

# **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**

| <b><u>Test</u></b>             | <b><u>Method</u></b>      | <b><u>Units</u></b> | <b><u>Specification</u></b> | <b><u>Results</u></b> |
|--------------------------------|---------------------------|---------------------|-----------------------------|-----------------------|
| 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<br>(SRID)  | µg/mL               | < 350                       | 160                   |
| Endotoxin                      | Ph. Eur. 2.6.14           | EU/mL               | < 30                        | <1.2                  |
| Aerobic and Anaerobic Bacteria | USP<71>/Ph. Eur.<br>2.6.1 | N/A                 | Not detected                | Not detected          |
| Fungi (Yeast and Mould)        | USP<71>/Ph. Eur.<br>2.6.1 | N/A                 | Not detected                | Not detected          |

#### **Viruses / Mycoplasma**

| <b><u>Test</u></b>                        | <b><u>Method</u></b> | <b><u>Units</u></b> | <b><u>Specification</u></b> | <b><u>Results</u></b> |
|---|----------------------|---------------------|-----------------------------|-----------------------|
| 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)**

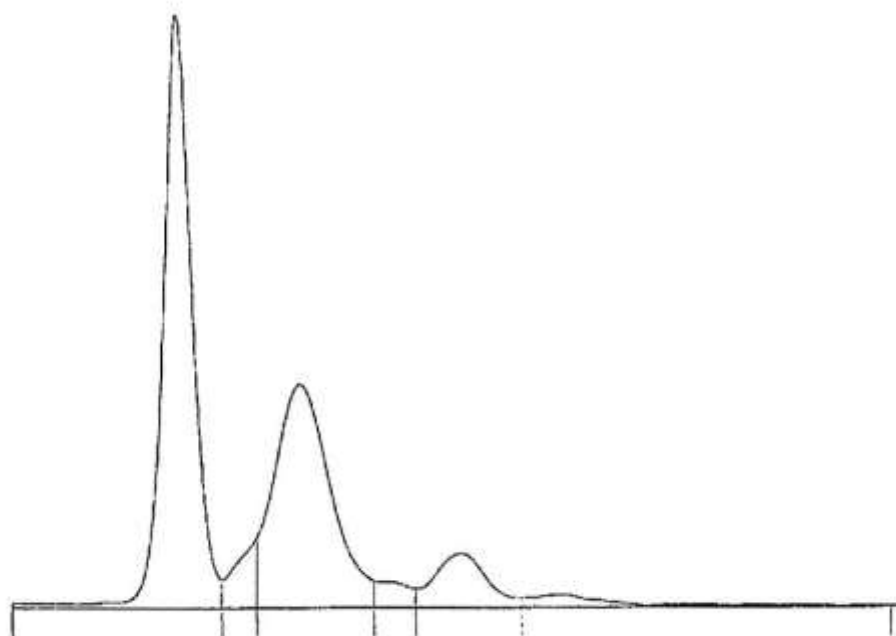
| <b><u>Test</u></b>       | <b><u>Method</u></b> | <b><u>Units</u></b> | <b><u>Specification</u></b> | <b><u>Results</u></b> |
|--------------------------|----------------------|---------------------|-----------------------------|-----------------------|
| Bovine Parvovirus (BPV)  | 9CFR 113.53          | 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**

| <b><u>General / Protein Test</u></b> | <b><u>Units</u></b> | <b><u>Specification</u></b> | <b><u>Results</u></b> |
|--------------------------------------|---------------------|-----------------------------|-----------------------|
| 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**

| <b><u>Protein</u></b> | <b><u>Units</u></b> | <b><u>Specification</u></b> | <b><u>Results</u></b> |
|-----------------------|---------------------|-----------------------------|-----------------------|
| 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:

*M Camacho*

06/11/2017