

# Corning® Fetal Bovine Serum

Supply Chain, Capabilities, and Product Offerings





Are you looking for a steady source of serum to help accelerate your journey from the bench to the production line and bring life-changing pharmaceuticals to market?

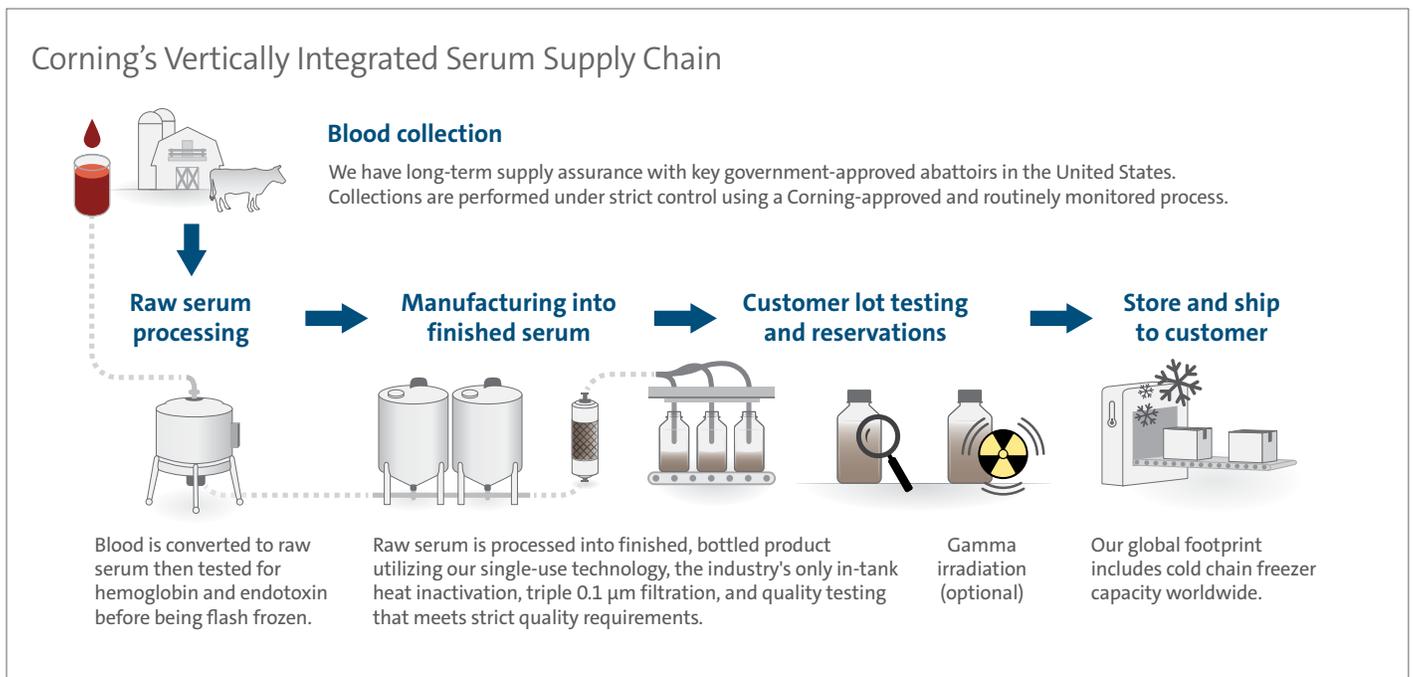
Corning is ready, willing, and able to provide you with a stable supply of quality serum – available when and where you need it. As a leader in cell culture products we are committed to providing you with the knowledge, expertise, and hands-on support to deliver what’s next. We’re ready when you are.

## Why Choose Corning Fetal Bovine Serum?

Corning offers a wide variety of fetal bovine serum (FBS) options to satisfy multiple applications from cell culture research to complete bioprocess production. Our FBS is a perfect complement to our classical and custom cell culture media products. We draw on our fully integrated supply chain, comprehensive product offering, and manufacturing capabilities to help you produce consistent, reliable, and reproducible results.

## Supply Chain

Our vertically integrated serum supply chain, from collection to scientist, allows us to provide a consistent supply of FBS, even during times of regional supply constraints – assuring you can continue your critical manufacturing work for the long-term. Corning’s direct relationship with abattoirs ensures that collectors use our tools and training and adhere to strict aseptic techniques for blood collection at government approved facilities. Corning Life Sciences is certified for traceability by the International Serum Industry Association (ISIA) and every lot is tested to confirm origin. You can be confident in the source of material from Corning.



## Comprehensive Product Offering

We offer FBS from various countries of origin for both Regular and Premium grade to meet your product demands.

**Regular FBS** is derived from government inspected abattoirs from countries that are USDA safety tested for import into the United States. Most countries are recognized by the World Organization for Animal Health (OIE) as having a negligible risk of Bovine Spongiform Encephalopathy (BSE) and being free from foot and mouth disease (FMD).

**Premium FBS** is only collected from government inspected abattoirs in the United States, Australia, and New Zealand and derived from healthy bovine cows and heifers that have passed ante- and post-mortem inspection. These countries are recognized by the World Organization for Animal Health (OIE) as having a negligible risk of Bovine Spongiform Encephalopathy (BSE) and being free from foot and mouth disease (FMD).

Product Specifications	Premium FBS			Regular FBS		
	United States	Australia	New Zealand	Mexico and Central America*	Canada**	Brazil***
Origin						
Endotoxin	≤5.0 EU/mL	≤5.0 EU/mL	≤5.0 EU/mL	≤20 EU/mL	≤20 EU/mL	≤20 EU/mL
Hemoglobin	≤25 mg/dL	≤25 mg/dL	≤25 mg/dL	≤30 mg/dL	≤30 mg/dL	≤30 mg/dL
Mycoplasma	✓	✓	✓	✓	✓	✓
Osmolality (260 - 350 mOsm/kg H <sub>2</sub> O)	✓	✓	✓	✓	✓	✓
pH (6.5 - 8.5)	✓	✓	✓	✓	✓	✓
Sterile Filtered (triple 0.1 μm filtration)	✓	✓	✓	✓	✓	✓
Total Protein	3.0 - 4.5 g/dL	3.0 - 4.5 g/dL	3.0 - 4.5 g/dL			
Cell Growth Performance	✓	✓	✓	✓	✓	✓
9CFR Part 113 Virus Testing	✓	✓	✓	✓	✓	N/A
EMA Virus Testing	Upon request	Upon request	Upon request	Upon request	Upon request	Upon request
Base Cat. Nos.	35-015 35-016	35-076 35-086	35-078 35-088	35-010 35-011	35-077 35-087	35-079 35-089

\*USDA safety tested.

\*\*Not available in EMEA.

\*\*\*Not available in North America.

## Treatments

To meet your specific work requirements, we offer additional processing capabilities.

Treatment	Purpose
Heat Inactivation	Validated unique bulk process is used to heat inactivate serum at 56°C ± 2°C for 30 minutes in our pooling tank prior to final filtration and bottling. This significantly reduces precipitate, creating a more consistent homogeneous product. Individual bottles may also be heat-inactivated post-production upon request.
Gamma Irradiation	Validated process is used to irradiate serum for viral inactivation. Irradiation dose can be customized to fit your specific application.

## Specialty FBS

All Specialty FBS is of US Origin.

Type	Description	Purpose
Charcoal Dextran Stripped	Charcoal-dextran (CD) treatment is commonly used to selectively remove hormones that can affect cell culture growth.	For researchers requiring controlled levels of specific types of hormones and growth factors.
Dialyzed	Dialyzed by tangential flow filtration (10,000 MW cut-off) against saline solution to remove small molecules such as amino acids, hormones, and cytokines.	For researchers requiring a reduced concentration of low molecular weight components while preserving serum proteins.
Tetracycline Negative	Tetracycline tested to a detection level of 0.001 mg/dL using the AOAC 995.09 testing method.	For researchers using tet-inducible gene expression systems and other applications in which the presence of tetracycline is not desired.
Ultra Low IgG	Affinity chromatography is used to reduce Immunoglobulin G (IgG) levels to ≤5 μg/mL.	For IgG antibody production and other work normally hindered by the presence of IgG.

## Other Types of Serum Available

Please contact your local Corning Account Manager for more information or visit [www.corning.com/serum](http://www.corning.com/serum).

- ▶ Bovine calf serum, iron-fortified
- ▶ Donor horse serum
- ▶ Sheep serum
- ▶ Rabbit serum

## Manufacturing

- ▶ Corning filters serum using 100% single-use technology. During the production process, serum is triple 0.1 micron filtered, true pooled, and aseptically bottled before undergoing rigorous quality testing. Additionally, our innovative heat inactivation process is performed at the lot level, producing a more consistent product when compared with traditional water bath heat inactivation.
- ▶ For bioproduction customers, Corning's validated irradiation protocols allows for the flexibility to provide the right product for each customer's process. Additionally, if our comprehensive Certificate of Analysis does not capture a specific test required, a customized testing solution is available upon request. Please inquire with your local Corning Account Manager for more information.

## Quality and Regulatory

- ▶ ISO 13485 Certified Quality Management System
- ▶ Manufacturing in a cGMP compliant facility operating under 21 CFR 820, Quality System Regulation for Medical Device Manufacturers
- ▶ Supply chain is certified for traceability by the International Serum Industry Association (ISIA)
- ▶ Every lot is country-of-origin verified using chemical fingerprinting by Oritain™
- ▶ Validated irradiation protocols
- ▶ Certificates of Suitability (CEP) from the European Directorate for the Quality of Medicines (EDQM) for US origin and Australian origin FBS



**Warranty/Disclaimer:** Unless otherwise specified, all products are for research use or general laboratory use only.\* Not intended for use in diagnostic or therapeutic procedures. Not for use in humans. These products are not intended to mitigate the presence of microorganisms on surfaces or in the environment, where such organisms can be deleterious to humans or the environment. Corning Life Sciences makes no claims regarding the performance of these products for clinical or diagnostic applications. \*For a listing of US medical devices, regulatory classifications or specific information on claims, visit [www.corning.com/resources](http://www.corning.com/resources).

*Corning's products are not specifically designed and tested for diagnostic testing. Many Corning products, though not specific for diagnostic testing, can be used in the workflow and preparation of the test at the customers discretion. Customers may use these products to support their claims. We cannot make any claims or statements that our products are approved for diagnostic testing either directly or indirectly. The customer is responsible for any testing, validation, and/or regulatory submissions that may be required to support the safety and efficacy of their intended application.*

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