Certificate of Analysis

charles river

Product Information

Catalog ID	Product Name	Size	Unit Volume	Vessel
M34C-GCSF-1	Cryopreserved HemaPrime™ Mobilized Peripheral Blood CD34+ Stem/Progenitor Cells; G-CSF	1 x 10^6 Cells	1 mL	2 mL Cryogenic Vial

Lot Number	Post Thaw Viability	Post Thaw Cell Count	Cryopreservation Date
24089171	≥ 90% - PASS	≥ 1M - PASS	2024-07-23

Description CD34+ hematopoietic stem and progenitor cells (HSPCs) were isolated from a mobilized leukopak by positive selection using CD34+ immunomagnetic bead separation. Mobilized leukopak was collected from a healthy donor consented under an IRB approved protocol. Donor was injected with G-CSF (Neupogen®), which stimulates the bone marrow to mobilize hematopoietic stem and progenitor cells into the periphery, per the below dosing regimen. After isolation, the CD34+ cells were tested for purity and viability by flow cytometry and then quickly cryopreserved on site in CryoStor® CS10 freeze media using a CoolCell® cell freezing container (BioCision) at -1°C/min.

Source Material Fresh mobilized leukopak stimulated with G-CSF

Target Dosing Regimen Donor is injected with G-CSF. Collection is performed upon completion of regimen.

Collection Site 8500 Balboa Boulevard, Suite 130, Northridge, CA, 91325, USA

Processing Site 8500 Balboa Boulevard, Suite 130, Northridge, CA, 91325, USA

Handling Instructions Upon receipt, either prepare cells for long-term storage in liquid nitrogen vapor phase or thaw for use. Storage in liquid phase nitrogen is NOT recommended. Long-term storage of cells at -80°C is NOT recommended. Once thawed, samples must be used immediately. **For research use only. Not for diagnostic or therapeutic use.**

Donor Information

Source ID	Age	Gender	Height	Weight	BMI	Ethnicity	ABO/Rh
D343899	34	Female	5'4"	166 lbs	28.49	Hispanic	O-POS

HLA -A	HLA-B	HLA-C	HLA-DRB1	HLA-DRB3	HLA-DRB4	HLA-DRB5	HLA-DQA1	HLA-DQB1	HLA-DPA1	HLA-DPB1
33:01:01	14:02:01	07:02:01	01:02:01	-	-	-	01:01:02	03:02:01	01:03:01	02:01:02
68:01:02	39:06:02	08:02:01	04:04:01	-	01:03:01	-	03:01:01	05:01:01	01:03:01	04:02:01

Testing Information

Samples collected from donors on the day of product collection are tested in accordance with FDA requirements for blood for transfusion according to current FDA requirements for allogeneic blood donation. The following screening tests have been performed:

- Serological test for Syphilis
- Unexpected red cell antibody screening
- Hepatitis B Core Antibody (Anti-HBc EIA)
- Hepatitis B Surface Antigen (HBsAg EIA)
- Hepatitis C Virus Antibody (Anti-HCV EIA)
- Human Immunodeficiency Virus Antibody (HIV 1/2 plus O)
- Human T-Lymphotropic Virus Antibody (HTLV-I/II)
- HIV-1/HCV/HBV Nucleic Acid Testing
- West Nile Virus Nucleic Acid Testing

Trypanosoma cruzi Antibody (Chagas Disease)*
*Chagas was tested at initial donor collection only.

Testing panel results: Negative/non-reactive or not detected for all donor screening tests performed.

CMV
POS as of 2023-12-06

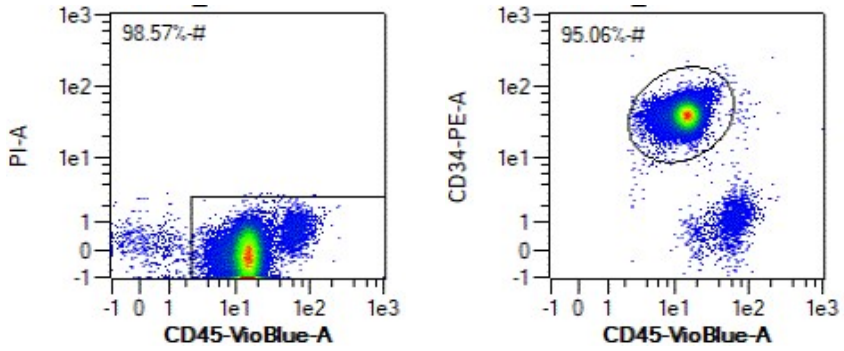
Provided test results are from the last date of testing and do not indicate current donor status. If a donor tests positive for CMV one time, they are considered “CMV positive”.

Charles River Laboratories Cell Solutions, Inc.
(877) 310-0717 | cell-support@crl.com | https://www.criver.com/cellsolutions

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Flow Cytometry Analysis



CD45 vs PI	CD45 vs CD34
98.57 %	95.06 %

Biosafety This material should be handled following biosafety level 2 biohazard procedures.

Released By *Ed Martinez Martinez* **Date** *2024-08-01*

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