Human T Cell Leukopak Isolation Kit - GMP

In-Bag Reagents

REF 13210-221GMP-B
Document Number IFU-45

Kit Contents:

QTY 1 × 157 mL Streptavidin Microbubbles - GMP - in storage buffer

1 × 12.5 mL Human T Cell Leukopak Isolation Antibody Cocktail - GMP in sterile butter containing 1% Human Serum Albumin (HSA).

1 × 500 mL Separation Buffer - GMP containing 1% Human Serum Albumin

Expiration dates are indicated on the labels for each component.

Storage

This product is shipped refrigerated and must be stored between +2 °C and +8°C immediately upon receipt. Do not freeze.

Product Description

The Akadeum Human T Cell Leukopak Isolation Kit - GMP was developed with BACS Microbubbles to isolate untouched T cells from washed leukopak material via negative selection.

The Human T Cell Leukopak Biotin Antibody Cocktail - GMP is added to the sample to label unwanted cell populations. Streptavidin Microbubbles - GMP are added to the sample and bind the biotin-labeled cells. By flotation, non-T cells are targeted and removed with microbubbles. The resulting negatively selected T cells are drained into a sterile vessel of choice and are suitable for cell culture, flow cytometry, scRNA-Seq, and downstream engineering in cell therapy workflows.

Intentions for Use

This kit is designed to isolate CD3+ T cells from a maximum of 12.5 × 10^9 total cells.

The components of the Human T Cell Leukopak Isolation Kit - GMP are intended for the ***ex vivo*** isolation of human T cells from various samples for cell-based clinical research. They are not intended for human ***in vivo*** uses.

Quality Statement

GMP Akadeum GMP products are manufactured according to GMP at Akadeum Life Sciences®, Ann Arbor, MI, under a quality management system in compliance with 21 CFR 820, 210, 211, and 11, and aligned with ISO 13485. They are developed following ISO 20399 and USP < 1043> recommendations on ancillary materials and tested according to ISO 10993.

All components tested for endotoxins as per USP < 85> Bacterial Endotoxins.

The antibody cocktail is tested per ICH Q5A(R2) Guideline on viral safety evaluation of biotechology products derived from cell lines of human or animal origin.

Sterile as per USP < 71 > Sterility Tests.

STERILE F Antibody cocktail and Separation Buffer manufactured aseptically. and processed with 0.2 µm filtration.

STERILE R Microbubbles sterilized with in-process electron beam and then filled aseptically.

Safety Information

For information regarding hazards and safe handling practices, please consult the Safety Data Sheet.

Related Products

Catalog Number	Product
13210-221	Human T Cell Leukopak Isolation Kit - RUO
13210-221GMP	Human T Cell Leukopak Isolation Kit - GMP (bottled)

Warnings

Do not use after the use-by date listed on the product label.

Do not use product if package is damaged.

Handling Guidelines

- When working with human blood products, including; cells, serum, and plasma, follow universal precautions.
- Proper Personal Protective Equipment (PPE) including lab coats, gloves, and eye protection are recommended when working with human tissues.
- Human blood products must be treated as a potential source of HIV, HBV, and other bloodborne pathogens.
- Materials contaminated with blood products should be disposed of in labeled biohazard containers or decontaminated by site approved decontamination methods.

Additional Supplies Required

- Cell washing instrument
- 20 rpm end-over-end tube rotator for mixing; for options other than a rotator, contact Tech Support (techsupport@akadeum.com)
- Leukopak hanger
- Sterile transfer bag(s) or vessel of choice
- Sterile tube welder
- Complete cell culture media

Limited Warranty

Akadeum Life Sciences® warrants their products as set forth in their General Terms and Conditions. Questions and requests can be sent to info@akadeum.com.

Before You Begin

- This user guide is designed for isolations using 1 x 10^9 - 12.5 x 10^9 cells total cells as starting sample. For samples outside of this range, please contact techsupport@akadeum.com.
- This product has been validated for use with washed apheresis (leukopak) material

Instructions for Use

The protocol below is Akadeum's standard protocol.

Modifications are the responsibility of the user for verification and validation for fit for use.

Bind Antibody Cocktail from the Human T Cell Leukopak Isolation Kit

1. Wash the apheresis material with a cell washing instrument to isolate cells and remove platelets. Harvest the cells in a sterile bag and concentrate the cells in separation buffer or complete cell culture media to between 2 × 10^8 to 4 × 10^8 cells / mL.
    a. If a cell washing instrument is not to be used, instructions for manual platelet removal can be found in the IFU Human T Cell Leukopak Isolation Kit Instructions for Use (IFU).
2. To enable even mixing, aseptically add air ≥ 20% volume of the bag.
3. Determine volume of antibody cocktail to add to sample: Add 1 mL of Human T Cell Leukopak Biotin Antibody Cocktail - GMP for every 1 × 10^9 cells.
4. Add antibody cocktail aseptically.
5. Mix bag by end-over-end rotation at 20 rpm for 15 minutes at room temperature.

Bind Streptavidin Microbubbles

6. Determine number of microbubbles to add to sample: Add 12.5 mL of Streptavidin Microbubbles - GMP for every 1 × 10^9 cells.
Note: Ensure microbubbles are evenly mixed immediately prior to addition.
7. Mix samples by end-over-end rotation at 20 rpm for 15 minutes at room temperature.

Separate cells

8. Add additional Separation Buffer - GMP or complete media as desired and separate microbubbles and cells via gravity. Suspend the sample bag from a hanger for 15 minutes to allow all the microbubbles to rise to the top of the sample.
9. Leaving the microbubbles behind, aseptically drain the untouched cellular material into a bag or collection vessel, either manually or with a cell washing instrument.
Note: For increased efficiency during manual draining, suspend the bag > 50cm above transfer bag.
10. The untouched cells are the negatively-selected cells of interest, ready for use in downstream assays or expansion.

Glossary of Symbols:

REF	Catalog Number
QTY	Contents of packaging
GMP	Manufactured using Good Manufacturing Practices and compliant with standards for Ancillary Materials in Cell and Gene Therapy
STERILE F	Sterilized using aseptic processing techniques
STERILE R	Sterilized using radiation sterilization techniques
	Temperature Limit
	Use-by date
	Do not use if package is damaged

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www.akadeum.com/patents
Visit www.akadeum.com for how-to videos, additional product information, and tech support.
For information regarding hazards and safe handling practices, please consult the Safety Data Sheet.
For Technical Support: techsupport@akadeum.com

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