

Certificate of Analysis

Fetalgro®- Triple 0.1 µm Filtered, US Origin

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

Lot Number: 20170425FG
 Date of Manufacture: 04/2017
 Expiration Date: 04/2022
 Storage Temperature: ≤ -10 ° C



BASIS FOR RELEASE

NOT FOR HUMAN OR ANIMAL CONSUMPTION

CHEMICAL ANALYSIS			
Test	Method	Specification	Result
Albumin	Chemistry Analyzer	As Reported	3.2 g/dL
ALT	Chemistry Analyzer	As Reported	8 U/L
AST	Chemistry Analyzer	As Reported	60 U/L
Bilirubin	Chemistry Analyzer	As Reported	0.5 mg/dL
Calcium	Chemistry Analyzer	As Reported	7.5 mg/dL
Cholesterol	Chemistry Analyzer	As Reported	70 mg/dL
Creatinine	Chemistry Analyzer	As Reported	1.5 mg/dL
Globulin	Chemistry Analyzer	As Reported	2.4 g/dL
Glucose	Chemistry Analyzer	As Reported	101 mg/dL
Hemoglobin	USP < 90 >	< 30 mg/dL	9.2 mg/dL
Osmolality	Osmometer	260-340 mOsm/kg	309 mOsm/kg
pH	pH Meter	6.5 - 8.5	7.4
Phosphorus	Chemistry Analyzer	As Reported	7.8 mg/dL
Potassium	Chemistry Analyzer	As Reported	15.6 mEq/L
Sodium	Chemistry Analyzer	As Reported	130 mEq/L
Total Protein	Chemistry Analyzer	As Reported	5.6 g/dL
Urea	Chemistry Analyzer	As Reported	7 mg/dL

MICROBIOLOGICAL ANALYSIS			
Test	Method	Specification	Result
Endotoxin	LAL	As Reported	2.3 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, Amber	Pass

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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	153.3 %	Not Requested			
CHO Cell Cytotoxicity	As Reported	1.5 %	Not Requested			
Vero	As Reported	74.2 %	Not Requested			
Vero Cell Cytotoxicity	As Reported	0.1 %	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		05 Jun 2017