AKRON BIO

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PRODUCT PAGE

Virus Inactivated Human AB Serum (viHABS) Closed System Solutions (CSS)®

Bags (60 mL) Cat. # AR1048-0060 | Bags (100 mL) Cat. # AR1048-0100

Product Description:

Virus Inactivated Human AB Serum (viHABS) Closed System Solutions (CSS)® is manufactured, tested, and released following relevant cGMP guidelines for blood-derived ancillary materials.

Raw material donor selection is limited to type AB plasma, which lacks anti A and anti B antibodies and helps minimize blood group related immune reactivity in cell culture. No animal derived components are used in the manufacture of this product, and virus inactivated plasma is used for all human derived components.

viHABS CSS provides a human derived alternative to fetal bovine serum and other animal derived serum products. The product is manufactured using Octaplas®, a pooled human plasma that undergoes virus inactivation and prion reduction processing. These manufacturing controls provide multiple measures to reduce biological risk while supporting consistent product performance.

viHABS CSS is packaged in a sterile single use bag with weldable tubing to support integration into closed system cell culture bioprocessing workflows. The packaging enables contained transfer of serum into culture media and helps reduce the need for open handling during processing. The final product is tested for bacterial endotoxins, mycoplasma, and sterility. See Packaging Features below.

Advantages:

Donor Eligibility

- Pooled plasma from US licensed plasma donation centers
- Collection performed in accordance with applicable requirements, including WHO Technical Report Series 840, The Collection, Fractionation, Quality Control, and Uses of Blood and Blood Products
- Nucleic acid virus testing (NAT) performed at multiple stages of manufacturing for HIV, B19, HAV, HBV, HCV, and HEV
- Donor screening and infectious disease testing performed in accordance with 21 CFR 610.40
- Type AB plasma selected to minimize anti A and anti B antibody activity

Plasma Source

- Octaplas® is an FDA-approved, sterile, pyrogen-free, frozen, S/D treated, prion-ligand treated, pooled human plasma
- Solvent Detergent (S/D) treatment for inactivation of enveloped viruses
- Immune Neutralization for inactivation of certain non-enveloped viruses
- Affinity Chromatography intended to reduce prion proteins
- Sterile microfiltration provides an additional control for removal of microorganisms, including parasites.

Manufacturing

- No animal-derived materials are used in the manufacture of this product
- Sterile microfiltration followed by aseptic filling

Packaging

- Sterile bag chamber – Ethylene-vinyl acetate (EVA) for inert biocompatibility and increased flexibility
- Weldable polyvinyl chloride (PVC) 6" outlet tubing (2.5 mm ID x 4.1 mm OD) with female Luer adapter
- Inlet tubing sealed using controlled radiofrequency or heat
- Two twist-off spike ports to accommodate multiple attachments and adapters to fit your purpose
- Tubes and ports are welded into the bag chamber eliminating potential failure points
- All primary packaging is plasticizer free
- Primary packaging materials extensively validated, controlled, and qualified to ensure a consistent experience

Quality

- Manufactured, tested, and released following relevant cGMP guidelines
- USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- ISO 20399:2022, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products and Gene Therapy Products

Release Testing:

- Appearance
- pH
- Osmolality
- Total Protein
- Mycoplasma
- Bacterial Endotoxins
- Sterility
- Comprehensive Metabolic Panel

Stability:

- 24-month shelf life
- Store at -20 °C
- Transport on dry ice
- Avoid repeated freeze-thaw cycles

For Use Statement:

For research use or further manufacturing use in *ex vivo* cell therapy applications. This product is not intended for direct *in vivo* use or for direct clinical use as a drug, therapeutic, biologic, or medical device.

