

Fetal Bovine Serum- Triple 0.1 µm Filtered, US Origin

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

Lot Number: 20170220FS
 Date of Manufacture: 02/2017
 Expiration Date: 02/2022
 Storage Temperature: ≤ -10 ° C



BASIS FOR RELEASE

NOT FOR HUMAN OR ANIMAL CONSUMPTION

CHEMICAL ANALYSIS			
Test	Method	Specification	Result
Albumin	Chemistry Analyzer	≤ 4.5 g/dL	2.0 g/dL
ALT	Chemistry Analyzer	As Reported	< 6 U/L
AST	Chemistry Analyzer	As Reported	34 U/L
Bilirubin	Chemistry Analyzer	As Reported	0.3 mg/dL
Calcium	Chemistry Analyzer	As Reported	13.8 mg/dL
Chloride	Chemistry Analyzer	As Reported	103 mEq/L
Cholesterol	Chemistry Analyzer	As Reported	< 50 mg/dL
Creatinine	Chemistry Analyzer	As Reported	2.9 mg/dL
Globulin	Chemistry Analyzer	As Reported	1.7 g/dL
Glucose	Chemistry Analyzer	As Reported	95 mg/dL
Hemoglobin	USP < 90 >	< 30 mg/dL	4.6 mg/dL
IgG	ELISA	As Reported	140.5 µg/mL
Iron	Chemistry Analyzer	As Reported	157 µg/dL
Osmolality	Osmometer	280-360 mOsm/kg	307 mOsm/kg
pH	pH Meter	6.5 - 8.5	7.4
Phosphorus	Chemistry Analyzer	As Reported	9.3 mg/dL
Potassium	Chemistry Analyzer	As Reported	9.8 mEq/L
Sodium	Chemistry Analyzer	As Reported	142 mEq/L
Total Protein	Chemistry Analyzer	3.0 - 4.5 g/dL	3.7 g/dL
Urea	Chemistry Analyzer	As Reported	16 mg/dL

MICROBIOLOGICAL ANALYSIS			
Test	Method	Specification	Result
Endotoxin	LAL	≤ 10.0 EU/mL	< 0.25 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

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ADDITIONAL LOT INFORMATION

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Additional Testing

GROWTH PROMOTION/CYTOTOXICITY			CUSTOMER SPECIFIC		
Test	Specification	Result	Test	Specification	Result
CHO	As Reported	97.4 %	Not Requested		
CHO Cell Cytotoxicity	As Reported	3.0 %	Not Requested		
Vero	As Reported	104.5 %	Not Requested		
Vero Cell Cytotoxicity	As Reported	0.6 %	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 RM BIO'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 for production of technical blood products.

Approval

Quality Assurance- Print Name:	Quality Assurance- Sign Name:	Date:
Terri Sorensen	<i>TSorensen</i>	10 Apr 2017