

CERTIFICATE OF ANALYSIS

Fetal Bovine Serum (USA Origin), GOLD

Batch N° :	XXXXXX	Storage :	-20°C
Catalog N° :	EU-006-100 : 100 mL	Filtration :	Triple 0.1 µm filtered
Validation Date :	XXX	Origin :	USA
Expiry date :	XXX		

QUALITY PROFILE				
Tests	Methods	Units	Specifications	Results
Appearance			Clear yellow to amber liquid	Clear yellow to amber liquid
Bacteria and Fungi	Culture		Not detected	Not detected
Mycoplasma	Culture		Not detected	Not detected
pH	Internal validated method		6.8 ± 8.2	7.05
Osmolality	Freezing point . EU Ph. 2.2.35	mOsm/kg	280 ± 400	303
Endotoxin	Chromokinetic test . Method D of EU Ph. 2.6.14	EU/ml	< 10	1.0
Haemoglobin	Internal validated method	mg/100ml	< 25	4.45
Total protein	Biuret colorimetry	g/ dl	3 ± 4.5	4.1
Pestivirus (e.g. BVDV-1, BVDV-2, BDV, CSFV, Giraffe-1 and Hobi-like viruses)	Cell culture observation and IFA		Tested	Not detected
Cytopathogenic Agents eg. IBR / BHV-1	Cell culture observation		Not detected	Not detected
Haemadsorbing Agents eg. PI3 virus	Cell culture observation		Not detected	Not detected

CHEMICAL PARAMETERS				
Tests	Methods	Units	Specifications	Results
ALAT (SGPT)	UV kinetic at 37°C	IU/l		8
Alkaline Phosphatase	Colorimetry kinetic at 37°C	IU/l		464
ASAT (SGOT)	UV kinetic at 37°C	IU/l		48
Bilirubin	DPD / caffeine colorimetry	mg/100ml		0.25
Calcium	Arsénazo colorimetry	mg/100ml		13.8
Gamma GT	Colorimetry kinetic at 37°C	IU/l		8
Cholesterol	Cholesterolase Trinder colorimetry	mg/100ml		31
Creatinine	Colorimetry Kinetic (Jaffé)	mg/100ml		3.3
Chloride	Indirect potentiometry	mmol/l		100
Glucose	Hexokinase UV	mg/100ml		49
Iron	TPTZ colorimetry	µg/100ml		176
Lactate Dehydrogenase	UV kinetic at 37°C	IU/l		864
Phosphorus	Phosphomolybdate colorimetry	mg/100ml		8.8
Potassium	Indirect potentiometry	mmol/l		12.4
Sodium	Indirect potentiometry	mmol/l		134
Triglycerides	Glycerokinase Trinder colorimetry	mg/100ml		55
Urea	Urease UV	mg/100ml		36
Uric Acid	Uricase trinder colorimetry	mg/100ml		1.2

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PROTEIN ELECTROPHORESIS				
Tests	Methods	Units	Specifications	Results
Albumin	Immunoturbidimetry	g/l		17.3
Alpha Globulins	Immunoturbidimetry	g/l		12.7
Beta Globulins	Immunoturbidimetry	g/l		7.1
Gamma Globulins	Immunoturbidimetry	g/l		0.7

ELISA TEST				
Tests	Methods	Units	Specifications	Results
IgG	ELISA test	mg/l		132.5

BIOLOGICAL PERFORMANCE				
Tests	Methods	Units	Specifications	Results
L929 cell growth : 3rd day	Internal validated method	%		119
L929 cell growth : 6th day	Internal validated method	%	> 80	110
SP2/O-Ag14 cell growth : 3rd day	Internal validated method	%		66
SP2/O-Ag14 cell growth : 6th day	Internal validated method	%	> 80	90
HELA cell growth : 3rd day	Internal validated method	%		92
HELA cell growth : 6th day	Internal validated method	%	> 80	84
MRC-5 cell growth : 3rd day	Internal validated method	%		81
MRC-5 cell growth : 6th day	Internal validated method	%	> 80	83
Plating efficiency - cells implanted	Internal validated method		500	500
Plating efficiency - number of colonies	Internal validated method			288
Plating efficiency - PE absolute	Internal validated method	%		58
Plating efficiency - PE relative	Internal validated method	%		81
Cloning efficiency - cells implanted per well	Internal validated method		1	1
Cloning efficiency - number of clones	Internal validated method			63
Cloning efficiency - CE absolute	Internal validated method	%		66
Cloning efficiency - CE relative	Internal validated method	%		98

All fetal bovine sera are collected from registered slaughterhouses under the supervision of government veterinary authorities.
All sera are collected from EU approved countries

Cailleau Laura

Quality Service

Date : _____

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Web-site: www.immunologicalsciences.com - E-Mail: info@immunologicalsciences.com

Fetal Bovine Serum (USA origin), Gold

CAT N° : EU-006-100

Collected from the source :

When searchers choose their serum an important factor that should be taken into consideration is the source, which also emphasises 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.

Immunological Sciences Fetal Bovine Serum Gold is derived from clotted whole blood aseptically collected from fetus via cardiac puncture.

The serum is imported and 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 (PI3)

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.

Immunological Sciences Foetal Bovine serum has an endotoxin level lower than 5 EU/ml

Haemoglobin :

The haemoglobin level is measured by spectrophotometer.

Immunological Sciences Foetal Bovine serum has an haemoglobin level lower than 25 mg/100ml.

Osmolality :

Determined by a lowered freezing temperature. The osmometer is calibrated against standard solutions

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.

Immunological Sciences Foetal Bovine serum has a cell growth promotion higher than 80% after the day 6, compared to a serum of reference.

Cell Culture Tests :

Cell Growth, Plating Efficiency, Cloning Efficiency.

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Web-site: www.immunologicalsciences.com - E-Mail: info@immunologicalsciences.com

TECHNICAL DATA SHEET

Fetal Bovine Serum (USA origin), Gold

Cell Lines Tested :

The following cell lines are tested with the serum:

HELA -Cancer Cell/Human.

L929 -Fibroblast-Mouse/ As Macrophage

MRC- 5 -Human/Lung.

Total Protein :

Determined by Biuret Colorimetry.

Country of Origin :

The country in which the serum was taken from the donor/animal: USA

Immunological Sciences sera are sourced from USA, Brazil, New Zealand, Australia, Canada, France

Storage conditions : Store at -20°C

Shelf life : 5 years

Recommended use :

- Respect storage conditions of the serum
- Do not use the serum after its expiry date
- Store serum in an area protected from light
- 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 preserve all serum qualities, it is recommended to thaw out the flask, to aliquote, then to re-freeze the produced flasks rather than to thaw out and re-freeze the flask at each use.
- It is recommended to use the serum immediately after its thaw out. However, if it is not useful, it is possible to store thaw out serum, at +2°C / +8°C, until 26 weeks without significant decrease of its performances in cell culture.

The product is intended to be used in vitro, in laboratory only. Do not use it in therapy, human or veterinary applications.

Note:

The raw serum may be gamma irradiated before filtration for different reasons:

- Importation regulation
- Exportation necessity
- Technical or quality aspects.