



GIBCO<sup>®</sup> serum—  
it passes the test



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# GIBCO® serum—it delivers

- Highest quality and integrity
- New services, packaging, and products
- Global supplier, support, and service

## A history of quality and innovation

In 1962 Watson, Crick, and Wilkins shared the Nobel Prize in Medicine for their work on the structure of DNA; and working from their garage in Grand Island, New York, Bob and Earline Ferguson recognized the business potential of supplying animal sera for research use. From this humble beginning, Grand Island Biological Company (GIBCO®) has risen to the forefront of companies supporting global life science research, and is now an important part of Invitrogen Corporation.

How did the GIBCO® brand become the world leader for sera, media, and reagents? Our company understood then, and still does today, that the secret is the consistent delivery of quality products that reduce the number of unknowns that scientists experience in their work. Throughout the life sciences, GIBCO®

products have a leading reputation for their reliability—allowing scientists to focus on more important things than troubleshooting cell culture problems. In addition, Invitrogen has become a leading supplier to the global biopharmaceutical industry. Our success is due to our commitment to both small and large laboratories, ranging from the research bench to production-scale facilities.

The original GIBCO® site in Grand Island is now just one of the multiple manufacturing facilities worldwide that make GIBCO® cell culture products. Renowned for its unassailable quality, the GIBCO® brand is ideally positioned for the future to build on its leadership in global markets with the same focus on quality, service, value, and innovation that has guided it through its first 45 years.



## Delivering value

Invitrogen supplies a wide range of GIBCO® animal sera, both bovine and nonbovine, for cell culture applications, the most widely used being fetal bovine serum (FBS).

As a by-product of the beef industry, FBS supply is affected by complex factors, including health concerns and market conditions. For these reasons, Invitrogen ensures supply by obtaining FBS from many countries on many continents (Figure 1), including the following, for global distribution:

- Australia and New Zealand—free of BSE (Table 1)
- Australia, New Zealand, USA, Mexico, Central America, and Canada—free of FMD and rinderpest (Table 2)

In addition, for regional markets, we source FBS from other origins approved by the local veterinary control authorities.

By obtaining FBS from multiple origins, we can offer a selection of high-quality GIBCO® FBS options, allowing you to decide which is the best option and best value for your specific needs. When you rely on us, you have several choices and a guaranteed supply.

Table 1—Global GBR (geographical BSE risk) ratings for FBS.

Origin	GBR rating			
	low 1	2	3	high 4
Australia/New Zealand	●			
Central America	●	●		
South America	●	●		
US			●	
Canada			●	
Mexico			●	
EU		●	●	●

For biopharmaceutical applications, Invitrogen was the first company to offer selected batches of FBS, newborn calf serum, and donor bovine serum specially processed and tested to meet the requirements of the European Medicines Agency (EMA) guidelines for the use of bovine serum.

- Are shipped with a Certificate of Analysis that identifies the country of origin
- Are available with a Certificate of Origin (upon request)
- Are available with an EMA Compliance Package (selected batches only)

Recognizing the strategic importance and unrivalled animal health status offered by New Zealand, a comprehensive product range covering many species (bovine, equine, caprine, ovine, porcine, lapine) is available and sourced directly from New Zealand. This enables us to offer biopharmaceutical customers the highest level of biosecurity in the supply chain, minimizing risk with direct sourcing, in-country processing, and full documentation.



**Figure 1—Sources of GIBCO® sera.** As one of the world’s leading suppliers of FBS and serum products, we source and manufacture globally to meet customer and market needs. We obtain sera from countries recognized by regulatory authorities worldwide, such as the USDA and the OIE, as being free of foot-and-mouth disease and rinderpest.

In summary, Invitrogen’s GIBCO® sera:

- Comply with all appropriate regulatory requirements regarding import/export

**Table 2—Transmissible diseases reported by OIE (Office International des Epizooties).** These transmissible diseases have the potential for very extensive and rapid spread, irrespective of national borders; have serious socioeconomic or public health consequences; and are of major importance in the international trade of animals and animal products. For more information, visit the website of the Office International des Epizooties: [www.oie.int](http://www.oie.int).

