

Human AB Serum Converted from Octaplas®
Pooled Plasma (Human), Xeno-Free, Virus Inactivated
Closed System Solutions (viHABS CSS)™

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

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Product Description:

Akron's Human AB Serum, Converted from Octaplas®, Pooled Plasma (Human), Xeno-Free, Virus Inactivated (viHABS) Closed System Solutions (CSS)™ is manufactured, tested, and released following relevant cGMP guidelines for blood-derived ancillary materials.

Raw material donor selection ensures that the product is devoid of antibodies for A and B blood antigens, therefore minimizing immune reactivity in cell culture. No animal-derived components are used in the manufacture of this product. Virus-inactivated plasma is used for all human-derived components. This product is considered a comparable and superior alternative to fetal bovine serum or other animal-based products. By leveraging Octaplas®, a pharmaceutically licensed virus inactivated and prion-ligand treated plasma, as a raw material, Akron is now offering a high quality, virus inactivated human AB serum product with greater batch-to-batch consistency and a unique safety profile.

The viHABS CSS product is packaged in a sterile single-use bag with weldable tubing, allowing for easy incorporation into modern closed-system cell culture bioprocessing protocols. viHABS CSS increases safety and ease of use by allowing for the introduction of supplement material into culture media in a fully contained manner. The final product undergoes Endotoxin, Mycoplasma, and Sterility testing. See product Packaging features below.

Advantages:

Donor Eligibility

- Pharmaceutically licensed, pooled plasma from US licensed plasma donation centers
- Collection complies with WHO Technical Report Series 840: "The Collection, Fractionation, Quality Control, and uses of Blood and Blood Products"
- Nucleic acid virus testing (NAT) during multiple stages of manufacturing (HIV, B19, HAV, HBV, HCV, HEV)
- Donor screening and virus testing per 21 CFR 610.40
- Type AB donations devoid of antibodies for A and B blood antigens

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 minimizes the presence of bacteria and parasites

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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
- End of inlet tubing sealed using controlled radiofrequency or heat
- Two twist-off spike ports allowing for various 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

- Relevant cGMP guidelines used in manufacture, testing, and release
 - USP Chapter <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
 - ISO 13485:2016, Medical devices - Quality management systems - Requirements for Regulatory Purposes
 - ISO/TS 20399-1-3:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products

Release Testing:

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

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Stability:

- Under long-term stability program
- 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

Human AB Serum Converted from Octaplas®

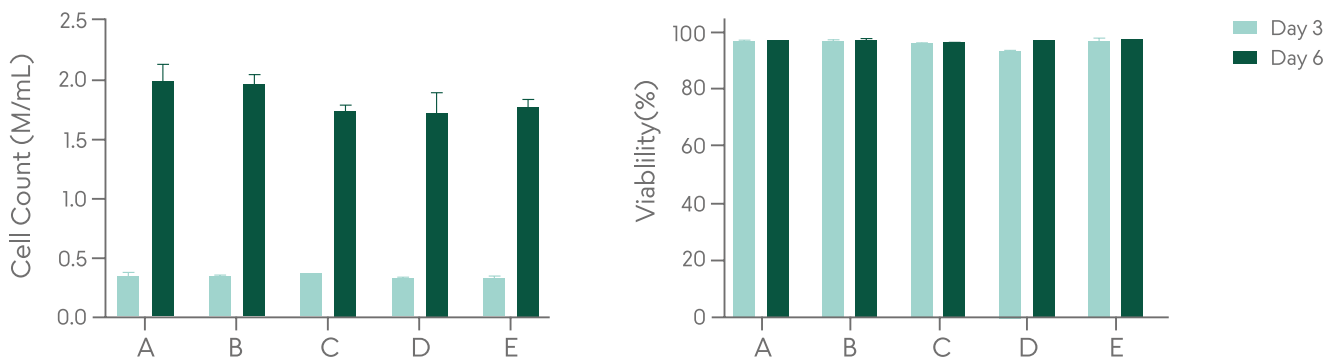
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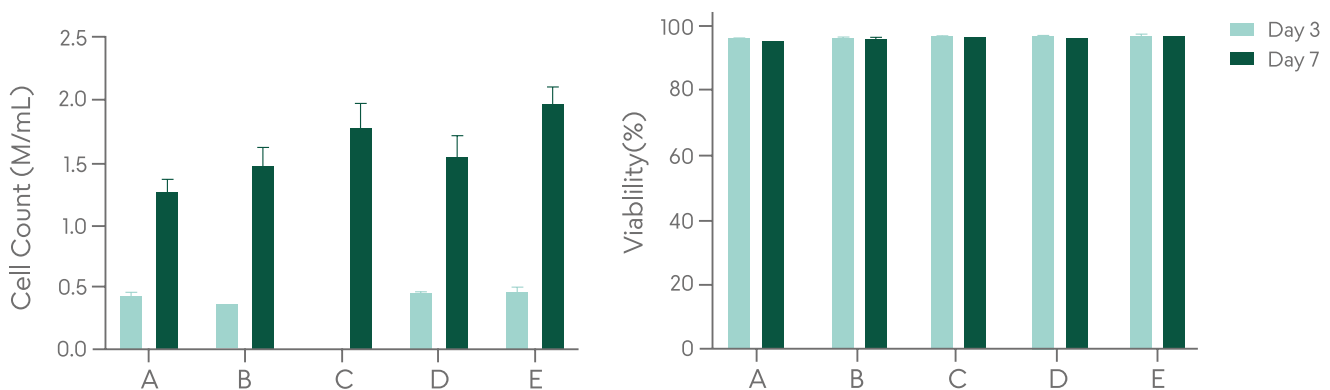
Functionality Data:

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 μ L 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 μ L 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.