

HyClone™ Defined Fetal Bovine Serum

HYCLONE SERA

HyClone™ Defined Fetal Bovine Serum (FBS) is our highest quality FBS, designed to deliver exceptional quality and security of supply.

Defined FBS is filtered through our proprietary serial 40 nm (0.04 µm) pore-size-rated filters, which are the most retentive filters used in commercial FBS production. We found that this filtration regimen has no adverse effect on cell growth performance compared to triple 100 nm filtration (Fig. 2 and 3).

Our process delivers high-quality serum with low endotoxin and hemoglobin levels. We use true pooling technology to ensure uniformity and consistency, thereby minimizing lot-to-lot and bottle-to-bottle variability. This product is globally manufactured and is sourced from BSE-negligible countries (United States, New Zealand, and Australia origins) to ensure security of supply.

Over 60 components are analyzed in the Defined FBS finished product, and the results are included in the certificate of analysis for each lot of serum. Testing procedures and results are compliant with EP2262.

Key features of Defined Fetal Bovine Serum include:

- Proprietary serial 40 nm filtration process
- Available from multiple origins
- Full traceability back to original source
- Low in antibodies and high in growth factors
- Low endotoxin level for reduced research and production risk
- Broad virus panel testing according to 9 CFR 113.53
- Certificate of suitability (CEP) available
- US Origin batch sizes available up to 3000 L
- AU and NZ Origin batch sizes available up to 2000 L
- Post-filtration treatments, irradiated and heat inactivated available
- Suitable for adherent, cell and gene therapy applications



Fig 1. HyClone Defined Fetal Bovine Serum

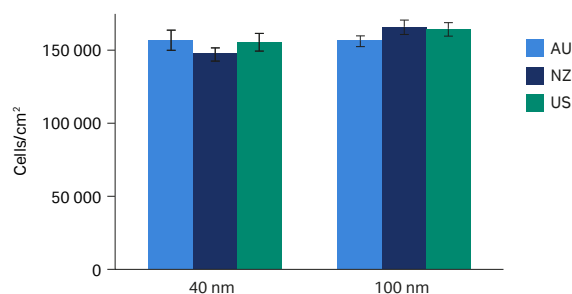


Fig. 2 Vero cell density vs filtration method. Vero cell density on day 5 after culture in T-25 flasks. Cells were cultured with FBS sourced from the United States, New Zealand, or Australia, and Serial 40 nm filtered FBS or triple 100 nm filtered FBS. (n = 9, error bars represent standard deviation)

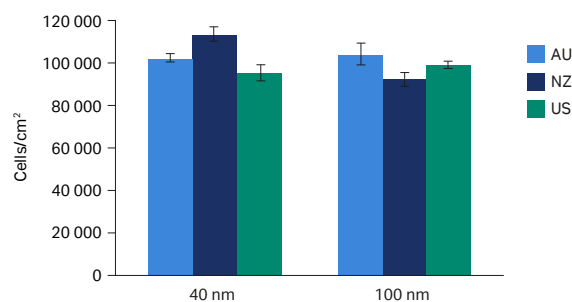


Fig. 3. Hek cell density vs filtration method. Hek cell density on day 5 after culture in T-25 flasks. Cells were cultured with FBS sourced from the United States, New Zealand, or Australia, and serial 40 nm filtered FBS or triple 100 nm filtered FBS. (n = 9, error bars represent standard deviation)

Product storage and handling

Sera should be stored at -10°C or lower. Once thawed, sera should be stored at 2°C to 8°C for up to six weeks in order to maintain quality. If the serum needs to be stored longer than six weeks after opening, it is recommended to aliquot the serum into convenient volumes and refreeze. Handle bottles that have been stored in freezer carefully. Avoid large temperature shifts and protect the serum from exposure to light. Refer to safety data sheet for any safety recommendations. Storage requirements are listed on the product label.

Traceability

Origin of sera is important. To ensure proper origin, traceability, and truth in labeling, we are traceability certified by the International Serum Industry Association (ISIA). In addition, we go a step further than current industry standards by having every batch of Defined FBS from the United States, Australia, and New Zealand independently tested by Oritain.