	Australia	Canada	Central America	Mexico	New Zealand	US
African horse sickness	●	●	○	●	●	●
African swine fever	●	●	○	●	●	●
Bluetongue		●	○		●	
Classical swine fever	●	●	○		●	●
Contagious bovine pleuropneumonia	●	●	○	●	●	●
FMD (foot-and-mouth disease)	●	●	●	●	●	●
Highly pathogenic avian influenza	●	●	○	●	●	●
Lumpy skin disease	●	●	○	●	●	●
Newcastle disease	●	●	○		●	●
Peste des petits ruminants	●	●	○	●	●	●
Rift Valley fever	●	●	○	●	●	●
Rinderpest	●	●	●	●	●	●
Sheep pox and goat pox	●	●	○	●	●	●
Swine vesicular disease	●	●	○	●	●	●
Vesicular stomatitis	●	●	○		●	

● Countries in which the disease has never been reported or diseases reported absent in 2006.  
○ Refer to the World Animal Health Report 2006 for specific disease status for Central America.



## Delivering quality

The collection and processing methods used to process sera can affect the quality of the final product.

For over 45 years, GIBCO® cell culture products have set the global standard for quality and performance. As the world's leading supplier of sera, Invitrogen adds value to each product through all stages of collection, processing, filtration, testing, and delivery using stringent process controls and the highest quality standards.

Processed lots of Invitrogen's GIBCO® FBS are:

- Never blended with FBS from other locations
- Manufactured in the country of origin, where applicable, to ensure product integrity and to avoid the risk of cross-contamination
- Processed and tested according to cGMP requirements



Figure 2—Invitrogen's key manufacturing sites for GIBCO® sera.

Invitrogen maintains rigorous control of every step in the production of GIBCO® FBS and other sera. Complete vertical integration, from collection to final product validation, minimizes risk of contamination with adventitious agents, improves lot-to-lot consistency, and results in superior performance.

We manufacture in compliance with the Food and Drug Administration's (FDA) Quality System Regulation (cGMP) at our ISO 9001–certified facilities in the US, Australia, and New Zealand (Figure 2). Comprehensive documentation ensures traceability and control of our processes.

Using aseptic cardiac puncture procedures, we collect fetal bovine blood in bags specifically designed to improve clotting efficiency and serum yield. We then quickly refrigerate the raw material, separating, evaluating, and filtering it according to our stringent specifications. A typical FBS batch size is 1,000–1,600 L; some sources permit batch sizes up to 2,000 L (depending on the manufacturing site). Following final filtration (to triple 0.1 micron precision), which removes bacteria without removing critical serum components, we aseptically dispense the serum into sterile bottles. We then label and freeze the final product and place it on quarantined status until all quality control tests have been completed. Our Process Engineering Department fully validates all procedures and processes to ensure quality and reproducibility. Our Quality Systems Department can trace the raw serum back to the original farm or abattoir where it was collected. Only serum that meets all of our particular manufacturing and finished-product specifications is approved for sale.



## Delivering choice

Looking for some hard-to-find specialty serum product? Invitrogen offers the widest variety of GIBCO® serum products to meet your specific research needs (Tables 3–5).

**NEW** One Shot™ FBS (50 ml) has been tested for tetracycline and found to be below the limit of detection.

Table 3—Types of FBS.

