

Fetalgro – Sterile Filtered, Gamma Irradiated**

Part Number: FGR-BTG-XXX Lot Number: 20140930FG
 Date of Manufacture: 10/2014 Expiration Date: 10/2019*
 Storage temperature: -5 to -20°C



Not for human or animal consumption

Chemical Analysis				Microbiological Analysis			
Test	Method	Specification	Result	Test	Method	Specification	Result
Total Protein	Chemistry Analyzer	As Reported	5.5 g/dL	Sterility	9CFR 113.26	No Growth	No Growth
Albumin	Chemistry Analyzer	As Reported	3.5 g/dL	Mycoplasma	9CFR 113.28	Not Detected	Not Detected
Globulin	Chemistry Analyzer	As Reported	2.0 g/dL	Endotoxin	LAL	As Reported	< 50 EU/mL
Bilirubin	Chemistry Analyzer	As Reported	0.4 mg/dL	Viral Analysis			
ALT	Chemistry Analyzer	As Reported	8 U/L	Test	Method	Specification	Result
AST	Chemistry Analyzer	As Reported	47 U/L	BVD Cytopathic	9CFR 113.53	Not Detected	Not Detected
Cholesterol	Chemistry Analyzer	As Reported	52 mg/dL	BVD Non-Cytopathic	9CFR 113.53	Tested	Not Detected
Glucose	Chemistry Analyzer	As Reported	115 mg/dL	PI3	9CFR 113.53	Not Detected	Not Detected
Urea	Chemistry Analyzer	As Reported	6 mg/dL	IBR	9CFR 113.53	Not Detected	Not Detected
Creatinine	Chemistry Analyzer	As Reported	0.4 mg/dL	Bovine Adeno 3	9CFR 113.53	Not Detected	Not Detected
Sodium	Chemistry Analyzer	As Reported	122.0 mmol/L	Bovine Adeno 5	9CFR 113.53	Not Detected	Not Detected
Calcium	Chemistry Analyzer	As Reported	7.0 mg/dL	BPV	9CFR 113.53	Not Detected	Not Detected
Phosphorus	Chemistry Analyzer	As Reported	6.9 mg/dL	BRSV	9CFR 113.53	Not Detected	Not Detected
Osmolality	Osmometer	260-340 mOsm/Kg	304 mOsm/Kg	REO Virus	9CFR 113.53	Not Detected	Not Detected
Hemoglobin	Spectrophotometer	≤ 25.0 mg/dL	1.2 mg/dL	Rabies	9CFR 113.53	Not Detected	Not Detected
pH	pH meter	6.80-8.20	7.31	Blue Tongue	9CFR 113.53	Not Detected	Not Detected
IgG	ELISA	As Reported	5490 µg/mL	Identity Analysis			
				Test	Method	Specification	Result
				Appearance	Visual	Clear yellow-amber	Clear yellow-amber

*Stability testing pending.

**All test results reported on this C of A are from representative batch samples prior to irradiation.

STATEMENT OF ORIGIN

The raw bovine serum used in the manufacture of Fetalgro is collected and processed from an approved abattoir in the United States. Animals were inspected ante- and post-mortem at the abattoir by a U.S. veterinary services inspector and are fit for human consumption.

Approval

Quality Assurance – Print Name: <i>Stacey Black</i>	Quality Assurance – Sign Name: <i>Stacey Black</i>	Date: <i>02/12/16</i>
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