

CERTIFICATE OF ANALYSIS

FOETAL BOVINE SERUM – STERILE



BOVOGEN BIOLOGICALS

CERTIFICATE OF ANALYSIS

Product:	Foetal Bovine Serum - Sterile
Product Code:	SFBS
Lot No:	1709A
Manufacture date:	September, 2017
Expiration date:	September, 2022
Country of Origin:	New Zealand
Country of Manufacture:	Australia
Certificate of Suitability:	R1-CEP 2007-361-Rev 02
Filtration:	Triple 0.1µm filtered complies with FDA regulations 21 CFR 211.72
Storage requirements:	Product to be stored at -15°C to -40°C

GENERAL SPECIFICATIONS

General

<u>Test</u>	<u>Method</u>	<u>Units</u>	<u>Specification</u>	<u>Results</u>
Appearance		N/A	Clear amber liquid	Clear amber liquid
pH	USP<791>	N/A	6.7 – 8.0	7.4
Osmolality	Ph. Eur. 2.2.35	mOsm/kg	260 -340	314
Haemoglobin	USP<851>	mg/100mL	< 25	9.4
Total Protein	Ph. Eur. 2.5.33	g/L	30 -50	39
Total IgG	Ph. Eur. 2.7.1	µg/mL	< 350	160
Endotoxin	(SRID) Ph. Eur. 2.6.14	EU/mL	< 30	<1.2
Aerobic and Anaerobic Bacteria	USP<71>/Ph. Eur. 2.6.1	N/A	Not detected	Not detected
Fungi (Yeast and Mould)	USP<71>/Ph. Eur. 2.6.1	N/A	Not detected	Not detected

Viruses / Mycoplasma

<u>Test</u>	<u>Method</u>	<u>Units</u>	<u>Specification</u>	<u>Results</u>
Mycoplasma	Ph. Eur. 2.6.7	N/A	Not detected	Not detected
Bovine Viral Diarrhoea Virus (BVDV)	9CFR 113.53	N/A	Not detected	Not detected
Bovine Adenovirus Type 3 (BAV3)	9CFR 113.53	N/A	Not detected	Not detected
Bovine Adenovirus Type 5 (BAV5)	9CFR 113.53	N/A	Not detected	Not detected
Bovine Respiratory Syncytial Virus (BRSV)	9CFR 113.53	N/A	Not detected	Not detected

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Viruses / Mycoplasma (cont)

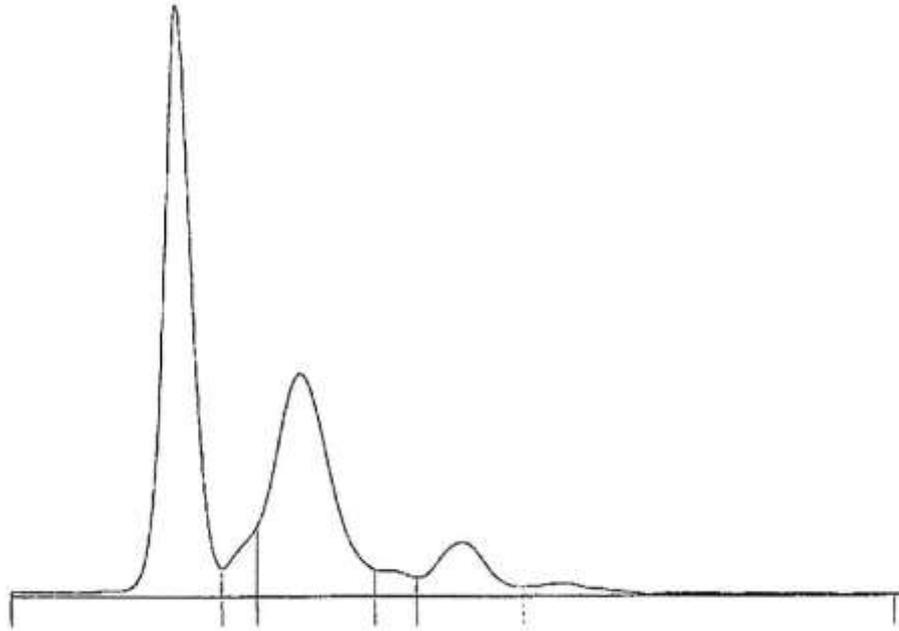
<u>Test</u>	<u>Method</u>	<u>Units</u>	<u>Specification</u>	<u>Results</u>
Bovine Parvovirus (BPV)	9CFR 113.53	N/A	Not detected	Not detected
Bluetongue (BTV)	9CFR 113.53	N/A	Not detected	Not detected
Rabies Virus	9CFR 113.53	N/A	Not detected	Not detected
Reovirus	9CFR 113.53	N/A	Not detected	Not detected
Cytopathic effects (IBR)	9CFR 113.53	N/A	Not detected	Not detected
Haemadsorption (PI-3)	9CFR 113.53	N/A	Not detected	Not detected

Biochemical Assay**General / Protein Test**

	<u>Units</u>	<u>Specification</u>	<u>Results</u>
Alkaline Phosphatase (ALP)	U/L	As reported	203
Aspartate Aminotransferase (AST)	U/L	As reported	49
Albumin	g/L	As reported	24
Beta Hydroxybutyrate (BHB)	mmol/L	As reported	0.1
Bicarbonate	mmol/L	As reported	16
Bilirubin (total)	µmol/L	As reported	3
Calcium	mmol/L	As reported	3.6
Chloride	mmol/L	As reported	99
Cholesterol	mmol/L	As reported	1.0
Creatinine	µmol/L	As reported	198
Creatinine Phosphokinase (CK)	U/L	As reported	162
Gamma Glutamyltransferase (GGT)	U/L	As reported	8
Globulin	g/L	As reported	15
Glutamate Dehydrogenase (GLDH)	U/L	As reported	9
Magnesium	mmol/L	As reported	1.4
Phosphorus	mmol/L	As reported	3.6
Potassium	mmol/L	As reported	11.8
Sodium	mmol/L	As reported	136
Urea	mmol/L	As reported	6.3

Serum Protein Electrophoresis

<u>Protein</u>	<u>Units</u>	<u>Specification</u>	<u>Results</u>
Albumin	%	As reported	48.5
Alpha 1	%	As reported	4.0
Alpha 2	%	As reported	34.9
Beta Globulins	%	As reported	9.8
Gamma Globulins	%	As reported	2.8

Serum Electrophoretogram**QUALITY ASSURANCE**

M. Camacho (Quality Assurance Manager)	Sign & date: <i>M Camacho</i> 06/11/2017
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