

Fetal Bovine Serum HI

Triple 0.1 µm sterile filtered

Cat. No.: E5051
 Lot No.: 23031921
 Origin: BRAZIL
 Date of Manufacture: 03/2021
 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	1.0171	g/ml
pH	Electronic pH Meter	6.8 - 8.2	7.33 (21.3°C)	n/a
Osmolality	Osmometer	260 - 340	316	mOsm/kg
Endotoxin	LAL Kinetic	< 10	0.4	EU/ml
Free Hemoglobin	Colorimetric	< 25	22.11	mg/dl

Protein Profile

Test	Method	Specifications	Results	Units
Total Protein	IDEXX Catalyst One	3.0 - 4.5	4.1	g/dl
Albumin	IDEXX Catalyst One	1.4 - 3.4	2.0	g/dl
Globulin	IDEXX Catalyst One	0.4 - 2.4	2.1	g/dl
IgG	ELISA	< 500	376	µg/ml

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	Test and report	Not detected	n/a
Oxytetracycline	IDEXX Snap Test	Test and report	Not detected	n/a
Chlortetracycline	IDEXX Snap Test	Test and report	Not detected	n/a

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	Specifications	Results	Units
BVDV (CPE)	Not detected	Not detected	n/a
Parainfluenza Virus: PI-3 (CPE)	Not detected	Not detected	n/a
Bovine Herpesvirus: BHV-1,4 (CPE)	Not detected	Not detected	n/a
Rabies Virus	Not detected	Not detected	n/a
Bluetongue Virus (BTV)	Not detected	Not detected	n/a
Bovine Respiratory Syncytial Virus (BRSV)	Not detected	Not detected	n/a
Reo Virus	Not detected	Not detected	n/a
Bovine Adenovirus: BAV-3,5	Not detected	Not detected	n/a
Bovine Parvovirus: BPV-1,2	Not detected	Not detected	n/a

Biochemistry

Test	Method	Specifications	Results	Units
Aspartate Aminotransferase (AST)	IDEXX Catalyst One	Test and report	57	U/L
Alanine Aminotransferase (ALT)	IDEXX Catalyst One	Test and report	25	U/L
Lactate Dehydrogenase (LDH)	IDEXX Catalyst One	Test and report	2936	U/L
Alkaline Phosphatase (ALKP)	IDEXX Catalyst One	Test and report	314	U/L
Gamma-Glutamyl Trans. (GGT)	IDEXX Catalyst One	Test and report	7	U/L
Cholesterol (CHOL)	IDEXX Catalyst One	Test and report	0.26	mmol/L
Glucose (GLU)	IDEXX Catalyst One	Test and report	1.68	mmol/L
Urea (BUN)	IDEXX Catalyst One	Test and report	5.4	mmol/L
Creatinine (CREA)	IDEXX Catalyst One	Test and report	211	µmol/L
Uric Acid (URIC)	IDEXX Catalyst One	Test and report	68	µmol/L
Calcium (Ca)	IDEXX Catalyst One	Test and report	3.18	mmol/L
Phosphorus (PHOS)	IDEXX Catalyst One	Test and report	2.61	mmol/L
Total Bilirubin (TBIL)	IDEXX Catalyst One	Test and report	7	µmol/L
Magnesium (Mg)	IDEXX Catalyst One	Test and report	1.38	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	106	mmol/L
Triglyceride (Trig)	IDEXX Catalyst One	Test and report	0.75	mmol/L
Iron (Fe)	Colorimetric	Test and report	199	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 [%]	6.35/0 vs. 6.28/0
HELA	Cell Count	Cell count [log ₁₀ /ml]/dead cells [%]	6.04/0 vs. 6.16/0.8

Scoring System (vs. Control Serum):

- ¹ 0 cells dead; 1 many degenerated and many dead cells; 2 cells partially degenerated and many dead cells; 3 few cells degenerated and few dead cells; 4 w/o pathological findings.
- ² 0 single cells/cell aggregates; 1 <50% confluency; 2 50 – 90% confluency; 3 confluency; 4 overly confluent

Interpretation:

The cultures with test serum 23031921 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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