

DOMINIQUE DUTSCHER SAS

HyClone™ Defined Fetal Bovine Serum (FBS), United States Origin

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Overview

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- **Well-defined:** assay results for over 50 components, with additional testing available.
- **US origin:** sourced and processed in the United States with complete traceability to origin.
- **Ultra-low endotoxin:** ≤ 5 EU/mL endotoxin for reduced research and production risk.
- **Sterile-filtered:** proprietary serial 40 nm filter process.
- **Post-filtration treatments:** γ-irradiated and heat-inactivated FBS options also available.
- **Virus-tested:** broad virus panel testing in accordance with 9 CFR 113.53.

Purchase orders with specific lot requests, quoted reserves and/or call off orders should be submitted through Customer Service.

Fetal bovine serum (FBS) is a nutrient-rich cell culture supplement that is high in growth factors and low in antibodies, compared to non-fetal sera.

Defined FBS for cell culture confidence and consistency

HyClone™ Defined FBS is widely used by cell culturists who have a concern for viral contaminants and require an extensive biochemical profile. The final serum is assayed for over 50 components, including proteins, hormones, growth factors, metabolites, and nutrients important for cell culture. Assay results are included in the certificate of analysis and the biochemical assay list. Additional testing, including EMEA conformance testing, is also available.

Exceptionally low endotoxin levels

Endotoxin contamination is a significant concern when producing cell culture-derived products for use in humans or animals. The presence of endotoxin in cell cultures can also have adverse and unpredictable effects on cell growth, function and phenotype that can compromise research results. Our patented closed-system blood collection method and rigorous quality control testing ensure that HyClone™ Defined FBS contains ≤ 5 EU/mL endotoxin and ≤ 15 mg/dL hemoglobin. Low hemoglobin levels in the final product are an indication that extensive cell lysis has not occurred, confirming that the fetal blood has been handled appropriately during collection and transport.

Virus-tested and quality-assured for reduced contamination risk

HyClone™ Defined FBS is filtered through proprietary serial 40 nm (0.04 µm) pore size-rated filters, which are the most retentive filters used in commercial FBS production. This type of filtration is practical in reducing risk while maintaining high performance in cell growth.

Studies demonstrate that this filtration regimen has no adverse effect on cell growth. Before dispensing, each lot of serum is pooled using true pool technology to ensure uniformity and consistency between bottles.

The final serum is virus-tested according to 9 CFR 113.53 to demonstrate that there are no detectable levels of specified viruses, pathogenic agents, and hemadsorbing agents. Robust sterility testing further confirms that the final product contains no detectable growth of bacteria or fungi (current USP) and no detectable mycoplasma.

Post-filtration treatments for added process security

Gamma-irradiated and heat-inactivated FBS options are available to further reduce the risk of adventitious agents, particularly when manufacturing products for use in humans or animals. The irradiation process is validated to deliver a multiple validated dose ranges starting at a minimum dose of 25 kGy.

Regulatory and supply chain security

For decades, Cytiva's HyClone™ premium bovine serum products have exceeded industry standards for quality, purity, and regulatory compliance. HyClone™ serum processes are traceability-certified by the International Serum Industry Association (ISIA). In addition, Cytiva has chosen to be an early adopter of scientific traceability by Oritain™ to prove the country of origin of their premium bovine serum products from the United States, Australia, and New Zealand. Premium bovine serum samples from different regions have been analyzed and Oritain™ has created a database of the unique 'Origin Fingerprint' that is exclusive to each country of origin. Learn more.

Temperature excursions happen, both in transport and on the bench. Storage condition effects on fetal bovine serum for cell culture whitepaper shows how HyClone™ serum maintain viable cell density and cell growth and stay within specification under various temperatures and timeframes.

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Product specifications
HyClone™ Defined FBS, U.S. origin, heat-inactivated, 500 mL

Catalog code	SH30070.03HI
Storage	Sera should be stored at -10°C or lower. Once thawed, sera should be stored at 2° to 8°C.
Origin	US
Endotoxin Concentration	≤ 5 EU/mL
Hemoglobin Concentration	≤ 15 mg/dL
Mycoplasma	Not detected