Product	Description/usage guidelines	Source	Quantity	Cat. no.
Certified FBS	Undergoes special biochemical/hormonal profile and bacterial tests. Guaranteed low endotoxin ( $\leq 10$ EU/ml) and low hemoglobin ( $\leq 15$ mg/dl) levels Use with your most sensitive cells	United States	50 ml	16000-077
			40 × 50 ml	16000-085
			100 ml	16000-036
			500 ml	16000-044
			1,000 ml	16000-069 <sup>5</sup>
Certified, Heat-Inactivated FBS	Heated for 30 min at 56°C with mixing to inactivate complement Especially suited to immunological work	United States	100 ml	10082-139
			500 ml	10082-147
			1,000 ml	10082-170 <sup>1</sup>
Qualified FBS	Our most popular FBS product. High quality and exceptional value Suitable for general applications, especially those that do not require defined biochemical/hormonal profiles or bacteriophage testing Endotoxin $\leq 50$ EU/ml—levels routinely less than 10 EU/ml Hemoglobin $\leq 25$ mg/dl	United States	50 ml	26140-111
			40 × 50 ml	26140-129
			100 ml	26140-087
			500 ml	26140-079
			1,000 ml	26140-095 <sup>5</sup>
		Canada <sup>2</sup>	100 ml	12483-012
			500 ml	12483-020
		Australia	100 ml	10099-133
			500 ml	10099-141
			1,000 ml	10099-158 <sup>5</sup>
		Countries that meet USDA importation requirements (Mexico, Central America)	50 ml	10437-077
			40 × 50 ml	10437-085
			100 ml	10437-010
			500 ml	10437-028
		New Zealand	1,000 ml	10437-036 <sup>5</sup>
			100 ml	10091-130
			500 ml	10091-148
		Countries that meet EU importation requirements (South America) <sup>3</sup>	1,000 ml	10091-155 <sup>5</sup>
			100 ml	10270-098 10499-036 <sup>6</sup>
			500 ml	10270-106 10499-044 <sup>6</sup>
Countries that meet EU importation requirements (excluding South America) <sup>3</sup>	100 ml	10106-151 10109-153 <sup>6</sup>		
	500 ml	10106-169 10109-163 <sup>6</sup>		

Product	Description/usage guidelines	Source	Quantity	Cat. no.
Qualified, Heat-Inactivated FBS	Heated for 30 min at 56°C with mixing to inactivate complement Especially suited for immunological work	United States	100 ml	16140-063
			500 ml	16140-171
			1,000 ml	16140-089 <sup>5</sup>
		Canada <sup>2</sup>	100 ml	12484-010
			500 ml	12484-028
		Australia	100 ml	10100-139
			500 ml	10100-147
			1,000 ml	10100-154 <sup>5</sup>
		Countries that meet USDA importation requirements (Mexico, Central America)	100 ml	10438-018
			500 ml	10438-026
			1,000 ml	10438-034 <sup>5</sup>
		New Zealand <sup>4</sup>	100 ml	10093-136 <sup>5</sup>
			500 ml	10093-144 <sup>5</sup>
			1,000 ml	10093-151 <sup>5</sup>
		Countries that meet EU importation requirements (South America) <sup>3</sup>	100 ml	10500-056
			500 ml	10500-064
		Countries that meet EU importation requirements (excluding South America) <sup>3</sup>	100 ml	10108-157
			500 ml	10108-165

1. Available upon request.

2. Available in Canada and countries within Asia Pacific that meet importation requirements.

3. Available in Europe and countries within Asia Pacific that meet importation requirements.

4. Not available in the US.

5. Available upon request in Europe.

6. Gamma irradiated.

red One Shot™ format.



Table 4—Specialty sera.

Product	Description/usage guidelines	Source	Quantity	Cat. no.
Dialyzed FBS	Dialyzed by tangential flow filtration utilizing 10,000 MW cutoff filters Performance tested for cloning and plating efficiency Ideal for radiolabeling assays	United States	100 ml	26400-036
			500 ml	26400-044
		New Zealand	100 ml	000-4018DG
			500 ml	000-4018DJ
Ultra-low IgG FBS	IgG levels are less than 5 µg/ml, and the BVD antibody titer is low or not detectable Suitable for antibody production and veterinary applications	United States	100 ml	16250-086
			500 ml	16250-078
		New Zealand	100 ml	192-1005PG
			500 ml	192-1005PJ
ES Cell-Qualified FBS	Specially tested for the ability to sustain undifferentiated cellular morphology of embryonic stem cells Crucial for the successful maintenance of embryonic stem cells	United States	100 ml	16141-061
			500 ml	16141-079
		Countries that meet USDA importation requirements (Mexico, Central America)	100 ml	10439-016
			500 ml	10439-024
<b>New</b> MSC Qualified FBS	Performance tested using a standard 14-day MSC CFU-f assay Each lot is tested against an in-house FBS reference standard using cells from a master cell bank of MSCs from normal bone marrow donors. This ensures lot-to-lot performance consistency.	Countries that meet USDA importation requirements (Mexico, Central America)	100 ml	12662-011
			500 ml	12662-029
		Australia	100 ml	12664-017
			500 ml	12664-025
		New Zealand	100 ml	12665-014
			500 ml	12665-022
		United States	100 ml	12763-017
			500 ml	12763-025
<b>New</b> Charcoal Stripped FBS	A serum product that will reduce lot-to-lot variability on hormone levels, which will help eliminate some of the influences steroids and other components have on cells Ideal for customers doing cell culture work using immunoassay systems and insulin assay methods	Countries that meet USDA importation requirements (Mexico, Central America)	100 ml	12676-011
			500 ml	12676-029

Table 5—Other sera.

Product	Description/usage guidelines	Source	Quantity	Cat. no.
Newborn Calf Serum	Collected from calves typically 20 days old or younger	New Zealand	100 ml	16010-167
			500 ml	16010-159
			1,000 ml	16010-142*
Newborn Calf Serum, Heat-Inactivated	Collected from calves typically 20 days old or younger Heated for 30 min at 56°C with mixing to inactivate complement	New Zealand	100 ml	26010-066
			500 ml	26010-074
Bovine Serum	Collected from prime cattle with an age range of 12–36 months, but usually 24 months or younger	New Zealand	100 ml	16170-086
			500 ml	16170-078
			1,000 ml	16170-060
Bovine Serum, Heat-Inactivated	Collected from prime cattle with an age range of 12–36 months, but usually 24 months or younger Heated for 30 min at 56°C with mixing to inactivate complement	New Zealand	100 ml	26170-035
			500 ml	26170-043
Donor Bovine Serum	Collected from prime cattle with an age range of 12–36 months, but usually 24 months or younger	New Zealand	500 ml	16030-074
Donor Bovine Serum, with Iron	Collected from prime cattle with an age range of 12–36 months, but usually 24 months or younger Ferric citrate complex at 6.0 mg/dl	New Zealand	500 ml	10371-029
Horse Serum	EIA tested (negative) from a donor herd	New Zealand	100 ml	16050-130
			500 ml	16050-122
			1,000 ml	16050-114*
Horse Serum, Heat-Inactivated	EIA tested (negative) from a donor herd Heated for 30 min at 56°C with mixing to inactivate complement	New Zealand	100 ml	26050-070
			500 ml	26050-088
Chicken Serum	Collected from healthy birds slaughtered for human consumption	New Zealand	500 ml	16110-082
Goat Serum	Collected from donor herd	New Zealand	100 ml	16210-064
			500 ml	16210-072
Lamb Serum	Collected from animals younger than 1 year old	New Zealand	500 ml	16070-096
Porcine Serum	Collected from animals younger than 1 year old	New Zealand	500 ml	26250-084
Rabbit Serum	Collected from animals typically 6 months old or younger	United States	100 ml	16120-099
			500 ml	16120-107

\* Available upon request in Europe.



## Delivering confidence

Can you trust our serum products to be used in your research? We perform a wide range of quality control tests to ensure the quality of the final product and to ensure that you get the consistent performance you expect from GIBCO® serum products. The following quality control tests are performed on each production lot, depending on the use of the serum (Tables 6 and 7).

Table 6—FBS quality control tests.

