

MANUFACTURER'S DECLARATION

FOETAL BOVINE SERUM



BOVOGEN BIOLOGICALS

MANUFACTURER'S DECLARATION

To whom it may concern,

FBS Lot no. 2212A

Bovogen Biologicals Pty Ltd hereby confirms that, based on extended stability testing, Bovogen Foetal Bovine Serum (FBS) should remain suitable for use for up to 6 years from the date of manufacture, provided that it has been stored, thawed, and handled in accordance with the specified guidelines.

For Lot No. 2212A, this six-year period extends until December, 2028.

QUALITY ASSURANCE

M. Camacho (Quality Assurance Manager)	Sign & date: <i>M Camacho</i> 11/05/2026
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CERTIFICATE OF ANALYSIS

FOETAL BOVINE SERUM – STERILE



BOVOGEN BIOLOGICALS

CERTIFICATE OF ANALYSIS

Product: Foetal Bovine Serum - Sterile
Product Code: SFBS
Lot No: 2212A
Manufacture date: December, 2022
Expiration date: December, 2027
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	7.3
Osmolality	Ph. Eur. 2.2.35	mOsm/kg	260 -340	311
Haemoglobin	USP<851>	mg/100mL	< 25	8.2
Total Protein	Ph. Eur. 2.5.33	g/L	30 -50	38
Total IgG	Ph. Eur. 2.7.1 (SRID)	µg/mL	< 350	107.0
Endotoxin	Ph. Eur. 2.6.14	EU/mL	< 30	< 1.0
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

Page 1 of 3

Viruses / Mycoplasma (cont)

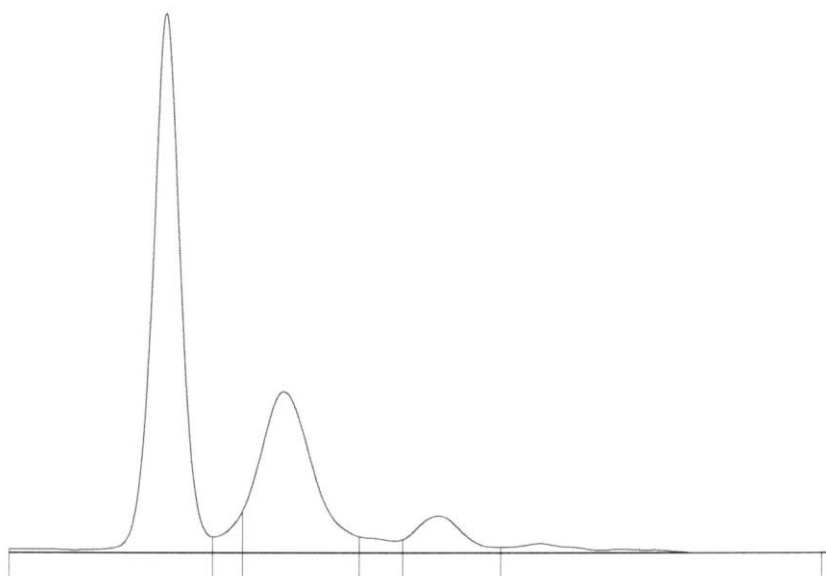
<u>Test</u>	<u>Method</u>	<u>Units</u>	<u>Specification</u>	<u>Results</u>
Bovine Parvovirus (BPV)	9CFR 113.53	N/A	Not detected	Not detected
Bluetongue (BTV)	9CFR 113.53	N/A	Not detected	Not detected
Rabies Virus	9CFR 113.53	N/A	Not detected	Not detected
Reovirus	9CFR 113.53	N/A	Not detected	Not detected
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	261
Aspartate Aminotransferase (AST)	U/L	As reported	38
Albumin	g/L	As reported	26
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	3.38
Chloride	mmol/L	As reported	99
Cholesterol	mmol/L	As reported	0.7
Creatinine	µmol/L	As reported	236
Creatinine Phosphokinase (CK)	U/L	As reported	139
Gamma Glutamyltransferase (GGT)	U/L	As reported	4
Globulin	g/L	As reported	12
Glutamate Dehydrogenase (GLDH)	U/L	As reported	6
Magnesium	mmol/L	As reported	1.4
Phosphate	mmol/L	As reported	3.25
Potassium	mmol/L	As reported	10.6
Sodium	mmol/L	As reported	135
Urea	mmol/L	As reported	5.9

Serum Protein Electrophoresis

<u>Protein</u>	<u>Units</u>	<u>Specification</u>	<u>Results</u>
Albumin	%	As reported	46.5
Alpha 1	%	As reported	2.8
Alpha 2	%	As reported	37.9
Beta Globulins	%	As reported	9.9
Gamma Globulins	%	As reported	2.9

Serum Electrophoretogram**QUALITY ASSURANCE**

M. Camacho (Quality Assurance Manager)	Sign & date: <i>M Camacho</i> 30/01/2023
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