

# Fetal Bovine Serum HI

Triple 0.1 µm sterile filtered

Cat. No.: E5053  
Lot No.: 53012025  
Origin: COLOMBIA  
Date of Manufacture: 01/2025  
Storage: -20°C

## Physical and Chemical Analysis

| Test             | Method               | Specifications                      | Results                             | Units   |
|------------------|----------------------|-------------------------------------|-------------------------------------|---------|
| Identity         | Internally Validated | Bovine                              | Bovine                              | n/a     |
| Appearance       | Visual               | Clear yellow-amber<br>Frozen Liquid | Clear yellow-amber<br>Frozen Liquid | n/a     |
| Specific Gravity | Mass Balance         | > 1.01                              | 1.018                               | g/ml    |
| pH               | Electronic pH Meter  | 6.8 - 8.2                           | 7.52 (21.3°C)                       | n/a     |
| Osmolality       | Osmometer            | 260 - 340                           | 302                                 | mOsm/kg |
| Endotoxin        | LAL Kinetic          | < 10                                | < 0.5                               | EU/ml   |
| Free Hemoglobin  | Colorimetric         | < 25                                | 15.05                               | mg/dl   |

## Protein Profile

| Test                    | Method                    | Specifications  | Results | Units |
|-------------------------|---------------------------|-----------------|---------|-------|
| Total Protein           | IDEXX Catalyst One        | 3.0 - 4.5       | 3.80    | g/dl  |
| Albumin                 | IDEXX Catalyst One        | 1.4 - 3.4       | 1.87    | g/dl  |
| Globulin                | IDEXX Catalyst One        | 0.4 - 2.4       | 1.93    | g/dl  |
| Alpha 1                 | Capillary Electrophoresis | Test and report | 1.06    | g/dl  |
| Alpha 2                 | Capillary Electrophoresis | Test and report | 0.65    | g/dl  |
| Beta                    | Capillary Electrophoresis | Test and report | 0.20    | g/dl  |
| Gamma                   | Capillary Electrophoresis | Test and report | 0.02    | g/dl  |
| IgG                     | ELISA                     | < 500           | 202.75  | µg/ml |
| Electrophoretic Pattern | Capillary Electrophoresis | Normal          | Normal  | n/a   |

## Sterility

| Test       | Method         | Specifications | Results      | Units |
|------------|----------------|----------------|--------------|-------|
| Sterility  | Eur. Ph. 2.6.1 | Pass           | Pass         | n/a   |
| Mycoplasma | qPCR           | Not detected   | Not detected | n/a   |

## Antibiotics

| Test              | Method          | Specifications  | Results      | Units |
|-------------------|-----------------|-----------------|--------------|-------|
| Tetracycline      | IDEXX Snap Test | Test and report | Not detected | n/a   |
| Oxytetracycline   | IDEXX Snap Test | Test and report | Not detected | n/a   |
| Chlortetracycline | IDEXX Snap Test | Test and report | Not detected | n/a   |

## Prions

The product is BSE/TSE safe, following the European Pharmacopoeia (monograph 5.2.8) and the European Commission NFGs (EMA/410/01 rev.3). According to the World Organization for Animal Health (OIE), Colombia is recognized as having negligible risk for BSE/TSE.

Our FBS products are manufactured following the main criteria defined by international guidelines (e.g., EMA/CHMP/BWP/457920/2012; FBS specifications published by International Serum Industry Association, European Pharmacopoeia 2262).

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## Virus Testing

| Test                   | Method                          | Specifications | Results      | Units |
|------------------------|---------------------------------|----------------|--------------|-------|
| BRSV/BHV-1/PI-3 (CPE)  | Cell Culture Immunofluorescence | Not detected   | Not detected | n/a   |
| Rabies Virus           | qPCR                            | Not detected   | Not detected | n/a   |
| Bluetongue Virus (BTV) | qPCR                            | Not detected   | Not detected | n/a   |
| BRSV                   | qPCR                            | Not detected   | Not detected | n/a   |
| Reo Virus              | qPCR                            | Not detected   | Not detected | n/a   |
| BAV                    | qPCR                            | Not detected   | Not detected | n/a   |
| BoPV-1, 2              | qPCR                            | Not detected   | Not detected | n/a   |

## Antibody Testing

| Test         | Method                          | Specifications  | Results      | Units |
|--------------|---------------------------------|-----------------|--------------|-------|
| BVDV-1, 2, 3 | Detection of Antibodies (ELISA) | Test and report | Not detected | n/a   |
| BHV-1        | Detection of Antibodies (ELISA) | Test and report | Not detected | n/a   |
| PI-3         | Detection of Antibodies (ELISA) | Test and report | Not detected | n/a   |