Thawing

Remove serum from storage at -10°C or lower and place in a refrigerator overnight at 2°C to 8°C. Transfer the serum to a 37°C water bath, agitate periodically to mix the solutes concentrated at the bottom of the container. Do not hold the serum at 37°C any longer than necessary after thawing. Thawing serum in a bath above 40°C without mixing can denature the concentrated proteins in the bottom of the container and precipitates might form in the bottle. Thawing serum at higher temperatures is not recommended.

Alternatively, bottles can be placed directly from storage at -10°C or lower into a 37°C water bath. Bottles should be agitated to enhance mixing and thawing. Turbidity and flocculent material might be present after thawing or after prolonged storage.

Experience indicates that regardless of the method used to thaw serum, it is critical that it is mixed during the thawing process to prevent the formation of gradients and subsequent precipitation. Because of differences in thawing rates of different components, serum will form a gradient if it is not mixed as it thaws. If serum is allowed to remain in such a gradient state, precipitation is likely to occur.

Quality control testing

Defined FBS is assayed for progesterone, insulin, cholesterol, high density lipoprotein cholesterol, low density lipoprotein cholesterol, triglycerides, gamma globulin, phospholipids, alkaline phosphatase, lactate dehydrogenase, glutamic pyruvic transaminase (SGPT), glutamic oxaloacetic transaminase (SGOT), thiamine (B1), riboflavin (B2), pyridoxine (B6), nicotinic acid (niacin), vitamin H (biotin), vitamin A (retinol), carotene, total vitamin E (tocopherol), cyanocobalamin (B12), pteroylglutamic acid (folate), vitamin C, 1,25 dihydroxy vitamin D, pH, total protein, albumin, blood urea nitrogen, creatinine, total bilirubin, inorganic phosphorus, osmolality, iron, selenium, IgG, sodium, potassium, calcium, chloride, magnesium, glucose, copper, total iron binding capacity (TIBC), and percent saturation. Assays are subject to change without notice.

Test specifications are listed in Table 1.

Table 1. Test specifications

Endotoxin (Limulus amoebocyte lysate gel clot assay)	≤ 5 EU/mL
Hemoglobin (spectrophotometric)	≤ 15 mg/dL
Sterility testing (current USP)	
Bacteria and fungi	No growth
Virus Testing (9 CFR 113.53)	
Fluorescent antibody	
Bluetongue	Not detected
Bovine adenovirus	Not detected
Bovine parvovirus	Not detected
Bovine respiratory syncytial virus	Not detected
Bovine viral diarrhea virus	Not detected
Rabies	Not detected
Reovirus	Not detected
Cytopathogenic agents (e.g., IBR)	Not detected
Hemadsorbing agents (e.g., PI3)	Not detected
Mycoplasma	
Large volume, direct culture	Not detected
Hoechst DNA stain	Not detected
Certificate of suitability	Included

General culture recommendations

Supplementation of classical media such as Dulbecco's Modified Eagle's Medium (DMEM) is recommended at a range between 5% and 10% Defined FBS to support culture of a wide variety of cell lines and applications.

Related products

HyClone classical media

HyClone classical media are manufactured using ISO 9001- and ISO 13485-certified processes. All raw material components have passed strict quality control testing to ensure the appropriate level of quality. The classical media are hydrated using purified process water and have undergone 0.1 µm sterile filtration.

HyClone phosphate buffered saline (PBS)

Our PBS products are manufactured according to cGMP guidelines using ISO 9001- and ISO 13485-certified processes. The products have full traceability and documented origin of all formula ingredients.

HyClone trypsin protease

Our trypsin protease is derived from porcine pancreas and is gamma irradiated prior to hydration and filling. The product is formulated without calcium and magnesium.

Ordering information

Product	Size	Product code
HyClone Defined Fetal Bovine Serum, United States Origin	50 mL	SH30070.01
	100 mL	SH30070.02
	500 mL	SH30070.03
HyClone Defined Fetal Bovine Serum, New Zealand Origin	50 mL	SH31194.01
	100 mL	SH31194.02
	500 mL	SH31194.03
	50 mL (CHINA)	SH31194.05
	100 mL (CHINA)	SH31194.06
	500 mL (CHINA)	SH31194.07
HyClone Defined Fetal Bovine Serum, Australian Origin	50 mL	SH31195.01
	100 mL	SH31195.02
	500 mL	SH31195.03

Find certificates of analysis, safety data sheets, standard formulations, product inserts, and protocols at www.cytiva.com/hyclonecerts.

cytiva.com/hyclone

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