Fetal Bovine Serum Plus (South America origin)- EU Approved

Triple Filtered 0.1 µm

Cat.# EU-015-500

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	7.16 at 22.4°C	n/a
Osmolality	Osmometer	260 - 340	307	mOsm/kg
Endotoxin	LAL Kinetic	< 10	0.5	EU/ml
Free Hemoglobin	Colorimetric	< 50	12.95	mg/dl

Protein Profile

Test	Method	Specifications	Results	Units
Total Protein	IDEXX Catalyst One	3.0 - 4.5	4.1	g/dl
Electrophoretic Pattern	Capillary Electrophoresis	Normal	Normal	n/a
Albumin	IDEXX Catalyst One	1.4 - 3.4	2.55	g/dl
Globulin	IDEXX Catalyst One	0.4 - 2.4	1.56	g/dl
Alpha 1	Capillary Electrophoresis	Test and report	1.05	g/dl
Alpha 2	Capillary Electrophoresis	Test and report	0.30	g/dl
Beta	Capillary Electrophoresis	Test and report	0.16	g/dl
Gamma	Capillary Electrophoresis	Test and report	0.05	g/dl
IgG	ELISA	< 500	173.5	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

Virus Testing

Test	Method	Specifications	Results	Units
BVDV/BRSV/BHV-1/PI-3 (CPE)	Immunofluorescence Cell Culture	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	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	39	U/L
Alanine Aminotransferase (ALT)	IDEXX Catalyst One	Test and report	17	U/L
Lactate Dehydrogenase (LDH)	IDEXX Catalyst One	Test and report	1146	U/L
Alkaline Phosphatase (ALKP)	IDEXX Catalyst One	Test and report	200	U/L
Gamma-Glutamyl Trans. (GGT)	IDEXX Catalyst One	Test and report	1	U/L
Cholesterol (CHOL)	IDEXX Catalyst One	Test and report	0.43	mmol/L
Glucose (GLU)	IDEXX Catalyst One	Test and report	5.13	mmol/L
Urea (BUN)	IDEXX Catalyst One	Test and report	4.6	mmol/L
Creatinine (CREA)	IDEXX Catalyst One	Test and report	241	µmol/L
Uric Acid (URIC)	IDEXX Catalyst One	Test and report	88	µmol/L
Calcium (Ca)	IDEXX Catalyst One	Test and report	2.58	mmol/L
Phosphorus (PHOS)	IDEXX Catalyst One	Test and report	3.46	mmol/L
Total Bilirubin (TBIL)	IDEXX Catalyst One	Test and report	6	µmol/L
Magnesium (Mg)	IDEXX Catalyst One	Test and report	1.52	mmol/L
Sodium (Na)	IDEXX Catalyst One	Test and report	129	mmol/L
Potassium (K)	IDEXX Catalyst One	Test and report	>10.0	mmol/L
Chloride (CL)	IDEXX Catalyst One	Test and report	94	mmol/L
Triglyceride (Trig)	IDEXX Catalyst One	Test and report	2.49	mmol/L
Iron (Fe)	Colorimetric	Test and report	<100	µg/dl

Cell-Culture Test

Cell-Culture Test Cell Line	Method	Specifications	Results
L-929	Morphology	Tested vs. Control Serum1	3/3
HELA	Morphology	Tested vs. Control Serum1	3-/3-
MRC-5	Morphology	Tested vs. Control Serum1	3/3
L-929	Density	Tested vs. Control Serum2	3+/3+
HELA	Density	Tested vs. Control Serum2	3+/3+
MRC-5	Density	Tested vs. Control Serum2	3/3
L-929	Cell Count	Cell count [log_{10}/ml]/dead cells [%]	5.91/0.0 Vs. 5.86/0.0
HELA	Cell Count	Cell count [log_{10}/ml]/dead cells [%]	5.85/0.71 Vs. 5.83/0.0
MRC-5	Cell Count	Cell count [log_{10}/ml]/dead cells [%]	5.68/1.04 Vs. 5.68/0.0

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

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

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Collected from the source:
When searchers choose their serum an important factor that should be taken into consideration is the source, which also emphasizes the traceability of the serum.
Our system of vertical integration allows us to be certain of the origins and traceability of our FBS.
Each manufactured batch is rigorously controlled, from the collection of serum and throughout all stages of its treatment and production through to final packaging on our premises.
Fetal Bovine Serum Plus (South America) is derived from clotted whole blood aseptically collected from fetus via cardiac puncture.
The serum is imported from South America and it is treated in agreement with the European regulations.

