RMBIO

Rocky Mountain Biologicals, Inc

Certificate of Analysis

Fetal Bovine Serum–Triple 0.1 µm Filtered, US origin

Product number: FBS-BBT-XXX

Lot Number: 20141230FS

Date of Manufacture: 12/2014

Expiration date: 12/2019

Storage temperature: -5 to -20°C

Not for human or animal consumption

Basis for Release

Chemical Analysis				Microbiological Analysis			
Test	**Method**	**Specification**	**Result**	**Test**	**Method**	**Specification**	**Result**
Total Protein	Chemistry Analyzer	≤ 4.5 g/dL	3.5 g/dL	Sterility	USP/EP	No growth	No growth
Albumin	Chemistry Analyzer	≤ 2.5 g/dL	2.2 g/dL	Mycoplasma	Direct Culture	Not Detected	Not Detected
Globulin	Chemistry Analyzer	As reported	1.3 g/dL	Endotoxin	LAL	< 10.0 EU/mL	< 1.0 EU/mL
Bilirubin	Chemistry Analyzer	As reported	0.2 mg/dL	**Viral Analysis**			
ALT	Chemistry Analyzer	As reported	5 U/L	**Test**	**Method**	**Specification**	**Result**
AST	Chemistry Analyzer	As reported	52 U/L	BVDV	9CFR 113.53	Tested	Tested
Cholesterol	Chemistry Analyzer	As reported	31 mg/dL	Rabies	9CFR 113.53	Not Detected	Not Detected
Glucose	Chemistry Analyzer	As reported	95 mg/dL	Blue Tongue	9CFR 113.53	Not Detected	Not Detected
Urea	Chemistry Analyzer	As reported	14 mg/dL	Bovine Adeno 1	9CFR 113.53	Not Detected	Not Detected
Creatinine	Chemistry Analyzer	As reported	2.4 mg/dL	Bovine Adeno 5	9CFR 113.53	Not Detected	Not Detected
Sodium	Chemistry Analyzer	As reported	133 mEq/L	BPV	9CFR 113.53	Not Detected	Not Detected
Potassium	Chemistry Analyzer	As reported	> 10 mEq/L	BRSV	9CFR 113.53	Not Detected	Not Detected
Calcium	Chemistry Analyzer	As reported	13.6 mg/dL	REO Virus	9CFR 113.53	Not Detected	Not Detected
Phosphorus	Chemistry Analyzer	As reported	10.6 mg/dL	Hemadsorbing Agents (PI3)	9CFR 113.53	Not Detected	Not Detected
Osmolality	Osmometer	As reported	298 mOsm/kg	Cytopathic Agents (IBR)	9CFR 113.53	Not Detected	Not Detected
Hemoglobin	Spectro-photometer	≤ 25.0 mg/dL	10.5 mg/dL	**Identity Analysis**			
pH	pH meter	6.80 – 8.20	7.23	**Test**	**Method**	**Specification**	**Result**
IgG	ELISA	As reported	70 µg/mL	Serum Identity	Electrophoresis	Characteristic	Characteristic
				Appearance	Visual	Clear yellow-amber	Clear yellow-amber

PRODUCT MEETS EUROPEAN UNION REQUIREMENTS FOR PRODUCTION OF TECHNICAL BLOOD PRODUCTS

STATEMENT OF ORIGIN

This serum has been derived from blood collected in approved abattoirs in the United States of America. The serum was processed and filtered in the US. The country of origin of the crude blood is the United States.

Approval

Quality Assurance – Print Name:	Quality Assurance – Sign Name:	Date:
Terri Sorensen	TKSorensen	12 Apr 2016

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