Test	Certified 16000	Certified Heat-Inactivated 10082	Qualified 26140,12483, 10437, 10099, 10091, 10270, 10106
Bacteriophage tested	●	●	● <sup>1</sup>
Biochemical profile	●	●	● <sup>1,6</sup>
Bovine IgG (<5 µg/ml)			
Determination of % oxy Hb (>70%)	●		● <sup>1</sup>
Electrophoretic pattern	●	●	●
Endotoxin (EU/ml)	●	●	●
ES cell performance assays			
MSC CFU-f assay			
Glucose (<5 µg/ml)			
Hemoglobin (mg/dl)	●	●	●
Hormone profile	●	●	● <sup>1,6</sup>
Mycoplasmas	●	●	●
Osmolality	●	●	●
Performance tested	●	●	●
pH	●	●	●
Sf9 cell assay	●	●	● <sup>1,2</sup>
Sterility testing (bacteria/fungi)	●	●	●
Tetracycline*	●	●	● <sup>3</sup>
Total protein	●	●	●
Viral testing			
Akabane virus			● <sup>1</sup>
Bluetongue virus	●	●	● <sup>4</sup>
Bovine adenovirus FA	●	●	● <sup>4</sup>
Bovine parvovirus FA	●	●	● <sup>4</sup>
Bovine respiratory syncytial virus FA	●	●	● <sup>4</sup>
Bovine viral diarrhea virus FA	●	●	●
Bovine viral diarrhea neutralization assay			
Cytopathic agents (e.g., IBR)	●	●	●
Hemadsorbing agents (e.g., PI3)	●	●	●
Reovirus FA	●	●	● <sup>4</sup>
Rabies virus FA	●	●	● <sup>4</sup>

1. Indicates test performed and passed on Australian sourced product (10099, 10100) sold in the US.

2. Sf9 testing performed on selected lots of 26140, 16140, 10437, 10438.

3. Indicates testing done on US and USDA Approved (26140, 10437) sources only.

4. Excludes EU approved origins.

5. Estradiol testing only.

6. Indicates test performed on Canadian-sourced product (12483, 12484).

\* Test was added in January 2006.

Qualified Heat-Inactivated 16140, 12484, 10438, 10100, 10093, 10500, 10108	Dialyzed 26400	Ultra-Low IgG 16250, 192-1005	Charcoal Stripped 12676	ES Cell-Qualified 16141, 10439	MSC Qualified 12662, 12664, 12665, 12673
● <sup>1</sup>					● <sup>1</sup>
● <sup>1,6</sup>					● <sup>1</sup>
		●			
● <sup>1</sup>					● <sup>1</sup>
●	●	●		●	●
●	●	●	●	●	●
				●	
	●				●
●	●	●		●	●
● <sup>1,6</sup>			● <sup>5</sup>		● <sup>1</sup>
●	●	●	●	●	●
●	●	●	●	●	●
●	●	●	●	●	●
●	●	●	●	●	●
● <sup>1,2</sup>					● <sup>1</sup>
●	●	●	●	●	●
● <sup>3</sup>				●	● <sup>3</sup>
●	●	●	●	●	●
● <sup>1</sup>					● <sup>1</sup>
● <sup>4</sup>	●	●	●	●	●
● <sup>4</sup>	●	●	●	●	●
● <sup>4</sup>	●	●	●	●	●
● <sup>4</sup>	●	●	●	●	●
●	●	●	●	●	●
		●			
●	●	●	●	●	●
●	●	●	●	●	●
● <sup>4</sup>	●	●	●	●	●
● <sup>4</sup>	●	●	●	●	●



Table 7—Other serum quality control tests.

