EURx MOLECULAR BIOLOGY PRODUCTS

Certificate of Analysis

Fetal Bovine Serum

Triple 0.1 µm sterile filtered

Cat. No.: E5052
Lot No.: 53091223
Origin: COLOMBIA
Date of Manufacture: 09/2023
Storage: -20°C

Physical and Chemical Analysis

Test	Method	Specifications	Results	Units
Identity	Internally Validated	Bovine	Bovine	n/a
Appearance	Visual	Clear yellow-amber Frozen Liquid	Clear yellow-amber Frozen Liquid	n/a
Specific Gravity	Mass Balance	> 1.01	1.017	g/ml
pH	Electronic pH Meter	6.8 - 8.2	7.39 (21.7°C)	n/a
Osmolality	Osmometer	260 - 340	338	mOsm/kg
Endotoxin	LAL Kinetic	< 10	0.9	EU/ml
Free Hemoglobin	Colorimetric	< 25	23.39	mg/dl

Protein Profile

Test	Method	Specifications	Results	Units
Total Protein	IDEXX Catalyst One	3.0 - 4.5	3.40	g/dl
Albumin	IDEXX Catalyst One	1.4 - 3.4	1.45	g/dl
Globulin	IDEXX Catalyst One	0.4 - 2.4	1.95	g/dl
Alpha 1	Capillary Electrophoresis	Test and report	1.63	g/dl
Alpha 2	Capillary Electrophoresis	Test and report	0.18	g/dl
Beta	Capillary Electrophoresis	Test and report	0.12	g/dl
Gamma	Capillary Electrophoresis	Test and report	0.02	g/dl
IgG	ELISA	< 500	179.4	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	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), Colombia 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	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	63	U/L
Alanine Aminotransferase (ALT)	IDEXX Catalyst One	Test and report	33	U/L
Lactate Dehydrogenase (LDH)	IDEXX Catalyst One	Test and report	1442	U/L
Alkaline Phosphatase (ALKP)	IDEXX Catalyst One	Test and report	240	U/L
Gamma-Glutamyl Trans. (GGT)	IDEXX Catalyst One	Test and report	2	U/L
Cholesterol (CHOL)	IDEXX Catalyst One	Test and report	0.22	mmol/L
Glucose (GLU)	IDEXX Catalyst One	Test and report	4.44	mmol/L
Urea (BUN)	IDEXX Catalyst One	Test and report	5.3	mmol/L
Creatinine (CREA)	IDEXX Catalyst One	Test and report	223	µmol/L
Uric Acid (URIC)	IDEXX Catalyst One	Test and report	118	µmol/L
Calcium (Ca)	IDEXX Catalyst One	Test and report	3.25	mmol/L
Phosphorus (PHOS)	IDEXX Catalyst One	Test and report	2.91	mmol/L
Total Bilirubin (TBIL)	IDEXX Catalyst One	Test and report	9	µmol/L
Magnesium (Mg)	IDEXX Catalyst One	Test and report	1.31	mmol/L
Sodium (Na)	IDEXX Catalyst One	Test and report	137	mmol/L
Potassium (K)	IDEXX Catalyst One	Test and report	>10	mmol/L
Chloride (CL)	IDEXX Catalyst One	Test and report	101	mmol/L
Triglyceride (Trig)	IDEXX Catalyst One	Test and report	1.53	mmol/L
Iron (Fe)	Colorimetric	Test and report	155.8	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]	4/4
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 [%]	6.29/0.0 vs. 6.27/0.0
HELA	Cell Count	Cell count [log_{10}/ml]/dead cells [%]	6.10/0.40 vs. 6.14/0.0
MRC-5	Cell Count	Cell count [log_{10}/ml]/dead cells [%]	6.03/0.46 vs. 6.03/0.0

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

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

Interpretation:

The cell growth using test serum Lot: 53091223 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.

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