



Rocky Mountain Biologicals, Inc

Certificate of Analysis

Donor Equine Serum- 0.2 µm Filtered, Gamma Irradiated, US Origin

Product Number: DES-BTG-5XM
 DES-BTG-01L
 DES-BTG-SMP
 DES-BTG-CSP

Lot Number: 20160915ES
 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	2.8 g/dL
ALT	Chemistry Analyzer	As Reported	10 U/L
AST	Chemistry Analyzer	As Reported	305 U/L
Bilirubin	Chemistry Analyzer	As Reported	0.8 mg/dL
Calcium	Chemistry Analyzer	As Reported	10 mg/dL
Cholesterol	Chemistry Analyzer	As Reported	78 mg/dL
Creatinine	Chemistry Analyzer	As Reported	1 mg/dL
Globulin	Chemistry Analyzer	As Reported	4 g/dL
Glucose	Chemistry Analyzer	As Reported	70 mg/dL
Osmolality	Osmometer	206-345 mOsm/kg	277 mOsm/kg
pH	pH Meter	6.0 - 8.5	8.1
Phosphorus	Chemistry Analyzer	As Reported	4.2 mg/dL
Potassium	Chemistry Analyzer	As Reported	4.4 mEq/L
Sodium	Chemistry Analyzer	As Reported	133 mEq/L
Total Protein	Chemistry Analyzer	6.0 - 9.5 g/dL	6.8 g/dL

MICROBIOLOGICAL ANALYSIS

Test	Method	Specification	Result
Endotoxin	LAL	≤ 50 EU/mL	2.4 EU/mL
Mycoplasma	9CFR 113.28	Not Detected	Not Detected
Sterility	9CFR 113.26	No Growth	No Growth

VIRAL ANALYSIS

Test	Method	Specification	Result
BVD	9CFR 113.53	Not Detected	Not Detected
CPE	9CFR 113.53	Not Detected	Not Detected
EHV	9CFR 113.53	Not Detected	Not Detected
EIA	9CFR 113.53	Not Detected	Not Detected
EVA	9CFR 113.53	Not Detected	Not Detected
Hemadsorbing	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 Amber Solution	Pass

All test results reported on this Certificate of Analysis are from representative batch samples tested prior to gamma irradiation.

Rocky Mountain Biologicals, Inc.
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 www.rmbio.com



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ADDITIONAL LOT INFORMATION

NOT FOR HUMAN OR ANIMAL CONSUMPTION

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 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.

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