOT NO:** 07137**DATE OF
MANUFACTURE:** March 12, 2015**DATE OF
EXPIRATION:** March 12, 2017**ORIGIN:** U.S.A.**STORAGE:** At or below -10 °C**EU
REQUIREMENTS:** Product meets European Union
requirements of production of technical
blood products.**CUSTOMER
PART NO:** 15-02708-00**PROCEDURE:** Whole blood from young healthy rabbits (New Zealand 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 at
0.22µm filter, bottled, and frozen.

ASSAYS:	Required Assays	Specification	Result
	Total Protein:	5.0 – 7.5 g/dL	6.18 g/dL
	Hemoglobin:	≤ 20 mg/dL	10.00 mg/dL
	pH:	7.0 – 8.5	7.80
	Sterility:	No growth at 14 days	Passed. No growth at 14 days.
	Bioburden:	0 cfu/plate	Heat tank: 0 cfu/plate Pressure tank: 9 cfu/plate
	Endotoxin:	≤ 200 EU/mL	< 1.6 EU/mL
	Glucose:	≥ 100 mg/dL	133 mg/dL

QUALITY ASSURANCE

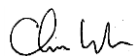
Quality Control Release Date: April 10, 2015

Sarah Graves
Quality Systems Technician**Meets or exceeds specifications** ☒**Does not meet specifications** ☐

Addendum: Re: Pel-Freez Nonconforming Material Report #15-017.

Description of Nonconformity: Alconox is specified in the manufacture procedure for cleaning equipment used during the heat inactivation and sterile filtration processes for this custom product; however, Alconox was on extended backorder at the time of manufacturing and did not arrive in time for this production run. Liquinox is another detergent that was on hand at the time of the manufacturing event and was used to clean the equipment.

As this run was scheduled in conjunction with a site visit by representatives of IDEXX, IDEXX representatives were informed of this issue during the site visit, just prior to the manufacturing event. After review with IDEXX representatives, the differences in detergents were deemed significant enough to warrant a manufacturing change. In order for the IDEXX representatives to complete their audit of the manufacturing process, the manufacturing event proceeded and the lot was produced with the expectation that the lot will need to be evaluated by IDEXX prior to acceptance.



Chris Lyle
Director, Biologicals Division and
Scientist, Operational Technical Support
Pel-Freez Biologicals

SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES