



GeminiBio®

Empowering cell culture
and process liquid workflows®

Industry-Leading Human Serum



GeminiBio enables **advanced therapy developers** – working with human immune cells – to optimize their cell culture workflows to improve productivity and speed.

We Get You – We understand that advanced therapy researchers and developers require cell culture products that can support their **productivity and speed**, and that can **meet regulatory requirements** when their projects move through the clinic and into commercial production.

GeminiBio's human serum product portfolio enables customers to optimize their cell culture workflow, improving their productivity, regulatory compliance, and ability to scale.

Human Serum – Manufactured under cGMP

GeminiBio offers normal human serum for research applications, as well as human AB serum for research and commercial applications. All grades are produced under cGMP conditions that meet US and EU production standards and are manufactured from source plasma from healthy male donors of the AB serotype in FDA-registered facilities located in the USA. Our proprietary manufacturing process removes aggregates resulting in a clearer product.

Supporting the Development of Advanced Therapies

GeminiBio's human serum product portfolio is specifically designed to support advanced therapy researchers and developers as they scale from early-stage research through clinical development and ultimately commercial production. Our research grade products offer high-quality performance at an economical price, while our clinical grade products are Xeno-Free, include comprehensive viral testing, and offer donor pool size options that address global regulatory requirements.

Product Name	Product #	Suggested Workflow	Typical Donor Pool Size	Product Description
Normal Human Serum	100-110-100	R&D	NA	Collected from healthy male and/or female donors of all ABO serotypes. Supports basic research and development applications.
GemCell™	100-512-100	R&D	> 200 donors	Collected from healthy male donors of the AB serotype. Product is defibrinated from source plasma using recombinant human thrombin. Supports basic research and development applications.
Human Serum AB Off-the-Clot	100-318-100 (Bottle) 100-318-750 (Cryo-Bag)	Clinical & Commercial	> 50	Collected from healthy male donors of the AB serotype. Off-the-clot serum is collected from blood that is allowed to coagulate naturally after collection, so there are no anticoagulants or preservatives. Based on extensive testing, supports clinical and commercial applications.
GemCell™ Plus Xeno-Free	100-912-100 (Bottle) 100-912-750 (Cryo-Bag)	Clinical & Commercial	> 200 donors	Collected from healthy male donors of the AB serotype. Product is defibrinated from source plasma using therapeutic grade recombinant human thrombin. Based on extensive testing and manufacturing process that is Xeno-Free, supports clinical and commercial applications. Larger lots available to support commercial production due to large donor pool size.
GemCell™ Plus Xeno-Free, World Grade	100-916-100 (Bottle) 100-916-750 (Cryo-Bag)	Clinical & Commercial (meets EU requirements)	16 donors	Collected from a maximum of 16 healthy male donors of the AB serotype. Product is defibrinated from source plasma using therapeutic grade recombinant human thrombin. Based on extensive testing and manufacturing process that is Xeno-Free, supports clinical and commercial applications.

Heat Inactivation and Gamma Irradiation

Heat inactivation (HI) and gamma irradiation (GI) have the potential to negatively impact product performance, as such, GeminiBio does not HI or GI our “off-the-shelf” products. However, customers can request heat inactivation and/or gamma irradiation services to optimize regulatory compliance while maintaining larger pool sizes for more confidence in security of supply.

Research to Commercial Production – Scale with Confidence

As advanced therapy developers progress their therapies to other regions of the world, they need to carefully consider regional regulatory requirements, while also ensuring that product performance is optimized. Further, developers must consider the workflow implications presented by product packaging.

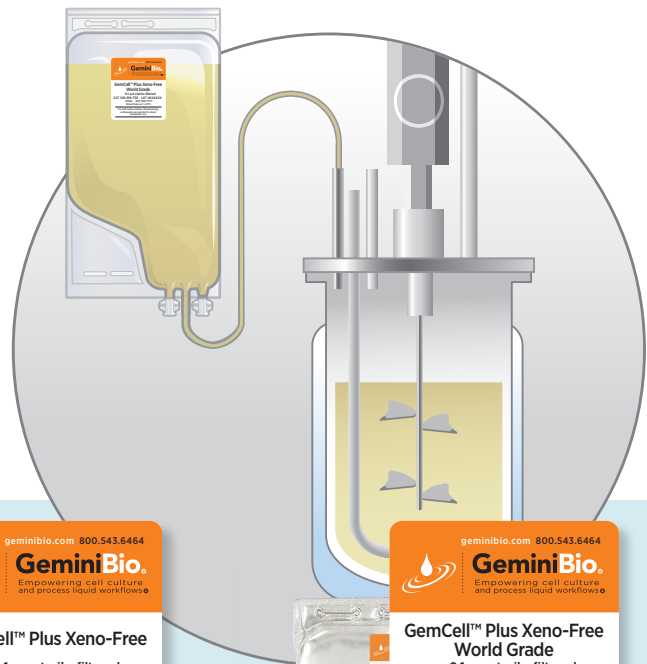
GeminiBio's human serum portfolio simplifies product selection and our **Aseptic Assurance System™** packaging can streamline development and manufacturing workflows.

