

Certificate of Analysis

Calf Serum- 0.2 µm Filtered, US Origin

Product Number: CSF-BBT-5XM
 CSF-BBT-01L
 CSF-BBT-SMP
 CSF-BBT-CSP

Lot Number: 20160906CS
 Date of Manufacture: 09/2016
 Expiration Date: 09/2021
 Storage Temperature: ≤ -10 °C



BASIS FOR RELEASE

NOT FOR HUMAN OR ANIMAL CONSUMPTION

CHEMICAL ANALYSIS			
Test	Method	Specification	Result
Albumin	Chemistry Analyzer	As Reported	3.3 g/dL
ALT	Chemistry Analyzer	As Reported	20 U/L
AST	Chemistry Analyzer	As Reported	106 U/L
Bilirubin	Chemistry Analyzer	As Reported	0.4 mg/dL
Calcium	Chemistry Analyzer	As Reported	10.3 mg/dL
Chloride	Chemistry Analyzer	As Reported	99 mEq/L
Cholesterol	Chemistry Analyzer	As Reported	141 mg/dL
Creatinine	Chemistry Analyzer	As Reported	0.4 mg/dL
Globulin	Chemistry Analyzer	As Reported	3.7 g/dL
Glucose	Chemistry Analyzer	As Reported	80 mg/dL
Hemoglobin	USP < 90 >	≤ 30 mg/dL	13.1 mg/dL
Iron	Chemistry Analyzer	As Reported	79 µg/dL
Magnesium	Chemistry Analyzer	As Reported	2.1 mg/dL
Osmolality	Osmometer	260-340 mOsm/kg	293 mOsm/kg
pH	pH Meter	As Reported	7.8
Phosphorus	Chemistry Analyzer	As Reported	9.3 mg/dL
Potassium	Chemistry Analyzer	As Reported	6 mEq/L
Sodium	Chemistry Analyzer	As Reported	141 mEq/L
Total Protein	Chemistry Analyzer	As Reported	7 g/dL
Triglyceride	Chemistry Analyzer	As Reported	< 15 mg/dL
Urea	Chemistry Analyzer	As Reported	7 mg/dL

MICROBIOLOGICAL ANALYSIS			
Test	Method	Specification	Result
Endotoxin	LAL	As Reported	1.3 EU/mL
Mycoplasma	9CFR 113.28	Not Detected	Not Detected
Sterility	9CFR 113.26	No Growth	No Growth

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

IDENTITY ANALYSIS			
Test	Method	Specification	Result
Appearance	Visual	Clear Yellow-Amber	Pass
Serum Identity	Electrophoresis	Characteristic	Characteristic

Rocky Mountain Biologicals, Inc.

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 www.rmbio.com

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ADDITIONAL LOT INFORMATION

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Additional Testing

GROWTH PROMOTION/CYTOTOXICITY			CUSTOMER SPECIFIC			
Test	Specification	Result	Test	Method	Specification	Result
CHO	As reported	Not Tested	Not Requested			
CHO Cell Cytotoxicity	As reported	Not Tested	Not Requested			
Vero	As reported	Not Tested	Not Requested			
Vero Cell Cytotoxicity	As reported	Not Tested	Not Requested			

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).

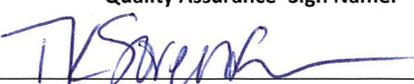
ISIA CERTIFICATE TRACEABILITY

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	Quality Assurance- Sign Name:	Date:
Terri Sorensen		10/25/16