Test	Newborn Calf Serum 16010	Newborn Calf Serum Heat-Inactivated 26010	Bovine Serum 16170	Bovine Serum Heat-Inactivated 26170	Donor Bovine Serum 16030	Donor Bovine Serum with Iron 10371
Cytotoxicity assay						
Electrophoretic pattern	●	●	●	●	●	●
Endotoxin (EU/ml)	●	●	●	●	●	●
Hemoglobin (mg/dl)	●	●	●	●	●	●
Mycoplasmas	●	●	●	●	●	●
Osmolality	●	●	●	●	●	●
pH	●	●	●	●	●	●
Sp2 performance assay						
Sterility testing (bacteria/fungi)	●	●	●	●	●	●
Total protein	●	●	●	●	●	●
Vero performance assay	●	●	●	●	●	●
Viral testing						
Bluetongue virus	●	●	●	●	●	●
Bovine adenovirus FA	●	●	●	●	●	●
Bovine parvovirus FA	●	●	●	●	●	●
Bovine respiratory syncytial virus FA	●	●	●	●	●	●
Bovine viral diarrhea virus FA	●	●	●	●	●	●
Cytopathic agents	●	●	●	●	●	●
EIA coggins						
Equine herpes virus						
Equine viral arteritis						
Hemadsorbing agents	●	●	●	●	●	●
Porcine adenovirus						
Porcine hemagglutinating encephalitis						
Porcine parvovirus						
Rabies FA	●	●	●	●	●	●
Reovirus FA	●	●	●	●	●	●
Transmissible gastroenteritis virus						

Horse Serum 16050	Horse Serum Heat-Inactivated 26050	Chicken Serum 16110	Goat Serum 16210	Lamb Serum 16070	Porcine Serum 26250	Rabbit Serum 16120
		•		•	•	
•	•	•	•	•	•	•
•	•					
•	•	•	•	•	•	•
•	•	•	•	•	•	•
•	•	•		•	•	
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### Delivering service

Invitrogen is focused on offering you additional programs and services to further reduce variability in your research.

While Invitrogen works to reduce lot-to-lot variation in our GIBCO® FBS through carefully controlled and validated methods of serum performance and quality testing, we recognize that some cell types are sensitive to slight variations in serum; therefore, we offer several additional ways to minimize the effect of these variations on your research.

#### **New sera lot matching database:** **iMATCH™ MPA sera lot matching tool (Figure 3)**

Serum is variable from lot to lot, but that doesn't mean your cell culture needs to be, too.

Invitrogen has solved the puzzle of serum lot variability with iMATCH™—a tool that our FBS specialists use to find you the most consistent or highest-performing lot of serum available. iMATCH™ uses a proprietary algorithm—conducting MPA (multiparametric analysis) of Certificate of Analysis performance parameters.

The iMATCH™ service:

- Saves time by reducing or eliminating serum testing
- Makes serum choices based on performance, not source
- Minimizes fluctuations in cell culture performance
- Increases confidence in your research results

We're also going one step further to characterize sera, by conducting proliferation screening research assays on every lot of US Qualified, US Certified, and USDA Approved FBS for the following cell lines:

- **CHO-K1 (hamster ovary)**—used in studies of genetics, toxicity screening, nutrition, and gene expression, particularly expression of recombinant proteins
- **293F (human embryonic kidney)**—used in the production of lentiviral and retroviral vectors
- **Jurkat (human T cell leukemia)**—used to determine the mechanism of differential susceptibility of cancers to drugs and radiation; also used to study acute T cell leukemia and T cell signaling; Jurkat cells are also useful due to their ability to produce IL-2
- **THP-1 (human monocyte)**—used as a model for understanding activation mechanisms of macrophages and multinucleation
- **ME-180 (human cervical carcinoma)**—used as a model representative of the cervical epithelium *in vivo*, morphologically resembling the vagina and ectocervix
- **A549 (human lung carcinoma)**—used in studying diffusion of water, electrolytes, and other substances across membranes

This information is available only through iMATCH™ and creates a virtual fingerprint of every lot. With your input, iMATCH™ enables us to provide you with a lot of serum that will work in your application, allowing you to remain focused on scientific discovery.

Visit [www.invitrogen.com/imatch](http://www.invitrogen.com/imatch) to learn more.



## Standard performance testing

### Cloning efficiency

We test FBS for its ability to support cloning and growth of murine myeloma cells and derived hybridomas. This is appropriate for most applications where low-density cloning of nonadherent cells or hybridoma development and monoclonal antibody (mAb) production are of primary interest.