PRODUCTS	RESEARCH GRADE*		CLINICAL GRADE		
	Normal Human Serum	GemCell™	Human Serum AB Off-the-Clot	GemCell™ Plus Xeno-Free	GemCell™ Plus Xeno-Free, World Grade
Catalog No. & Packaging Options	100-110-100 100mL in Bottle	100-512-100 100mL in Bottle	100-318-100 100mL in Bottle 100-318-750 100mL in Cryo-Bag	100-912-100 100mL in Bottle 100-912-750 100mL in Cryo-Bag	100-916-100 100mL in Bottle 100-916-750 100mL in Cryo-Bag
Type of Thrombin	Bovine	Recombinant Human	None	Therapeutic Grade Recombinant Human	Therapeutic Grade Recombinant Human
Suggested Workflow	R&D	R&D	Clinical & Commercial	Clinical & Commercial	Clinical & Commercial (meets EU requirements)
VIRAL TESTING AT DONOR LEVEL					
HBsAg	■	■	■	■	■
Anti-HCV	■	■	■	■	■
Anti-HIV-1/HIV-2	■	■	■	■	■
Syphilis	■	■	■	■	■
HBV-NAT	■	■	■	■	■
HIV-NAT	■	■	■	■	■
HCV-NAT	■	■	■	■	■
West Nile Virus NAT			■	■	■
Chagas			■	■	■
Anti-HTLV I/II			■	■	■
Anti-HBc IgM			■	■	■
Anti-HBc IgG			■	■	■
PARVO B19 DNA NAT			■	■	■
HAV RNA NAT			■	■	■
ZIKA RNA NAT			■	■	■
HIV p24 Ag			■	■	■
VIRAL TESTING OF FINISHED POOL					
HBcAB			■	■	■
HTLV-I & II			■	■	■
West Nile Virus			■	■	■
Chagas			■	■	■

*Regulatory support for Research Grade products is limited.

Simplify Manufacturing Workflows – Process with Confidence

Advanced therapy developers and manufacturers have gravitated to closed systems to reduce contamination risk during manufacturing and streamline their workflow. GeminiBio's clinical grade products are now available in our **Aseptic Assurance System™** cryo-bags to improve customer's aseptic processes and reduce risk.



To further improve customer workflows, our **Aseptic Assurance System™** products can be customized as required with specific product fill requirements or additional customization (e.g., addition of supplements such as growth factors and cytokines).

Custom Packaging and Manufacturing

GeminiBio human serum comes standard in 125mL bottles, and now 750mL **Aseptic Assurance System™** cryo-bags. We can custom manufacture to meet customer's unique fill size, containment, or other requirements. In addition, GeminiBio can manufacture media or cell culture supplements containing human serum based on customer's specific formulations and packaging requirements. Our custom manufacturing streamlines customer workflows and improves their overall aseptic processes.

Aseptic Assurance System™ – Product Overview

Bag Design

- Bags are made of an EVA film optimized for complete drainage of the bags.*
- The bags are intended for a single-cycle of freezing, storage (down to -196°C), and subsequent thawing (at +37°C), but have been shown to be durable over multiple freeze-thaw cycles.
- Bag has the flexibility to have tubing welded to the tubing tail provided or can be accessed through the two spike ports giving flexibility to the user.

Manufacturing

- Manufactured in an environment where only tested human materials are utilized. No other animal derived materials are present.
- 0.1 micron sterile, filtered, and aseptically filled in ISO 5 environment.
- Product can be heat-inactivated or gamma irradiated upon request

Stability

- >3 years at -20°C
- Product stored at -20°C after manufacture
- Transport on dry ice to negate freeze-thaw cycling

Closed System Access

- The EVA tubing (~14.0 cm) is weldable and enables sterile connections to closed systems.
- Spike ports can be accessible through sealed twist-off protective caps that prevent cross-contamination.



* Source data from Miltenyi Biotec.

Details can be found at <https://www.miltenyibiotec.com/US-en/> or https://static.miltenyibiotec.com/asset/150655405641/document_uueu6ohcq938p8t28ce6uu481q?content-disposition=inline



Industry Leading Human Serum – Research to Production

GeminiBio enables **advanced therapy developers** – working with **human immune cells** – to optimize their cell culture workflows to improve productivity and speed.

GeminiBio's human serum is collected from healthy donors in FDA registered facilities located in the USA. Our proprietary manufacturing process removes aggregates resulting in a higher quality product that is more consistent lot-to-lot. Our human serum options range from normal human serum to Xeno-Free and off the clot human AB serum, to meet the needs from research to development and commercial production.

Wide Range of Options



R&D Applications:

- Normal Human Serum
- GemCell™

Clinical & Commercial Applications:

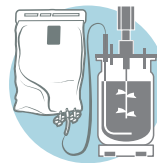
- Human Serum AB Off-the-Clot
- GemCell™ Plus Xeno-Free
- GemCell™ Plus Xeno-Free, World Grade

The Quality Customers Expect



- ISO 13485:2016 certified
- FDA registered Class 1 Medical Device Manufacturer
- cGMP compliant with 21 CFR Part 820

Aseptic Assurance System™



- Simplify development and manufacturing workflows
- Improve confidence and reduce risk with ready-to-use packaging for commercial applications

Custom Manufacturing



- Custom packaging in bottles or bioprocess containers
- Custom manufacturing of human serum containing media or supplements
- Improved workflow/aseptic processes

How can we help you?

<https://www.geminibio.com/contactus>

or contact your GeminiBio Account Manager

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GeminiBio®

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GeminiBio Customer Service

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