

ImmunoCell® Growth Medium (ICGM) Phenol Red Free Closed System Solutions (CSS)™

Bag (1000 mL) Cat # AK9988-1000

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1. Why use Akron's ICGM?

Akron's ImmunoCell® Growth Medium (ICGM) is manufactured in accordance with applicable cGMP guidelines for ancillary materials. ICGM has been evaluated for use with peripheral blood mononuclear cells, isolated monocyte cultures, and T cells, and has received positive feedback from partners evaluating the medium in cell therapy workflows using T cells isolated from healthy donors.

2. 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.

3. Which cell types are suitable for culture with Akron's ICGM?

Akron's ICGM can be used for the proliferation of a variety of human immune cells. Its effectiveness has been verified in peripheral blood mononuclear cells (PBMCs), isolated monocyte cultures, and T cells.

4. How does Akron measure functionality for this product?

Each lot of ICGM is tested for biological functionality via an *ex vivo* Jurkat T cell proliferation bioassay.

5. Do I need to supplement this medium?

Akron's ICGM is a serum-free basal medium designed to support cell growth without serum supplementation. The formulation is cytokine-free to provide flexibility across different cell types and manufacturing processes. Users may supplement the medium as needed based on their specific process requirements and intended use.

6. Are there any differences between the phenol red and the phenol red-free formulations?

The composition of phenol red-free formulation is identical to the phenol red-containing formulation, with the exception that phenol red has been omitted.

7. What is the shelf life?

24 months from date of manufacture.

8. What are the recommended storage conditions?

We recommend storing this product at 2-8 °C.

9. What are the shipping conditions?

This product ships on cold packs.

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10. Does the product maintain functionality when exposed to extreme conditions?

The product has been shown to maintain biological functionality when heated, kept at room temperature, frozen, or exposed to light. Heated conditions tested include 45 °C for 1 hour and 20-25 °C for 72 hours, frozen conditions tested were -20 °C for a single freeze thaw cycle, and light exposure testing was performed after 24 hours of exposure.

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

Yes. Our TSE/BSE statements are included in the Certificate of Origin (CoO), which is available upon request.

12. Are animal-derived materials used in the manufacture of this product?

No animal-derived materials are used in the manufacturing process or in the final product.

13. Are antibiotics used in the formulation or processes in the manufacturing facility?

No antibiotics are included or processed within the manufacturing facility.

14. What safety testing is done on this product?

Each lot of ICGM is tested for Mycoplasma via PCR, Bacterial Endotoxins per USP<85>, and Sterility per USP <71>.

15. Do you have an SDS for this product?

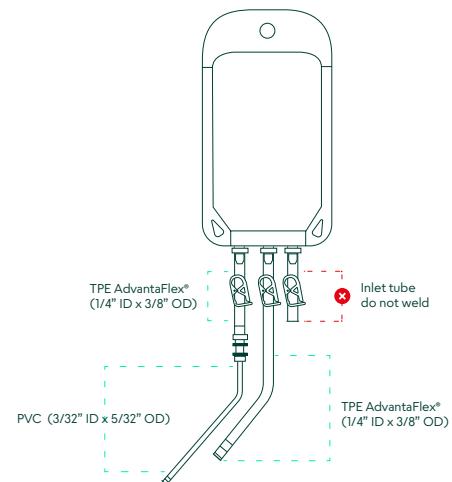
Yes, an SDS is available upon request and a physical copy is included with every shipment.

16. What packaging options are available?

Akron's ICGM is supplied as a ready to use liquid in 1 L PETG bottles or in 1 L polyethylene bag formats with multiple closed connection options, enabling sterile docking into modern closed system cell culture workflows. Each bag is supplied with a protective poly bag over pouch. Custom fill volumes are available upon request.

17. What are the tubing specifications in the 1 L CSS bag?

Our bags are equipped with 1 inlet and two outlet tubes. One outlet tube is made of weldable TPE AdvantaFlex® tubing (1/4" ID x 3/8" OD) and is approximately 12 inches in length. The second outlet consist of two sections made from different weldable tubing materials. The proximal section is made of weldable TPE AdvantaFlex® tubing (1/4" ID x 3/8" OD) and is approximately 6 inches in length. A reducer connector joins this to a distal section composed standard weldable PVC (3/32" ID x 5/32" OD), which is also approximately 6 inches in length.



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P 3**18. What closed connection options are available to remove the material from the bag?**

Both TPE and PVC outlet tubing may be used for material transfer from the ICGM CSS bag. Due to its larger inner diameter, the TPE outlet tubing allows for a higher flow rate and is recommended when faster bulk transfer is desired. The PVC outlet tubing, with its smaller inner diameter, may be used for controlled additions, such as the transfer of cytokines or other supplemental molecules into the bag.