

# Fetal Bovine Serum HI

Triple 0.1  $\mu m$  sterile filtered

Cat. No.: E5051 Lot No.: 61050824 Origin: BRAZIL

Date of Manufacture: 05/2024 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	1.017	g/ml
pН	Electronic pH Meter	6.8 - 8.2	7.30 (23.4°C)	n/a
Osmolality	Osmometer	260 - 340	312	mOsm/kg
Endotoxin	LAL Kinetic	< 10	< 0.5	EU/ml
Free Hemoglobin	Colorimetric	< 25	14.62	mg/dl

#### **Protein Profile**

Test	Method	Method Specifications Re		Units
Total Protein	IDEXX Catalyst One	3.0 - 4.5	3.80 g/e	
Albumin	IDEXX Catalyst One	1.4 - 3.4	1.91 g/c	
Globulin	IDEXX Catalyst One	0.4 - 2.4	1.89	g/dl
Alpha 1	Capillary Electrophoresis	Capillary Electrophoresis Test and report 1.31		g/dl
Alpha 2	Capillary Electrophoresis	horesis Test and report 0.36		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	175.3	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	Method Specifications		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 Pharmacopeia 2262).

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#### **Virus Testing**

Test	Method	Specifications	Results	Units
BRSV/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 Not detected	
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	44	U/L
Alanine Aminotransferase (ALT)	IDEXX Catalyst One	Test and report	17	U/L
Lactate Dehydrogenase (LDH)	IDEXX Catalyst One	Test and report	1404	U/L
Alkaline Phosphatase (ALKP)	IDEXX Catalyst One	Test and report	278	U/L
Gamma-Glutamyl Trans. (GGT)	IDEXX Catalyst One	Test and report	3	U/L
Cholesterol (CHOL)	IDEXX Catalyst One	Test and report	0.78	mmol/L
Glucose (GLU)	IDEXX Catalyst One	Test and report	2.00	mmol/L
Urea (BUN)	IDEXX Catalyst One	Test and report	5.2	mmol/L
Creatinine (CREA)	IDEXX Catalyst One	Test and report	318	μmol/L
Uric Acid (URIC)	Acid (URIC) IDEXX Catalyst One		100	μmol/L
Calcium (Ca)	IDEXX Catalyst One		3.18	mmol/L
Phosphorus (PHOS)	IDEXX Catalyst One Test and		2.78	mmol/L
Total Bilirubin (TBIL)	IDEXX Catalyst One	Test and report	7	μmol/L
Magnesium (Mg)	IDEXX Catalyst One	Test and report	1.34	mmol/L
Sodium (Na)	IDEXX Catalyst One	Test and report	137	mmol/L
Potassium (K)	K) IDEXX Catalyst One		>10	mmol/L
Chloride (CL)	IDEXX Catalyst One	Test and report	104	mmol/L
Triglyceride (Trig)	IDEXX Catalyst One	Test and report	0.90	mmol/L
Iron (Fe)	Colorimetric	Test and report	153.1	μg/dl

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#### **Cell-Culture Test**

Cell Line	Method	Specifications	Results
L-929	Morphology	Tested vs. Control Serum <sup>1</sup>	3/3
HELA	Morphology	Tested vs. Control Serum <sup>1</sup>	3-/3-
MRC-5	Morphology	Tested vs. Control Serum <sup>1</sup>	3/3
L-929	Density	Tested vs. Control Serum <sup>2</sup>	3/3
HELA	Density	Tested vs. Control Serum <sup>2</sup>	3+/3+
MRC-5	Density	Tested vs. Control Serum <sup>2</sup>	3/3
L-929	Cell Count	Cell count [log <sub>10</sub> /ml]/dead cells [%]	6.03/0.93 vs. 6.01/0.49
HELA	Cell Count	Cell count [log <sub>10</sub> /ml]/dead cells [%]	6.04/0.0 vs. 5.92/1.20
MRC-5	Cell Count	Cell count [log <sub>10</sub> /ml]/dead cells [%]	5.84/0.0 vs. 5.73/1.87

Cell Line	Method	Specifications	Results
BHK-21	Cloning Efficiency - Records results vs. control at the 8th day	>75% CE vs. control CE	>99%

#### Scoring System (vs. Control Serum):

- O 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
- <sup>2</sup> 0 single cells/small colonies; 1 < 50% confluent; 2 50 90% confluent; 3 confluent; 4 more than confluent

#### Interpretation:

The cell growth using test serum Lot: 61050824 was comparable to the internal standard serum. The viability of the cells before trypsinization was similar. Using the test serum all cells displayed good viability and cell growth.