



**GeminiBio**<sup>®</sup>

Empowering cell culture  
and process liquid workflows

**Thomas  
Scientific**



## 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 tools that can support their **productivity and speed**, and that can **meet regulatory requirements** if their projects move to the clinic.

GeminiBio's human serum product portfolio enables researchers and advanced therapies customers to optimize their cell culture workflow – whether in research, clinical development, or commercial production – to improve their productivity and ability to scale.

# Human Serum – Manufactured under cGMP

GeminiBio is a leading supplier of human serum and offers a wide range of quality options. Manufactured under cGMP, GeminiBio’s human serum products are extensively tested and have the ability to meet regulatory requirements using non-bovine options improving advanced therapy customer workflow productivity and ability to scale.

## Range of Human Serum Options

GeminiBio offers normal human serum for research applications, as well as an line of human AB serum. All grades of the converted plasma options are produced under cGMP conditions that meet US or 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.

Product Name	Thomas No. Manuf No.	Suggested Workflow	Donor Pool Size	Product Description
Normal Human Serum	CHM03W515 100-110	R&D	NA	Collected from healthy male and female donors of all ABO serotypes. Supports basic research and development applications.
GemCell™ US Origin Human Serum AB	CHM03W504 100-512	R&D	> 200 donors	Collected from healthy male donors of the AB serotype. Product is defibrinated from source plasma AB using bovine thrombin. Supports basic research and development applications.
GemCell Select™ US Origin Human Serum AB	CHM03W510 100-812	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 AB using bovine thrombin. Based on extensive testing, as well as donor pool restriction, supports clinical and commercial applications in both US and EU markets.
GemCell Plus™ US Origin Human Serum AB - Xeno-Free	CHM03W512 100-912	Clinical & Commercial	> 200 donors	Collected from healthy male donors of the AB serotype. Product is defibrinated from source plasma AB 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 pool size.
Human Serum AB Off-the-Clot	CHM03W514 100-318	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.

## Custom packaging and manufacturing

GeminiBio human serum comes standard in 100mL bottles but can be custom manufactured in various bottle sizes or in single use bioprocess containers. In addition, GeminiBio can custom manufacture medias or supplements containing human serum based on customer formulations. Our custom manufacturing streamlines customer workflows and improves their overall aseptic processes.

# Supporting research to commercial production



Product	Normal Human Serum	GemCell™	GemCell Select™	GemCell Plus™ Xeno-Free	Human Serum AB Off the Clot
<b>Thomas No.</b>	<b>CHM03W515</b>	<b>CHM03W504</b>	<b>CHM03W510</b>	<b>CHM03W512</b>	<b>CHM03W514</b>
<b>Manuf. No.</b>	100-110	100-512	100-812	100-912	100-318
<b>Suggested Workflow</b>	R&D	R&D	Clinical & Commercial (meets EU requirements)	Clinical & Commercial	Clinical & Commercial
<b>Type of Thrombin</b>	Bovine	Bovine	Bovine	Therapeutic Grade Human	None
<b>VIRAL TESTING DONOR LEVEL</b>					
HBsAg	■	■	■	■	■
Anti-HCV	■	■	■	■	■
Anti-HIV-1/ HIV-2	■	■	■	■	■
Syphilis	■	■	■	■	■
HBV-NAT	■	■	■	■	■
HIV-NAT	■	■	■	■	■
HCV-NAT	■	■	■	■	■
HAV RNA			■		
Parvo B19 DNA			■		
Atypical Antibodies	■	■	■	■	■
Anti-HBc IgG				■	
Anti-HTLV I/II				■	
Anti-HBc IgM				■	
West Nile Virus NAT				■	
Chagas				■	■
Zika					■
WNV RNA					■
<b>VIRAL TESTING FINISHED POOL</b>					
HBcAB			■	■	
HTLV-I & II			■	■	
West Nile Virus			■	■	
Chagas			■	■	
Hep E IgG			■		

# 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™ US Origin Human Serum AB

### Clinical & Commercial Applications:

- GemCell Select™ US Origin Human Serum AB
- GemCell Plus™ US Origin Human Serum AB - Xeno-Free
- Human Serum AB off the clot

## Custom Manufacturing



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

## The Quality Customers Expect



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

## Large Lots Sizes/Lot-to-lot Consistency



- Improve productivity
- Optimize scalability to support clinical & commercial applications

For Further Manufacturing Use Only.

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