

Human AB Serum Converted from Octaplas[®], Pooled Plasma (Human), Xeno-Free, Virus Inactivated

Bottles (100 mL) Cat. # AR1010-0100

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Product Description:

Akron's Human AB Serum, Converted from Octaplas[®], Pooled Plasma (Human), Xeno-Free, Virus Inactivated is manufactured, tested, and released following relevant cGMP guidelines for ancillary materials and is specifically formulated for cell and gene therapy applications. It is supported by a Type II Master File (MF) on file with the FDA which can be referenced during your drug or biologic application process. 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. Our Human AB serum is available in both sterile bottles and sterile single-use bags with weldable tubing, allowing for easy incorporation into modern closed-system cell culture bioprocessing protocols increasing safety and ease of use by allowing for the introduction of supplement material into culture media in a fully contained manner (ask for details).

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

Manufacturing

- Type II eCTD MF (#028121) on file with FDA
- No animal-derived materials are used in the manufacture of this product
- Sterile microfiltration followed by aseptic filling

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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
 - SO/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

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
AR1048-0100	Human AB Serum CSS, Converted from Octaplas [®]	100 mL
AR1048-0060	Human AB Serum CSS, Converted from Octaplas [®]	60 mL
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
AK8228-0100	Human Serum Albumin 25% Solution	100 mL
AK9930-0001	Human Fibronectin Solution, Virus Inactivated	1 mg
AK9930-0005	Human Fibronectin Solution, Virus Inactivated	5 mg

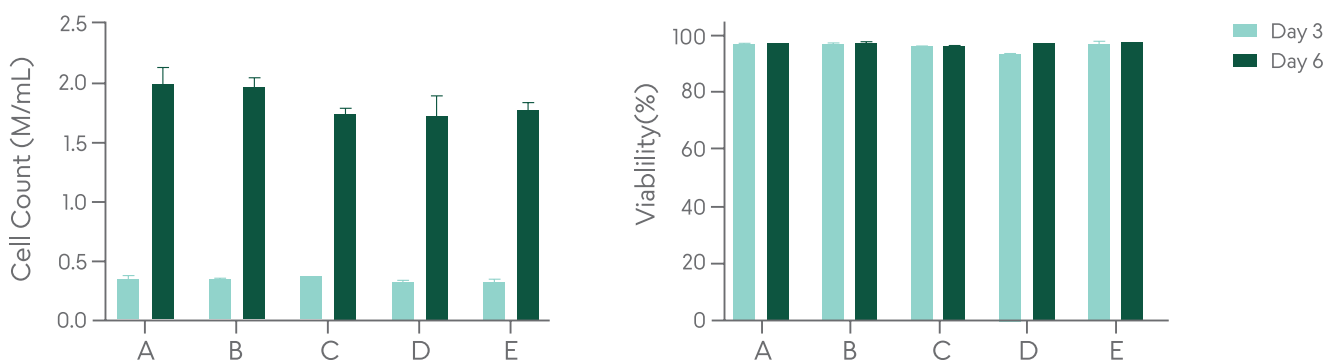
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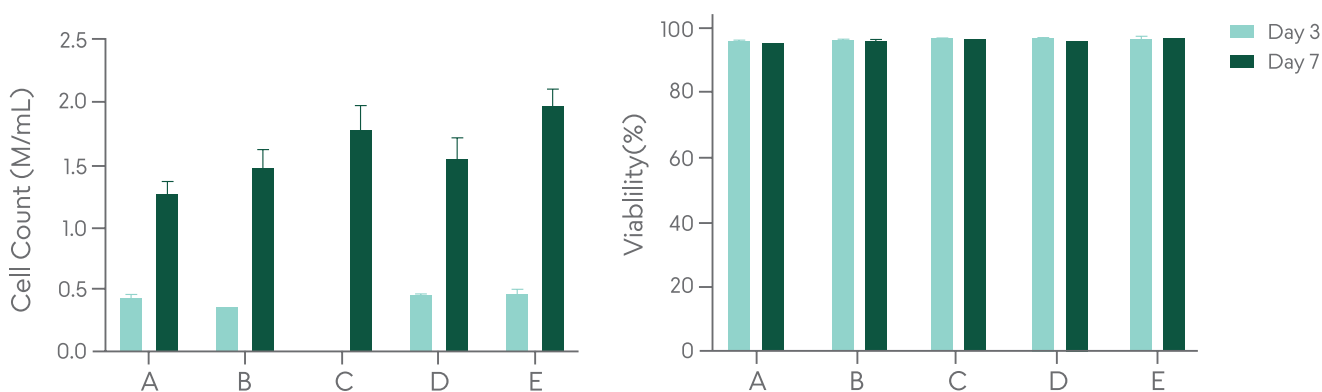
Functionality Data:

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.