### Plating efficiency

We use transformed human cell lines to determine the suitability of FBS for attachment and proliferation of adherent cell lines compared to previously qualified lots of FBS. This practice is suggested for applications using continuous transformed cells at low or normal densities, and when performing clonal selections.

### Growth promotion

We test FBS for its ability to support the proliferation of fastidious human diploid fibroblasts through multiple subcultures. This is useful in determining the lots that are most conducive to supporting the growth and viability of difficult-to-grow, adherent, normal, primary, or established cell lines.

### Heat inactivation

We have a wide range of products that have already been heat inactivated. In addition, heat inactivation can be requested for specific lots. Serum is heat inactivated by mixing in a water bath at a thermostatically controlled temperature of 56°C for 30 minutes.

### Gamma irradiation

At your request, we will gamma-irradiate serum to inactivate any residual common bovine viruses and mycoplasmas that may be present. We have validated a process for using gamma irradiation to inactivate viruses and mycoplasmas in animal sera, including FBS, newborn calf, porcine, and equine sera.<sup>1</sup> We have demonstrated that physiochemical properties and cell culture

performance of serum is not altered by gamma irradiation at levels established by European and FDA guidelines for virus titer reductions.<sup>2,3</sup>

### Reserve serum testing

Our reserve serum testing program allows you to obtain a sample of FBS to test in your own application. While you are testing the sample, we will hold your specified quantity until your assessment is complete. The minimum volumes we will set up on reserve are:

- 40 x 100 ml
- 10 x 500 ml
- 15 x 1,000 ml

We usually hold serum for four weeks. If you require a longer test period, please let us know at the time you make your reserve request.



**Figure 3—iMATCH™ MPA sera lot matching tool.** The iMATCH™ tool decreases variability and increases confidence in research results.



## Cell Culture

### BVD-Neg2 screening (only available with New Zealand and Australian FBS)

This process controls and isolates the potential BVD-contaminated serum prior to any pooling. The successful implementation of this innovative program:

- Greatly reduces the risk of final pooled lots testing BVD positive
- Ensures continuity of supply to customers
- Reduces risk associated with relying solely on detection of infectious virus in 9CFR testing
- Avoids the costs and delays associated with repeat testing after gamma irradiation as required under European regulations

### References

1. Daley, J.P. et al. (1998) Virus Inactivation by Gamma Irradiation of Fetal Bovine Serum. *Focus* 20.3: 86.
2. ICH Topic Q5A (1997) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human and Animal Origin.
3. "Design, Contribution and Interpretation of Studies Validating the Inactivation and Removal of Viruses," CPMP/BWP/268/95, February 1996.

## Delivering reliability

Reliability is undoubtedly one of your foremost considerations in selecting sera for your research, and researchers everywhere agree on the most reliable source. That's why GIBCO® serum is the serum of choice—worldwide. You know that GIBCO® serum provides excellent cell culture performance demonstrated by consistent, reproducible cell growth. You trust GIBCO® serum to be of the highest quality, be readily available, provide lot-to-lot consistency, and be supported by technical and regulatory expertise.

## GIBCO® serum—it passes the test

When it comes to selecting a provider of cell culture serum, reliability is everything. Reliable value. Reliable quality. Reliable choices. Reliable confidence. Reliable service.

To learn more, visit [www.invitrogen.com/FBS](http://www.invitrogen.com/FBS).

## FAQs

### **What is the new iMATCH™ service all about?**

Our FBS specialists use the iMATCH™ tool to find you the most consistent or highest-performing lot of serum available. The iMATCH™ tool uses a proprietary algorithm, conducting multiparametric analysis of Certificate of Analysis performance parameters.

The iMATCH™ tool enables you to save time by reducing or eliminating serum testing; make serum choices based on performance, not source; minimize fluctuations in cell culture performance; and increase confidence in your research results.

### **How can I be sure that the serum I'm using comes from the country I specify?**

Request information from the supplier. The supplier should have records indicating the origin of the material.

