

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

Bottles (100 mL) Cat. # AR1010-0100

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1. Why use Human AB Serum, Converted from Octaplas[®], Xeno-Free (XF), Virus Inactivated (VI)?

Akron's Human AB Serum is manufactured following all relevant cGMP guidelines for ancillary materials and is supported by a Type II Master File (MF) with the FDA. This product is manufactured using human-derived components and is considered a comparable alternative to fetal bovine serum or other animal-based products. 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. We leverage Octaplas[®] (pharmaceutically licensed virus inactivated and prion-ligand treated plasma) as the raw material, offering greater batch-to-batch consistency and a unique safety profile.

2. What are the recommended storage conditions for Human AB Serum, Converted from Octaplas[®], XF, VI?

We recommend storing this product at -20 °C. If serum content is not being used all at once, we suggest aliquoting into the desired volume and storing at -20 °C until needed. Avoid repeated freeze-thaw cycles.

3. What are the shipping conditions for Human AB Serum, Converted from Octaplas[®], XF, VI?

This product ships with dry ice.

4. What is the shelf-life for Human AB Serum, Converted from Octaplas[®], XF, VI?

This product has a shelf life of 24 months after the date of manufacture under recommended controlled storage conditions.

5. What is the thawing procedure for Human AB Serum, Converted from Octaplas[®], XF, VI?

Serum can be thawed overnight at 2 °C to 8 °C or in a 37 °C water/dry bath for ~2 hours before use. Once thawed, gently swirl to thoroughly mix contents. Avoid multiple freeze-thaw cycles, prolonged exposure to 37 °C, and temperatures above 37 °C.

6. Do particulates ever form after thawing?

Precipitates will form in certain units of serum during the thawing process. This is normal and common behavior for serum products and it will not negatively affect cell culture. These precipitates do not negatively impact the safety or quality of the material. This product is sterile filtered before filling and every lot is tested for mycoplasma and sterility per USP.

7. Should I heat inactivate the Human AB Serum before use?

Our Human AB Serum product is sold ready to use directly as a supplement to your culture medium, but we have seen increased performance with certain cell lines after a heat treatment process is applied to the product before use. If performing this, we recommend a temperature of about 56 °C for 30 minutes; inactivation for a longer time may have a negative effect on cell growth due to denaturing of proteins and growth factors.

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8. Where is the raw material sourced?

Human AB Serum is converted from Octaplas[®]. Only plasma from US donors (frozen within 8 hours of collection) is used to manufacture Octaplas[®] and ultimately the Human AB Serum. For Octaplas[®], individual donor identification, registration, and education takes place in FDA-licensed centers which comply to the requirements for the collection of source plasma as specified in “The Collection, Fractionation, Quality Control, and uses of Blood and Blood Products,” published by the WHO Technical Report Series 840. This allows for traceability down to the single donation unit, if needed.

9. How are the raw material donations screened?

There is a deferral check and questionnaire at each donation, as well as a physical assessment, per 21 CFR 630.10. Each plasma unit used as raw material is virus tested per 21 CFR 610.40 at the time of collection and found negative or non-reactive for Hepatitis B surface Antigen (HBsAg), antibodies to Human Immunodeficiency Virus (HIV)-1/2 (anti-HIV-1/2) and antibodies to Hepatitis C Virus (anti-HCV). HBV and HIV-1/2 serological tests are also performed on each plasma pool. Nucleic Acid Testing (NAT) is also performed at different manufacturing stages for HIV, B19V, HAV, HBV, HCV and HEV.

10. What process is used for viral inactivation?

Viral inactivation of enveloped viruses is accomplished via solvent detergent (S/D) treatment (see Technical Overview).

11. Do you have a Master File (MF) available for this product?

Yes, Akron's rHu IL-2 has a Type II eCTD MF (#028121) on file with the FDA. We can provide you a Letter of Authorization that will permit these agencies to refer to the information on file in support of your submissions.

12. What are the advantages of S/D treatment versus other inactivation methods currently used?

S/D treatment has long been a standard and robust virus inactivation process for plasma products. S/D and pH inactivation are generally effective against enveloped viruses. Heat inactivation, irradiation, chromatography and filtration methods have been shown to have some effect on non-enveloped viruses, as well as enveloped viruses. The viral safety for plasma products should be validated with a panel of characterized viruses, and pathogen safety studies should be incorporated for all relevant steps of the manufacturing process. A combination of these methods are used to reduce the overall risk of adventitious viruses and bloodborne pathogens in plasma products.

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13. Are non-enveloped viruses inactivated also?

S/D treatment is not effective against non-enveloped viruses. However, the presence of standardized levels of neutralizing antibodies in the Octaplas[®] plasma pool along with virus load control by NAT screening minimizes the risk of transmitting non-enveloped viruses such as HAV, and parvovirus B19V (see Technical Overview).

14. Is there S/D agent remaining in the plasma that might affect cell growth?

In the Octaplas[®] manufacturing process, the S/D reagents are removed by sequential oil and solid phase extraction procedures. Final levels of residual S/D agents in Octaplas[®] are below FDA-specified limits for product release. These remaining levels of S/D agents are below what has been found to impair cell growth.

15. What is the difference between plasma and serum?

Whole blood is composed of plasma, red and white blood cells, and platelets. Plasma is the part of blood that carries nutrients, antibodies and hormones throughout the body. It contains serum and clotting factors. Serum is plasma without clotting factors.

16. What thrombin component is used during the conversion from plasma to serum?

The in-process thrombin component is purified from the same Octaplas[®] virus-inactivated plasma that is used for the starting material.

17. Which cell types are suitable?

Akron's Human AB Serum, Converted from Octaplas[®], XF, VI can be used as a replacement in any cell culture protocols that currently use human AB serum or fetal bovine serum (FBS). Optimization may be required.

18. Is the performance comparable to competitor products / FBS?

Cell proliferation and viability are comparable to other serum products on the market, including FBS, while offering increased safety associated with the raw materials and manufacturing process (ask us for supporting data).

19. Do you have an SDS for this product?

Yes. To request the SDS, please contact info@akronbiotech.com.

20. Is this an injectable-grade or clinical-grade material?

No, this product is not for direct use in humans. See intended use below.

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21. What is the intended use for the product?

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.

22. What packaging options are available?

Off-the-shelf packing for this product is a 125mL capacity square PETG Nalgene™ bottle with an HDPE screw top closure. Both the bottle and closure are certified radiation sterilized (SAL 10⁻⁶), nonpyrogenic and noncytotoxic, and comply with USP Class VI guidelines. Custom packaging options are available with different materials or volumes under contract.

23. Do I need to use a sterile needle and syringe to remove the product from the vial?

No, our bottle packaging was designed for easy access with a laboratory pipette.

24. Have extractable and leachable (E&L) studies been performed on these products?

Yes, a forced extraction study has been completed by the packaging manufacturer to verify compatibility. Water, Ethanol, Hexane, and 10% Nitric acid were all analyzed via GS/MS, LC/MS, & ICP for their ability to potentially extract chemical compounds from the packaging components.

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