

METHODS OF USE

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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General:

Akron's Human AB Serum, Converted from Octaplas®, Pooled Plasma (Human), Xeno-Free, Virus Inactivated (viHABS) Closed System Solutions™ (CSS) is packaged in sterile Ethylene-vinyl acetate (EVA) bags with multiple connection options, allowing for easy incorporation into modern closed-system cell culture bioprocessing protocols. The closed-system packaging of Akron's viHABS CSS increases safety and ease of use by enabling the introduction of supplement material into culture media in a fully contained manner.

A clean space and proper aseptic technique are recommended when handling Akron's viHABS CSS. Do not place heavy objects directly on top of the bag, as too much pressure can jeopardize the integrity of the packaging. Each unit comes with a poly bag over-pouch and multiple units are packed into a storage cassette; it is recommended to keep the product within this cassette box for storage and thawing.

Thawing:

Akron's viHABS CSS must first be thawed before use, as the product is shipped frozen, and the recommended storage temperature is -20 °C. To thaw viHABS CSS before use, please follow the guidelines below.

- Remove units to be used from the -20 °C storage freezer while still packed in protective shipping cassette.
- Immediately place units to be thawed into a 2-8 °C refrigerator and keep the product at this temperature for 24 hours.
- After 24 hours, remove the units from the 2-8 °C refrigerator and allow product to reach room temperature prior to further warming.
- If further warming is required, use a controlled 37 °C environment to bring up to temperature.
- Remove sealed bag pouches from the cardboard cassettes and discard the cassette box.
- Sanitize the external over-pouch bag with IPA and remove by tearing off the tab at the top of the overpouch.
- Connect the viHABS CSS bag to your process line using one of the methods described below.

Heat Treatment:

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.

Note on Precipitates:

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.



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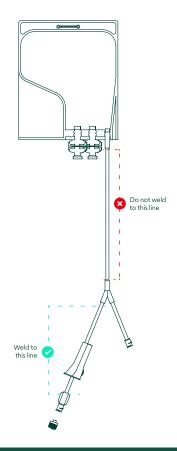
Method 1 - Weldable Connection:

Akron's viHABS CSS comes with a single proximal tube that splits into two shorter distal tubes used for an inlet and an outlet. Do not attempt welding to the longer proximal tube section; it is not weldable material.

The shortest tube has been used as an inlet tube and has been fuse sealed at the end. It is not recommended to use this portion.

The second distal portion comes with a rolling clamp and a female Luer lock adapter on the end. This portion is recommended to use as an outlet tube. This outlet tube is made from weldable polyvinyl chloride (PVC) material (2.5 mm ID \times 4.1 mm OD). To make a weldable connection to viHABS CSS, follow the proceeding steps:

- Place outlet tubing into tube welding machine along with process line.
- Run standard aseptic welding protocol.
- Release the rolling clamp on the outlet tube now welded to your process line.
- Allow solution from viHABS CSS bag to flow into your process line.
 - User can facilitate transfer by hand compressing the bag to expunge the Human AB Serum material.
 - User can allow for reverse flow to ensure full mixing of serum solution with culture media.





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Rev. 12/22

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Method 2 - Direct Connection via Female Luer Lock Adapter

Akron's viHABS CSS comes with a direct connection option on the outlet tube. To attach male Luer tubing to the female Luer adapter for use as an outlet port, follow the proceeding steps:

- Introduce the viHABS CSS bag along with the male Luer tubing into a BSC in an aseptic manner.
- Remove cap from the female Luer adapter.
- Clean the female Luer adapter with a pre-moist 70% alcohol wipe.
- Clean the male Luer connection with a fresh pre-moist 70% alcohol wipe.
- Connect male Luer tubing to female Luer connector, turning to lock into place.
- Release the rolling clamp on the outlet tube now directly connected to the male Luer tubing.
- Allow solution from viHABS CSS bag to flow into your process line.
 - User can facilitate transfer by hand compressing the bag to expunge the viHABS CSS material.
 - User can allow for reverse flow to ensure full mixing of viHABS solution with culture media.

Method 3 - Spike Port Adapter:

Two tear-off EVA spike ports are included as optional outlets. With the use of a spike adapter, these ports allow the user's desired tubing material and desired connectors to be attached to the product. To make a spike port connection to Akron's viHABS CSS, follow the proceeding steps:

- Introduce the viHABS CSS bag along with the desired spike adapter into a BSC in an aseptic manner.
- Tear off the protective EVA tab from chosen spike port (the port has another internal membrane seal).
- Insert a sterile spike, with desired adapter connections attached, into the port in a single continuous motion, puncturing the inner seal and fully inserting the spike into the bag.
- Connect your process line to the inserted adapter using the weldable tubing or direct connectors attached.
- Release any clamp that may be attached to the adapter tubing.
- Allow solution from viHABS CSS bag to flow into your process line.
 - User can facilitate transfer by hand compressing the bag to expunge the Human AB Serum material.
 - User can allow for reverse flow to ensure full mixing of serum solution with culture media.

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