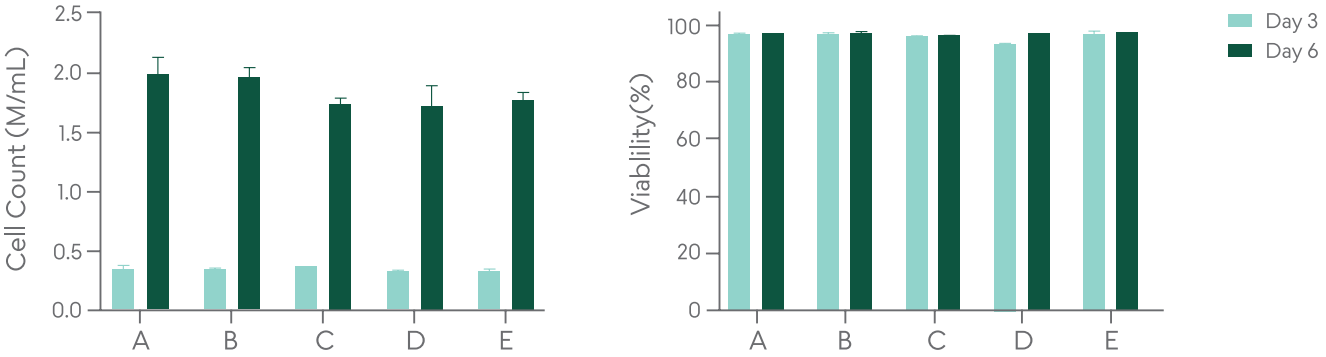
Related Products:

Catalog Number	Product Name	Size
AR1037-0100	Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)®	100 mL
AR1037-0060	Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)®	60 mL
AR1045-0010	Recombinant Human Interleukin-2 (rHu IL-2) Closed System Solutions (CSS)®	1 MIU
AR1050-0020	Recombinant Human Interleukin-2 (rHu IL-2) Closed System Solutions (CSS)®	15 MIU
AK8228-0100	Human Serum Albumin (HSA) 25% Solution	100 mL
AR1010-0100	Human AB Serum, Converted from Octaplas®, Pooled Plasma (Human), Xeno-Free, Virus Inactivated	100 mL
AR1037-0100	Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)®	100 mL
AK9930-0001	Human Fibronectin Solution, Virus Inactivated	1 mg

Virus Inactivated Human AB Serum (viHABS) Closed System Solutions (CSS)®

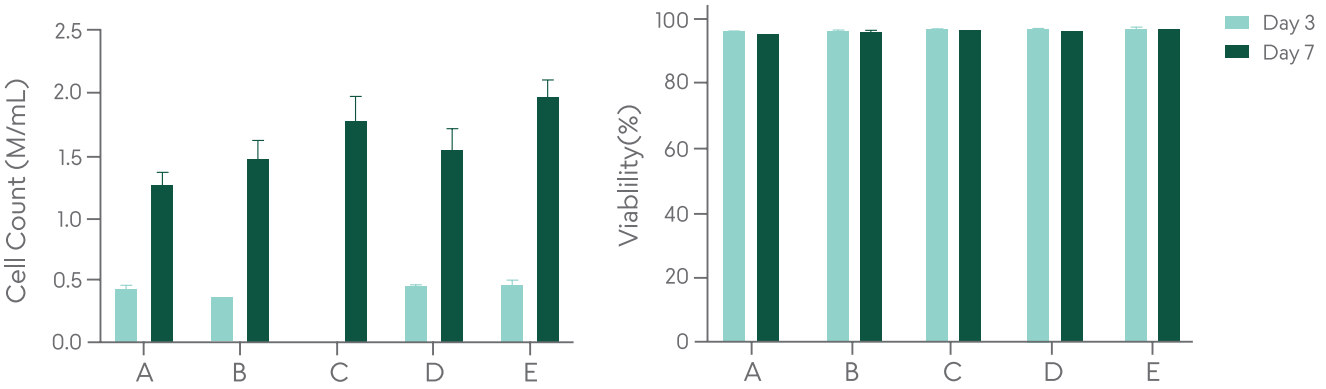
Functionality Data:

Expansion & Viability in Jurkat T Cells



Five different batches of Human AB Serum, Virus Inactivated were compared in Jurkat T cell cultures seeded at 0.02 M in 500 µL of RPMI-1640 media + 5% serum. Each sample was performed in triplicate. Expansion and viability measurements were taken using Vi-CELL BLU at day 3 and again at day 6.

Expansion & Viability in PBMC-derived T cells



Five different batches of Human AB Serum, Virus Inactivated were compared in PBMC-derived T cell cultures seeded at 0.02 M in 500 µL of RPMI-1640 media + 5% serum + 100 U/mL rHu IL-2. Each sample was performed in triplicate. Expansion and viability measurements were taken using Vi-CELL BLU at day 3 and again at day 7.

For more information on our available products or for technical assistance, see contact info below.
For contract orders under master supply agreement, please inquire.