Welcome to our Education Series

Phoenix Scientific

# Human Serum

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# Sustain Human Serum AB

## HS-100 & HS-101 (Xeno Free)

### Human AB Serum

Lacks antibodies against the A and B blood type antigens, preventing reaction with cultured cells. Thrombin is used to defibrinate and convert the plasma to serum.

The serum industry historically uses bovine thrombin for this process when used for research (HS-100).

For clinical research, our Human AB (HS-101) uses human thrombin for conversion when regulatory issues are a concern.

### Human AB Serum Heat-Inactivated

Our heat inactivation protocol involves bringing the temperature of the material to 56° C and maintaining this for 30 minutes.

| Viral Testing (via FDA approved methods) | Additional Testing |
|---|---|
| HBsAg | Mycoplasma |
| HIV-1, HIV-2 | Endotoxin |
| HCV | USP Sterility |
| HIV-1 NAT | Osmolality |
| HCV Nat | Hemoglobin |
| HBV NAT | pH |
| Syphilis | Chemistry |

### Human AB Serum is the serum of choice for work involving:

- Tissue engineering
- T-Cell Transplantation
- Cell therapy applications
- Cell line tested for PBMCs, bone marrow, CD9, CD3 and CD33.
- Recommended for use in biomedical applications involving human cells.

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# Sustain Human AB Serum - Off the Clot

## HS-200

Human Male AB OTC Serum lacks antibodies against the A and B blood type antigens which prevents reaction with cultured cells. Our OTC serum is collected from whole blood and coagulates naturally after collection (no anticoagulant used). This material can be used for the same applications as Human Male AB Serum.

Once clotted, the material is centrifuged to remove the clot and serum is separated. The individual units are then pooled, filtered and bottled. Human Male AB OTC tends to have a slightly higher protein content than plasma derived serums.

Our Human Male AB OTC material is collected and processed using a closed loop system, in an ISO certified manufacturing facility under cGMP allowing the material to be used worldwide in clinical trials and for commercial use.

Each Individual unit is tested and found negative for all required viral markers using FDA-approved methods

- Testing at CLIA certified labs
- Additional testing available upon request
- 0.1µm sterile-filtered

| Viral Testing (via FDA approved methods) | Additional Testing |
|---|---|
| HBsAg | Mycoplasma |
| HIV-1/2, anti HIV-1/2 | Endotoxin |
| HCV, anti HCV | USP Sterility |
| HIV-1 NAT | Osmolality |
| HCV Nat | Hemoglobin |
| HBV NAT | pH |
| Syphilis | Chemistry |
| HAV NAT | |
| Anti HBC | |
| Zika, Chagas, West Nile Virus | |

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# Sustain Human Serum Mixed
## HS-300

Our Human Serum Mixed is a non-AB human serum that is 100% mixed gender and mixed blood type. It is typically used on human cells as a FBS replacement. It uses *human thrombin* to convert the plasma to serum.

It is suitable for use in regenerative medicine where Male AB is not needed. It can also be used in cryopreservation and other various therapeutic applications where mixed blood type serum is acceptable.

Each Individual unit is tested and found negative for all required viral markers using FDA-approved methods:

- Tested at CLIA certified labs
- Additional testing available upon request
- 0.1µm sterile-filtered

| Viral Testing (via FDA approved methods) | Additional Testing |
|---|---|
| HBsAg | Mycoplasma |
| HIV-1/2, anti HIV-1/2 | Endotoxin |
| HCV, anti HCV | USP Sterility |
| HIV-1 NAT | Osmolality |
| HCV Nat | Hemoglobin |
| HBV NAT | pH |
| Syphilis | Chemistry |
| Parvo B19 | |
| HAV NAT | |
| Anti HBC | |
| Zika, Chagas, West Nile Virus | |

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# The Donor Selection Process

**Registration**

- New Donors are subject to Deferral Registry Search, Unacceptable Address Search and Cross-donation check.
- Repeat Donors are Donor ID Verified
- A physical exam is then conducted before donation (initially and annually)

**Screening and Donor Deferral**

- Donor Screening is conducted for Vital Signs, Hematocrit & Total Protein and Medical History Interview.
- Those donors deemed unacceptable are deferred.

**Donation Process**

- Acceptable donors start plasma donation with unique bleed # assigned to each donation.
- Plasma is processed and samples are sent for testing (Initially and annually for atypical antibodies, initially and every 4 months for Syphilis and SPE)
- Every donation is tested for Viral Markers and PCR
- Those units receiving Negative/Non-reactive test results are shipped to Customer or Phoenix.
- Those units testing Reactive or Positive are destroyed or reclassified. (Donor notification, Confirmatory Testing and Lookback Notification, if applicable).

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# Human AB Serum Collection and Processing

**Collection via Plasmapheresis**

- Process of separating whole blood into 2 main parts: plasma & red blood cells.
- Requires single venipuncture to sterile site
- Collection volumes determined by donor weight (690mL-880mL) using Haemonetics PCS2
- During procedure anticoagulant is added and mixed with the whole blood in specially designed centrifugal chamber.
- Whole blood components are then separated into plasma (collected in pooling bottle) and red blood cells (returned to donor)

**Traceability**

- Units are pooled, bottled and cell-culture tested
- Donor medical history & relevant personal data is retained
- A unique barcode bleed number is assigned to each donation
- Unique barcodes allow traceability for donor identification, test results and final disposition

**Disposition**

- All bar-coded samples are aseptically collected at the time of processing prior to freezing the unit.
- Plasma is placed in freezer storage within 20 minutes of delivery to processing lab.
- Samples from the unit for viral testing are immediately frozen to await further testing

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# Clean Room Facility

Processing is performed in a state-of-the-art Clean Room.

## Facility Overview

- Two ISO Class 8 anterooms for gowning/material movement
- ISO Class 7 Clean room, fully validated (IQ, OQ, PQ)
- ISO Class 5 Laminar Hood
- Aseptic techniques, Microbial Contamination Policies, HVAC Interruption Procedures in place

## Capabilities

- Sterile Contract Manufacturing customized to your needs (Formulation, Sterile Filtration/Filling, Large/Small Batch Pooling, Bulk Packaging)
- Aseptic Finish Fill Technical capabilities include continuous environmental monitoring, peristaltic/rotary piston pumping, custom labeling, temperature controlled vessels.

## Monitoring and Certifications

- Continuous monitoring provided by Technical Safety Services, Inc.
- 21 CFR 211, cGMP
- ISO 14644-1 to 14644-7: Cleanrooms and Associated Controlled Environments
- Maintained by Controlled Contamination Services (ABSA, ISPE, PDA and IFMA registered)

# Quarantine, Storage & Disposition

All plasma units collected are placed in a validated freezer within 30 minutes from collection and are completely frozen within 12 hours of donation. Each individual donation is kept in quarantine under suitable conditions until the results of testing have been received and verified as acceptable. Untested plasma is physically segregated from tested plasma within the freezer. Product is stored at -20 degrees C or colder and the temperature is monitored continuously.

All units are traceable to final disposition. Any units implicated in a look back or recall due to unsuitable test results, post donation information or other information obtained which would render the donor or unit unacceptable are identified and placed in secured quarantine until destroyed or appropriately relabeled for non-injectable use. Affected distributed products are identified and consignees are notified as required by federal guidelines.

- Segregated Storage
- Temperature Control
- Separation of unique lots
- Storage of raw materials and final products in separate locations
- Multiple freezer units, including palletized storage
- Worldwide shipping