

Human Fibronectin Solution, Virus Inactivated

Tubes (1 mg) Cat. # AK9930-0001 | Bottles (5 mg) Cat. # AK9930-0005 | Protein Concentration (1 mg/mL)

P 1

1. Why use Human Fibronectin Solution, Virus Inactivated?

Akron's Human Fibronectin Solution, Virus Inactivated is manufactured following all relevant cGMP guidelines for ancillary materials and is supported by a Type II Master File (MF) with the FDA.

It is used as a media supplement in cell culture primarily to facilitate attachment and cytoplasmic spreading during cell and tissue culture for all types of anchorage-dependent cells. Akron leverages pharmaceutically licensed virus and prion inactivated 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 Fibronectin Solution, Virus Inactivated?

We recommend storing this product at -20 °C upon receipt. Avoid repeated freeze-thaw cycles.

3. What are the shipping conditions for Human Fibronectin Solution, Virus Inactivated?

This product ships with dry ice.

4. What is the shelf-life for Human Fibronectin Solution, Virus Inactivated?

This product is currently under a long-term stability program.

5. What is the thawing procedure for Human Fibronectin Solution, Virus Inactivated?

Prior to use, thaw the fibronectin solution completely at 2-8 °C. This can be done up to 24 hours in advance. This protein is sensitive to perturbations; do not vortex or handle roughly. Do not repeatedly pipette to resuspend the fibronectin as this may cause the protein to irreversibly precipitate out of solution. See Methods of Use for further instructions.

6. Where is the raw material sourced?

Only plasma from US donors is used (frozen within 8 hours of collection). Individual donor identification, registration, and education takes place in FDA-licensed centers which comply to the requirements for the collection of source materials 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.

7. How are the plasma 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-1, HIV-2, B19V, HAV, HBV, HCV and HEV.



Human Fibronectin Solution, Virus Inactivated

Tubes (1 mg) Cat. # AK9930-0001 | Bottles (5 mg) Cat. # AK9930-0005 | Protein Concentration (1 mg/mL)

P 2

8. Does this product have a TSE/BSE statement?

Yes, a TSE/BSE statement is available upon request for this product.

9. What process is used for viral inactivation?

Viral inactivation is accomplished via solvent detergent (S/D) treatment and immune neutralization (see Technical Overview).

Please note that the virus inactivation process and virus testing have all been performed on the starting material plasma and not during the manufacturing of the final AK9930 product. It is recommended that the end user performs virus tests on their final processed cells.

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

Yes, Akron's rHu IL-2 has a Type II eCTD MF (#028120) 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.

11. What regulatory support does this product have outside of the United States?

Eligibility confirmation has been granted by Japan's PMDA for use in cellular and tissue-based products. (No. 1205004)

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 viral inactivation process for plasma products. S/D is extremely effective against enveloped viruses, reduces abnormal prion proteins, has mild effect on the overall protein quality and leaves most labile coagulation factors intact.

pH inactivation will irreversibly denature and destroy many viruses, but it might compromise the beneficial qualities of the material. Heat inactivation, irradiation, chromatography, and filtration methods have all been shown to have inactive effect on both non-enveloped and enveloped viruses. Overall, the virus inactivation of plasma products should be validated by antibody and PCR methods to detect a panel of regulatory agent defined adventitious viruses. The pathogen safety studies should be incorporated for all relevant steps of the manufacturing process. A combination of these methods is used to reduce the overall risk of adventitious viruses and bloodborne pathogens in plasma products.

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 plasma pool along with virus load control by redundant NAT screening minimizes the risk of transmitting non-enveloped viruses such as HAV and parvovirus B19V.



Human Fibronectin Solution, Virus Inactivated

Tubes (1 mg) Cat. # AK9930-0001 | Bottles (5 mg) Cat. # AK9930-0005 | Protein Concentration (1 mg/mL)

P 3

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

Remaining levels of S/D agents are below what has been found to impair cell growth.

15. What safety testing is done on the final product?

Every lot of final product is tested for the presence of Mycoplasma before release. Every lot is also tested and released with specifications and methods per USP/EP, for both Endotoxin (USP <85> / EP 2.6.14) and Sterility (USP <71> / EP 2.6.1).

16. Which cell types are suitable?

Human Fibronectin Solution, Virus Inactivated will facilitate attachment and cytoplasmic spreading during cell and tissue culture for all types of anchorage-dependent cells. Fibronectin has been shown to promote cell adhesion, spreading, proliferation, and differentiation for a variety of cultured cell types.

17. Is the performance comparable to competitor products?

To our knowledge, no other virus inactivated human fibronectin product currently exists on the market. Functionality data for this product is available upon request.

18. Do you have an SDS for this product?

Yes, an SDS is available upon request.

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

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

20. What is the intended use for the product?

For research 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.

21. How does Akron measure activity for Human Fibronectin, Virus Inactivated?

Activity is not measured as a release specification for this product. Functionality assays have been performed to characterize its effect in cell culture, and this data is available upon request. Each lot is tested for purity via Reducing SDS-PAGE and for protein concentration via absorbance at 280 nm.

22. What is the molecular weight of Akron's Human Fibronectin, Virus Inactivated?

Each lot meets molecular weight specifications based on SDS-PAGE analysis with resulting band appearing between 220-250 kDa.



Human Fibronectin Solution, Virus Inactivated

Tubes (1 mg) Cat. # AK9930-0001 | Bottles (5 mg) Cat. # AK9930-0005 | Protein Concentration (1 mg/mL)

P 4

23. What packaging options are available?

Akron's Human Fibronectin, Virus Inactivated product is available in two different standard aliquot sizes: 1 mg and 5 mg. Both package materials are sterile, RNase and DNase free, USP Class VI material, which were produced in a controlled environment in compliance with ISO 13485:2016. Our 1 mg aliquot is packaged in a 1.5 mL free standing microcentrifuge tube made from clear polypropylene closed with a matching screw cap including an ethylene propylene O-ring. These tubes are endotoxin-free, manufactured in an ISO 8 cleanroom environment in compliance with ISO 9001:2015, and meet the requirements of the Restriction of Hazardous Substances Directive 2002/95/EC. Our 5 mg aliquot is packaged in an 8 mL diagnostic bottle made from high density polyethylene with a white linerless polypropylene screw cap. These bottles are hDNA and pyrogen free. Custom packaging options are available with different materials or volumes for contract orders.

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