

Lipogro® - Triple 0.1 µm Filtered, US Origin

Product Number: LPG-BPG-1XM LPG-BPG-CSP
LPG-BPG-5XM LPG-BPG-SMP
LPG-BPG-01L

Lot Number: 20160908LP
Date of Manufacture: 09/2016
Expiration Date: 09/2018
Storage Temperature: 2 - 8°C



BASIS FOR RELEASE

NOT FOR HUMAN OR ANIMAL CONSUMPTION

CHEMICAL ANALYSIS			
Test	Method	Specification	Result
Calcium	Chemistry Analyzer	≤ 5 mg/dL	< 5 mg/dL
Cholesterol Concentration	Chemistry Analyzer	900 -1100 mg/dL	967 mg/dL
IgG	ELISA	As Reported	0.23 µg/mL
pH	pH Meter	7.0 - 8.4	7.6
Potassium	Chemistry Analyzer	≤ 10 mEq/L	< 1 mEq/L
Sodium	Chemistry Analyzer	≤ 50 mEq/L	< 5 mEq/L
Total Protein	Chemistry Analyzer	≤ 2 g/dL	< 2 g/dL

VIRAL ANALYSIS			
Test	Method	Specification	Result
Blue Tongue	9CFR 113.53	Not Detected	Not Detected
Bovine Adeno 1	9CFR 113.53	Not Detected	Not Detected
Bovine Adeno 5	9CFR 113.53	Not Detected	Not Detected
BPV	9CFR 113.53	Not Detected	Not Detected
BRSV	9CFR 113.53	Not Detected	Not Detected
BVD Cytopathic	9CFR 113.53	Not Detected	Not Detected
BVD Non-Cytopathic	9CFR 113.53	Tested	Not Detected
Cytopathic (IBR)	9CFR 113.53	Not Detected	Not Detected
Hemadsorbing (PI3)	9CFR 113.53	Not Detected	Not Detected
Rabies	9CFR 113.53	Not Detected	Not Detected
REO Virus	9CFR 113.53	Not Detected	Not Detected

MICROBIOLOGICAL ANALYSIS			
Test	Method	Specification	Result
Endotoxin	LAL	< 50 EU/mL	22.3 EU/mL
Mycoplasma	9CFR 113.28	Not Detected	Not Detected
Sterility	9CFR 113.26	No Growth	No Growth

IDENTITY ANALYSIS			
Test	Method	Specification	Result
Appearance	Visual	Clear, Yellow-Amber	Pass

STATEMENT OF ORIGIN

Raw serum used in the manufacture of this product was obtained from approved suppliers collecting from abattoirs in the United States from traceable animals originating from the United States. Full health, traceability, and required regulatory documentation are maintained under RMBIO's quality systems. The serum was processed, filtered, and finished in the United States.

BSE/TSE STATEMENT

The United States of America is recognized as having negligible BSE/TSE risk by the World Organization for Animal Health (OIE).


ISIA CERTIFICATE TRACEABILITY

All raw serum is certified by the International Serum Industry Association (ISIA) to be sourced in accordance with their strict guidelines. (www.serumindustry.org).

EUROPEAN UNION ELIGIBILITY

Product meets European Union Requirements of Technical Blood Products.

Approval

Quality Assurance- Print Name: Terri Sorensen	Quality Assurance- Sign Name: 	Date: 14 Nov 2014
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