We state the origin of every serum batch right on the GIBCO® product label. Additionally, the information is also provided on the Certificate of Analysis supplied with the shipment. Our Quality Systems Department personnel can also trace raw materials back to the original supplier and abattoir or donor farm where the material was collected.

### **Are there other sources, besides the United States, that are BSE free?**

Yes, there are other countries known to be BSE free, i.e., not known to have any reported cases of BSE in the native animals. Australia, Mexico, and New Zealand, for example, are excellent sources of serum.

Did you know that we maintain serum and protein manufacturing operations in New Zealand? New Zealand is considered one of the most pristine sources for materials of animal origin because of its geographic isolation and its conservative animal husbandry practices.

### **What can I do to ensure that the materials I purchase meet specifications?**

Audit your supplier and request the appropriate documentation to support the claims made either on the labeling or the Certificates of Analysis. Ask about registrations and licenses where appropriate. Know your supplier and the functionality of its operation almost as well as you know your own.



### **What is the difference between fetal bovine serum and fetal calf serum?**

Fetal bovine serum (FBS) was once known as fetal calf serum (FCS). They are one and the same thing.

### **My FBS contains flocculence. What could it be?**

Flocculence may appear in FBS for a variety of reasons. The most common reason is the denaturation of serum lipoproteins. You may observe fibrin, one of the clot-forming proteins present in the serum, after the serum has been thawed. This should not affect product performance.

To remove the flocculence, transfer the serum to sterile tubes and centrifuge the material briefly at 400 x g. Then filter the resulting supernatant along with your medium. Do not attempt to filter serum containing flocculence, as it may clog filters.

### **How should I thaw FBS to ensure that the performance is not compromised?**

We recommend you remove serum from the freezer and allow it to thaw in the refrigerator at 2–8°C overnight. The thawing process may then be completed at room temperature. Note: The serum must be regularly mixed during this process.

Warning: Do not incubate FBS at 37°C for extended periods of time. Under these conditions, the product may become cloudy and its performance may be affected due to the sensitivity of many serum components.

Once thawed, the serum can be used immediately.

### **If my FBS arrives partially thawed, can I still use it?**

All GIBCO® FBS is shipped frozen and packaged in dry ice, so it should arrive frozen. You can still use FBS that is partially thawed, but at least two-thirds frozen.

### **What does heat inactivation do to the serum?**

The heating process inactivates portions of the complement cascade. Complement occurs in the following events: cytolytic activities, contraction of smooth muscle, release of histamine from mast cells and platelets, enhanced phagocytosis, chemotaxis, and activation of lymphocytic and macrophage cell types.

### **At what temperature, and for how long, should serum be heat-inactivated?**

You can incubate the thawed product at a thermostatically controlled temperature of 56°C for 30 min. Serum can be heat-inactivated in both our plastic and glass bottles. Warning: do not attempt to heat-inactivate at a higher temperature for prolonged periods, as this may compromise the product's performance through protein denaturation.

### **What is the importance of gamma-irradiated sera?**

Gamma irradiation is recognized as an effective method of inactivating viruses in animal-origin material. Based on USDA regulations for the general requirements for antibody products (9CFR, Section 113.450), the minimum dosage for blood derivatives of animal origin is 25 kGy. Certain European countries require products to be treated prior to importation with a minimum dose of 25 kGy.

We will gamma-irradiate serum upon request. We have validated a process for using gamma irradiation in the range of 30–45 kGy to inactivate the most common bovine viruses and mycoplasmas which may be present in FBS. The level of inactivation is 6–8 logs for viruses and 6–7 logs for mycoplasmas. We have also demonstrated that physiochemical properties and cell culture performance of serum is not altered by gamma irradiation at levels of 30–45 kGy.

### **What packaging sizes are available?**

GIBCO® FBS is available in 50 ml (selected products), 100 ml, 500 ml, and 1,000 ml bottles, and by special order in 3.5 L and 4 L volumes. Other serum products can be offered in package sizes up to 20 L as custom manufacturing requests.



Cell Culture

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