Filtration :
Final Filter Size : 0.1µm, x 3

Sterility :
All sera are tested for the absence of aerobic and anaerobic bacteria, fungi, yeast and Mycoplasma. The sterility test is based on the European Pharmacopoeia requirements.
The sera are tested for the absence of *Mycoplasma* by culture.

Virus Tested :
All of our sera are tested for:
- Bovine Viral Diarrhoea (BVD)
- Cytopathogenic agents e.g. Infectious Bovine Rhinotracheitis (IBR) / BHV-1
- Hemadsorbing agents e.g. Parainfluenza Type 3 (Pl3)(CPE)
- Rabies Virus
- BAV
- BoPV-1, -2

Sera are tested for the absence of the indicated viruses by inoculation to permissive cells. The revelation is made by immunofluorescence for pestiviruses. Cytopathogenic agents and hemadsorbing agents are detected by microscopic observations.

Endotoxin :
All sera are tested to determine the levels of endotoxins. Immunological Sciences carries out a chromokinetic quantitative test, according to the method D of the European Pharmacopoeia.
The endotoxin reagent is standardized against the US reference endotoxin.
Fetal Bovine Serum Plus (South America origin) has an endotoxin level lower than 10 EU/ml

Hemoglobin :
The hemoglobin level is measured by spectrophotometer.
Fetal Bovine Serum Plus (South America origin) has an hemoglobin level less than 15 mg/dl, please refer to the specific lot.# number and require the Certificate of Analysis

Osmolality :
Determined by a lowered freezing temperature. The osmometer is calibrated against standard solutions
Osmolality specification: 260-340 mOsm/kg

Cell Culture :
Biological performance is assessed using cell culture medium supplemented with the serum being tested. During the test period, cultures are examined microscopically for any morphological abnormalities that may indicate toxic components in the serum.
Fetal Bovine Serum Plus South America origin has a cell growth promotion higher than 80% after the day 6, compared to a serum of reference.

Cell Lines Tested :

The following cell lines are tested with the serum:
HELA -Cancer Cell/Human.
L929 -Fibroblast-Mouse/ As Macrophage
SP2/0-AG14 -Mouse/Lymphoma
MRC- 5 -Human/Lung.

Total Protein :
Determined by Biuret Colorimetry:
Total Protein : 40±15 g/l

Country of Origin :
The country in which the serum was taken from the donor/animal: Brazil
Shelf life : 5 years

Recommended Use:
Respect Storage conditions
Do not use Serum after expiry date
Manipulate serum in aseptic conditions (e.g.under laminar air flow)
Wear clothes adapted to the manipulation of serum to avoid contamination (e.g. gloves, mask,hygiene cap, overall)
In order to all serum qualities, it is recommended to thaw out the flask, and prepare small aliquotes to be used within a short term (within 4 weeks). We suggest to freeze the aliquotes that won't be used in a short term, avoid the Room temperature.

Storage:
To effectively preserve the integrity of animal serum, it should be stored frozen and protected from light. The recommended storage temperature is <-15°C.

Multiple thaw/freeze cycles should be avoided, as they will accelerate the degradation of serum nutrients and can encourage the formation of insoluble precipitates. For this reason, serum should never be stored in **"no-frost- " freezers**. These types of freezers periodically warm themselves to avoid internal ice deposits and are detrimental to the stability of frozen serum products.

Suggested Thawing Procedure

1. Remove the serum bottles from the freezer and allow them to adjust to room temperature for approximately 10 minutes.
2. Place each container in a 30 to 37 °C water bath or incubator.
   Excessive temperatures will degrade heat labile nutrients. If using a water bath, prevent the bottle caps from being submerged.
3. Gently agitate the bottles every 10 – 15 minutes until the serum is completely thawed.
   Efficient and Effective Usage

After thawing, use the serum promptly.
Liquid serum may be stored refrigerated (2 to 8 °C) up to 4 weeks.

To avoid thaw/freeze cycles or long periods of refrigeration, it is recommended that any unused serum be immediately dispensed into small, useful aliquots and refrozen for future use.