

Fetal Bovine Serum

Triple 0.1 µm sterile filtered

Cat. No.: E5050
 Lot No.: 45110321
 Origin: BRAZIL
 Date of Manufacture: 11/2021
 Storage: -20°C

Physical and Chemical Analysis

Test	Method	Specifications	Results	Units
Identity	Internally Validated	Bovine	Bovine	n/a
Appearance	Visual	Clear yellow-amber	Clear yellow-amber	n/a
Specific Gravity	Mass Balance	> 1.01	1.018	g/ml
pH	Electronic pH Meter	6.8 - 8.2	7.44 (18.3°C)	n/a
Osmolality	Osmometer	260 - 340	330	mOsm/kg
Endotoxin	LAL Kinetic	< 10	1.2	EU/ml
Free Hemoglobin	Colorimetric	< 25	18.92	mg/dl

Protein Profile

Test	Method	Specifications	Results	Units
Total Protein	IDEXX Catalyst One	3.0 - 4.5	4.0	g/dl
Albumin	IDEXX Catalyst One	1.4 - 3.4	1.84	g/dl
Globulin	IDEXX Catalyst One	0.4 - 2.4	2.16	g/dl
Alpha 1	Capillary Electrophoresis	Test and report	1.32	g/dl
Alpha 2	Capillary Electrophoresis	Test and report	0.62	g/dl
Beta	Capillary Electrophoresis	Test and report	0.18	g/dl
Gamma	Capillary Electrophoresis	Test and report	0.04	g/dl
IgG	ELISA	< 500	217	µg/ml
Electrophoretic Pattern	Capillary Electrophoresis	Normal	Normal	n/a

Sterility

Test	Method	Specifications	Results	Units
Sterility	Eur. Ph. 2.6.1	Pass	Pass	n/a
Mycoplasma	qPCR	Not detected	Not detected	n/a

Antibiotics

Test	Method	Specifications	Results	Units
Tetracycline	IDEXX Snap Test	< 0.05	< 0.05	mg/l
Oxytetracycline	IDEXX Snap Test	< 0.05	< 0.05	mg/l
Chlortetracycline	IDEXX Snap Test	< 0.10	< 0.10	mg/l

Prions

The product is BSE/TSE safe, following the European Pharmacopoeia (monograph 5.2.8) and the European Commission NFGs (EMA/410/01 rev.3). According to the World Organization for Animal Health (OIE), Brazil is recognized as having negligible risk for BSE/TSE.

Our FBS products are manufactured following the main criteria defined by international guidelines (e.g., EMA/CHMP/BWP/457920/2012; FBS specifications published by International Serum Industry Association, European Pharmacopoeia 2262).

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Virus Testing

Test	Method	Specifications	Results	Units
BVDV/BHV-1/PI-3 (CPE)	Cell Culture Immunofluorescence	Not detected	Not detected	n/a
Rabies Virus	qPCR	Not detected	Not detected	n/a
Bluetongue Virus (BTV)	qPCR	Not detected	Not detected	n/a
BRSV	qPCR	Not detected	Not detected	n/a
Reo Virus	qPCR	Not detected	Not detected	n/a
BAV	qPCR	Not detected	Not detected	n/a
BoPV-1, 2	qPCR	Not detected	Not detected	n/a

Antibody Testing

Test	Method	Specifications	Results	Units
BVDV-1, 2, 3	Detection of Antibodies (ELISA)	Test and report	Not detected	n/a
BHV-1	Detection of Antibodies (ELISA)	Test and report	Not detected	n/a
PI-3	Detection of Antibodies (ELISA)	Test and report	Not detected	n/a

Biochemistry

Test	Method	Specifications	Results	Units
Aspartate Aminotransferase (AST)	IDEXX Catalyst One	Test and report	45	U/L
Alanine Aminotransferase (ALT)	IDEXX Catalyst One	Test and report	19	U/L
Lactate Dehydrogenase (LDH)	IDEXX Catalyst One	Test and report	1371	U/L
Alkaline Phosphatase (ALKP)	IDEXX Catalyst One	Test and report	256	U/L
Gamma-Glutamyl Trans. (GGT)	IDEXX Catalyst One	Test and report	6	U/L
Cholesterol (CHOL)	IDEXX Catalyst One	Test and report	0.18	mmol/L
Glucose (GLU)	IDEXX Catalyst One	Test and report	1.98	mmol/L
Urea (BUN)	IDEXX Catalyst One	Test and report	4.8	mmol/L
Creatinine (CREA)	IDEXX Catalyst One	Test and report	215	µmol/L
Uric Acid (URIC)	IDEXX Catalyst One	Test and report	62	µmol/L
Calcium (Ca)	IDEXX Catalyst One	Test and report	3.32	mmol/L
Phosphorus (PHOS)	IDEXX Catalyst One	Test and report	2.76	mmol/L
Total Bilirubin (TBIL)	IDEXX Catalyst One	Test and report	5	µmol/L
Magnesium (Mg)	IDEXX Catalyst One	Test and report	1.37	mmol/L
Sodium (Na)	IDEXX Catalyst One	Test and report	136	mmol/L
Potassium (K)	IDEXX Catalyst One	Test and report	>10	mmol/L
Chloride (CL)	IDEXX Catalyst One	Test and report	105	mmol/L
Triglyceride (Trig)	IDEXX Catalyst One	Test and report	0.93	mmol/L
Iron (Fe)	Colorimetric	Test and report	167.2	µg/dl

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Cell-Culture Test

Cell Line	Method	Specifications	Results
L-929	Morphology	Tested vs. Control Serum ¹	3/3
HELA	Morphology	Tested vs. Control Serum ¹	3-/3-
MRC-5	Morphology	Tested vs. Control Serum ¹	3/3
L-929	Density	Tested vs. Control Serum ²	3/3
HELA	Density	Tested vs. Control Serum ²	3/3
MRC-5	Density	Tested vs. Control Serum ²	3/3
L-929	Cell Count	Cell count [log ₁₀ /ml]/dead cells [%]	6.29/0 vs. 6.31/0
HELA	Cell Count	Cell count [log ₁₀ /ml]/dead cells [%]	6.21/0.8 vs. 6.12/1.0

Scoring System (vs. Control Serum):

- ¹ 0 cells dead; 1 many degenerated cells, plenty of dead cells; 2 cells partially degenerated; many dead cells; 3 few degenerated cells, some dead cells; 4 all cells ok.
- ² 0 single cells/small colonies; 1 <50% confluent; 2 50 – 90% confluent; 3 confluent; 4 more than confluent

Interpretation:

The cultures with test serum 45110321 showed comparable cell growth in all cases compared to the internal control serum. Using the test serum in general, all cells displayed satisfying viability and cell growth.

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