

Clinical Products

StemExpress offers clinically transfusable and clinically non-transfusable products. The collection of these products are the same but the approval process to receive clinically transfusable products requires additional steps. StemExpress processes are in place to only allow shipment of Clinical Grade Transfusable products to companies that have protocols with documented FDA (or relatable international agency) approval. These products will not be used to treat or be transfused to any patients without the associated FDA (or relatable international agency) approved IND and IRB approval.

Product Description

Peripheral blood mononuclear cells are collected using Spectra Optia[®] Apheresis System, an FDA approved closed, continuous-flow apheresis system, from healthy donors. Using a closed and automated FDA approved cell manufacturing system, CD19+ cells are depleted from the mononuclear cells using immunomagnetic anti-CD19 microbeads. Cell culture procedures, including open manipulation of vials, final filling, and closure of finished products, are performed inside ISO 5 air quality processing chambers.

Human tissue collection protocols are approved by StemExpress' Medical Review Board and Independent Review Board (IRB) in accordance with FDA CFR 21 Part 50 and 56.

Sample Collection and Processing

Clinical Grade Non-Transfusable primary cells are collected using aseptic techniques with FDA approved clinical grade reagents and components that are manufactured and controlled under an ISO 13485 certified quality system.

Infectious disease testing for HIV, HBV, and HCV is performed on a sample of donor blood. Only samples with negative results within 90 days of collection are shipped. All testing is performed by a CLIA-certified lab.

Format

Frozen Clinical Grade Non-Transfusable primary cells are frozen in CryoStor[™]. We can also use freezing media as specified by the customer.

Storage

Cryopreserved cells should be maintained at -135°C or colder (in liquid nitrogen). The cells are warranted for twelve months from the date of receipt if stored at -135°C or colder. Storage of cells at -80°C for less than one month should maintain cell viability but is not covered by the warranty.

Thawing Instructions for Cell Products

Refer to our "How to thaw StemExpress primary cells for optimal viability?" under our Frequently Asked Questions at stemexpress.com/faqs/ to access our online Thawing Protocol.

Warning

This product contains human tissue or other biological material and MUST be handled at Biosafety Level 2 or higher. All biological products should be treated as potentially infectious or contaminated material, even if infectious disease screening reports are negative. Follow universal precautions and wear appropriate personal protective equipment.

Product Warranty

For our product warranty, please review our Terms and Conditions at stemexpress.com/terms-and-conditions/.

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