## Biochemistry

| Test                             | Method             | Specifications  | Results | Units  |
|----------------------------------|--------------------|-----------------|---------|--------|
| Aspartate Aminotransferase (AST) | IDEXX Catalyst One | Test and report | 52      | U/L    |
| Alanine Aminotransferase (ALT)   | IDEXX Catalyst One | Test and report | 15      | U/L    |
| Lactate Dehydrogenase (LDH)      | IDEXX Catalyst One | Test and report | 1626    | U/L    |
| Alkaline Phosphatase (ALKP)      | IDEXX Catalyst One | Test and report | 262     | U/L    |
| Gamma-Glutamyl Trans. (GGT)      | IDEXX Catalyst One | Test and report | 2       | U/L    |
| Cholesterol (CHOL)               | IDEXX Catalyst One | Test and report | 0.62    | mmol/L |
| Glucose (GLU)                    | IDEXX Catalyst One | Test and report | 4.02    | mmol/L |
| Urea (BUN)                       | IDEXX Catalyst One | Test and report | 5.5     | mmol/L |
| Creatinine (CREA)                | IDEXX Catalyst One | Test and report | 294     | µmol/L |
| Uric Acid (URIC)                 | IDEXX Catalyst One | Test and report | 109     | µmol/L |
| Calcium (Ca)                     | IDEXX Catalyst One | Test and report | 3.27    | mmol/L |
| Phosphorus (PHOS)                | IDEXX Catalyst One | Test and report | 2.86    | mmol/L |
| Total Bilirubin (TBIL)           | IDEXX Catalyst One | Test and report | 4       | µmol/L |
| Magnesium (Mg)                   | IDEXX Catalyst One | Test and report | 1.2     | mmol/L |
| Sodium (Na)                      | IDEXX Catalyst One | Test and report | 138     | mmol/L |
| Potassium (K)                    | IDEXX Catalyst One | Test and report | >10     | mmol/L |
| Chloride (CL)                    | IDEXX Catalyst One | Test and report | 103     | mmol/L |
| Triglyceride (Trig)              | IDEXX Catalyst One | Test and report | 1.10    | mmol/L |
| Iron (Fe)                        | Colorimetric       | Test and report | 125.7   | µg/dl  |

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### Cell-Culture Test

| Cell Line | Method     | Specifications                                    | Results               |
|-----------|------------|---------------------------------------------------|-----------------------|
| L-929     | Morphology | Tested vs. Control Serum <sup>1</sup>             | 3/3                   |
| HELA      | Morphology | Tested vs. Control Serum <sup>1</sup>             | 3/3                   |
| MRC-5     | Morphology | Tested vs. Control Serum <sup>1</sup>             | 3/3                   |
| L-929     | Density    | Tested vs. Control Serum <sup>2</sup>             | 3/3                   |
| HELA      | Density    | Tested vs. Control Serum <sup>2</sup>             | 3+/3+                 |
| MRC-5     | Density    | Tested vs. Control Serum <sup>2</sup>             | 3/3-                  |
| L-929     | Cell Count | Cell count [log <sub>10</sub> /ml]/dead cells [%] | 5.79/0.0 vs. 5.56/0.0 |
| HELA      | Cell Count | Cell count [log <sub>10</sub> /ml]/dead cells [%] | 5.69/0.0 vs. 5.78/0.0 |
| MRC-5     | Cell Count | Cell count [log <sub>10</sub> /ml]/dead cells [%] | 5.61/0.0 vs. 5.56/0.0 |

### Scoring System (vs. Control Serum):

- <sup>1</sup> 0 cells dead; 1 many degenerated cells, plenty of dead cells; 2 cells partially degenerated; many dead cells; 3 few degenerated cells, some dead cells; 4 all cells ok.
- <sup>2</sup> 0 single cells/small colonies; 1 <50% confluent; 2 50 – 90% confluent; 3 confluent; 4 more than confluent

| Cell Line | Method                                                      | Specifications         | Results |
|-----------|-------------------------------------------------------------|------------------------|---------|
| BHK-21    | Cloning Efficiency - Records results vs. control on day 8th | >75% CE vs. control CE | 96%     |

### Interpretation:

The cell growth using test serum Lot: 53012025 was comparable to the internal standard serum.

The viability of the cells before trypsinization was similar. Using the test serum all cells displayed good viability and cell growth.

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