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|  | Document ID: | TDS-S-SFBS-EU-015 | Version: | 005 |
| | Date of Issue: | 10-JAN-2022 | Approved by: | Dr. Iman Kamranfar |
| | Review Date: | 10-JAN-2024 | Signature: |  |
| | Title: | TECHNICAL DATA SHEET | | |



SPECIMEN

| | | | |
|---------------------------------------|---|-----------------------|--------------|
| Product Name | Fetal ExCell | | |
| Filtration/Treatment | Triple 0.1µm sterile filtered | | |
| Origin | EU Eligible | | |
| Product Codes | S-SFBS-EU-015 | | |
| Shelf Life | 5 Years from DOM | | |
| Storage Temperature | <-15°C | | |
| Shipping Temperature | dry ice | | |
| | | | |
| Physical and Chemical Analysis | Method | Specifications | Units |
| Identity | Internally Validated | Bovine | n/a |
| Appearance | Visual | Clear yellow-amber | n/a |
| Specific Gravity | Mass Balance | > 1.01 | g/ml |
| pH | Electronic pH Meter | 6.8 - 8.2 | n/a |
| Osmolality | Osmometer | 260 - 340 | mOsm/kg |
| Endotoxin | LAL Kinetic | < 10 | EU/ml |
| Free Hemoglobin | Colorimetric | < 50 | mg/dl |
| | | | |
| Protein Profile | | | |
| Total Protein | IDEXX Catalyst One | 3.0 – 5.0 | g/dl |
| Albumin | IDEXX Catalyst One | 1.4 - 3.6 | g/dl |
| Globulin | IDEXX Catalyst One | 0.4 - 2.6 | g/dl |
| IgG | ELISA | < 500 | µg/ml |
| Electrophoretic Pattern | Capillary Electrophoresis | Normal | n/a |
| | | | |
| Sterility | | | |
| Sterility | Eur. Ph. 2.6.1 | Pass | |
| Mycoplasma | qPCR | Not detected | n/a |
| | | | |
| Antibiotic Testing | | | |
| Tetracycline | IDEXX Snap Test | Test and report | n/a |
| Oxytetracycline | IDEXX Snap Test | Test and report | n/a |
| Chlortetracycline | IDEXX Snap Test | Test and report | n/a |
| | | | |
| Virus Testing | | | |
| BVDV/BHV-1/PI-3 (CPE) | Cell Culture | Not detected | n/a |
| Rabies Virus | qPCR | Not detected | n/a |
| Bluetongue Virus (BTV) | qPCR | Not detected | n/a |
| BRSV | qPCR | Not detected | n/a |
| Reo Virus | qPCR | Not detected | n/a |
| BAV | qPCR | Not detected | n/a |
| BoPV-1, -2 | qPCR | Not detected | n/a |
| | | | |
| Antibody Testing | | | |
| BVDV - Antibody Type 1 | Serum Neutralization Test (Cell Culture) or Detection of Antibodies (ELISA) | Test and report | n/a |
| BVDV - Antibody Type 2 | Serum Neutralization Test (Cell Culture) or Detection of Antibodies (ELISA) | Test and report | n/a |
| BHV-1 | Detection of Antibodies (ELISA) | Test and report | n/a |
| PI-3 | Detection of Antibodies (ELISA) | Test and report | n/a |

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| Biochemistry | | | |
|--|--|--|------------------|
| Aspartate Aminotransferase (AST) | IDEXX Catalyst One | Record | U/L |
| Alanine Aminotransferase (ALT) | IDEXX Catalyst One | Record | U/L |
| Lactate Dehydrogenase (LDH) | IDEXX Catalyst One | Record | U/L |
| Alkaline Phosphatase (ALKP) | IDEXX Catalyst One | Record | U/L |
| Gamma-Glutamyl Trans.(GGT) | IDEXX Catalyst One | Record | U/L |
| Cholesterol (CHOL) | IDEXX Catalyst One | Record | mmol/L |
| Glucose (GLU) | IDEXX Catalyst One | Record | mmol/L |
| Urea (BUN) | IDEXX Catalyst One | Record | mmol/L |
| Creatinine (CREA) | IDEXX Catalyst One | Record | μmol/L |
| Uric Acid (URIC) | IDEXX Catalyst One | Record | μmol/L |
| Calcium (Ca) | IDEXX Catalyst One | Record | mmol/L |
| Phosphorus (PHOS) | IDEXX Catalyst One | Record | mmol/L |
| Total Bilirubin (TBIL) | IDEXX Catalyst One | Record | μmol/L |
| Magnesium (Mg) | IDEXX Catalyst One | Record | mmol/L |
| Sodium (Na) | IDEXX Catalyst One | Record | mmol/L |
| Potassium (K) | IDEXX Catalyst One | Record | mmol/L |
| Chloride (CL) | IDEXX Catalyst One | Record | mmol/L |
| Cell Culture Testing - Option 1 | | | |
| Cell Line | Method | Specifications | Results |
| L-929, HELA, MRC-5 | Morphology | Tested vs. Control Serum | Scoring System 1 |
| L-929, HELA, MRC-5 | Density | Tested vs. Control Serum | Scoring System 2 |
| L-929, HELA, MRC-5 | Cell Count | Cell count [log10/ml]/dead cells vs. Control | Record |
| Scoring system | | | |
| Scoring system | Meaning | | Results |
| 1 - Morphology | Dead Cells | | 0 |
| | Many Cells degenerate and many dead cells | | 1 |
| | Cells partially degenerate and many dead cells | | 2 |
| | Few cells degenerate and few dead cells | | 3 |
| | Without pathological findings | | 4 |
| 2 - Density | Single cells/cell aggregates | | 0 |
| | < 50% confluency | | 1 |
| | 50 - 90% confluency | | 2 |
| | confluency | | 3 |
| | overly confluent | | 4 |
| Cell Culture Testing - Option 2 | | | |
| Cell Line | Method | Specifications | Units |
| BHK-21, MRC-5 | Multiple Passage - Records results vs. control at day: 0, 3, 6, 12 | >75% of control growth | % |
| BHK-21, MRC-5 | Plating Efficiency - Records results vs. control at day: 0, 3, 6, 12 | >75% PE vs. control PE | % |
| BHK-21, MRC-5 | Cloning Efficiency - Records results vs. control at day: 0, 3, 6, 12 | >75% CE vs. control CE | % |



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RECOMMENDED USE:

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 “frost-free” 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 four 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.

THIS PRODUCT IS NOT INTENDED FOR HUMAN OR ANIMAL CONSUMPTION OR THERAPEUTIC USE.



India Contact:
 Life Technologies (India) Pvt. Ltd.
 306, Aggarwal City Mall, Opposite M2K Pitampura, Delhi – 110034 (INDIA). Ph: +91-11-42208000, 42208111, 42208222, Mobile: +91-9810521400, Fax: +91-11-42208444
 Email: customerservice@lifetechindia.com Website: www.lifetechindia.com