

# Certificate of Analysis

## Newborn Calf Serum- 0.2 µm Filtered, US Origin

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

Lot Number: 20161211NB  
 Date of Manufacture: 12/2016  
 Expiration Date: 12/2021  
 Storage Temperature: ≤ -10 °C



BASIS FOR RELEASE

NOT FOR HUMAN OR ANIMAL CONSUMPTION

### CHEMICAL ANALYSIS

Test	Method	Specification	Result
Albumin	Chemistry Analyzer	As Reported	2.6 g/dL
ALT	Chemistry Analyzer	As Reported	23 U/L
AST	Chemistry Analyzer	As Reported	92 U/L
Bilirubin	Chemistry Analyzer	As Reported	1.2 mg/dL
Calcium	Chemistry Analyzer	As Reported	10.8 mg/dL
Chloride	Chemistry Analyzer	As Reported	94 mEq/L
Cholesterol	Chemistry Analyzer	As Reported	< 50 mg/dL
Creatinine	Chemistry Analyzer	As Reported	1.1 mg/dL
Globulin	Chemistry Analyzer	As Reported	3.1 g/dL
Glucose	Chemistry Analyzer	As Reported	73 mg/dL
Hemoglobin	Spectro. Assay	< 30 mg/dL	15.3 mg/dL
Iron	Chemistry Analyzer	As Reported	81 µg/dL
Osmolality	Osmometer	240-360 mOsm/kg	288 mOsm/kg
pH	pH Meter	6.5 - 8.5	7.9
Phosphorus	Chemistry Analyzer	As Reported	7.1 mg/dL
Potassium	Chemistry Analyzer	As Reported	5.9 mEq/L
Sodium	Chemistry Analyzer	As Reported	137 mEq/L
Total Protein	Chemistry Analyzer	3.0 - 6.0 g/dL	5.7 g/dL
Urea	Chemistry Analyzer	As Reported	16 mg/dL

### MICROBIOLOGICAL ANALYSIS

Test	Method	Specification	Result
Endotoxin	LAL	≤ 35 EU/mL	< 0.6 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 Requested	Not Requested			
CHO Cell Cytotoxicity	As reported	Not Requested	Not Requested			
Vero	As reported	Not Requested	Not Requested			
Vero Cell Cytotoxicity	As reported	Not Requested	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).

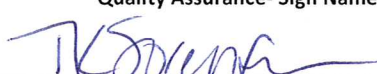
#### ISIA Certificate Traceability

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

#### EUROPEAN UNION ELIGIBILITY

Product meets European Union requirements for production of technical blood products.

#### Approval

Quality Assurance- Print Name <b>Terri Sorensen</b>	Quality Assurance- Sign Name: 	Date: 14 Jan 2017
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