

# STEM CELL LABORATORY (STCL)



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Separation Planner V2.40	
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Author: WATE02

Owner: WATE02

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### Separation Planner for CliniMACS software V2.40

Separation Program	ENRICHMENT 1.1
Tubing Set (select from list)	
Cell Concentration [*10 <sup>6</sup> /mL]	7
Frequency of Labelled Cells [%]	
Sample Loading Volume [mL]	

Range	
min	max

20	400
1	

Calculated Process Parameters	
max. Processing Time [min]	
Labelled Cells to be Processed [-]	
Number of Stages [-]	
Process Specifications	Inside Specifications

Calculated Process Parameters - Screen Output		
Buffer needed for Process [mL]		
Buildi fiedda foi i fodess [iiiL]		
Bag Size; Cell Collection Bag [mL]		
Bag Size:Negative Fraction Bag [mL] or Non-Target Cell Bag [mL]		
Bag Size: Buffer Waste Bag [mL]		
Bag Size: Priming Waste Bag [mL] or Re-Application Bag [mL]		

Additional Process Parameters	
Stage length in seconds	
Stage length in mL	

VH 08/2004-RS 02/2005, FGR0131.07

Version: V1.22, 24.04.2006

## IMPORTANT INFORMATION: IF YOU DO NOT AGREE TO THE FOLLOWING TERMS AND CONDITIONS, YOU MUST NOT USE THIS SOFTWARE.

Your use of the CliniMACS Separation Planner Tool (the "Software") is at your sole risk and responsibility. The results produced by this Software are provided for information purposes only to support logistic preparation of CliniMACS separations and have not been validated. Only calculations performed by the CliniMACS plus Instrument have been validated. Therefore, the results obtained from the use of the Software must not be used as a basis for diagnosis or choice of treatment. In no case the Software must be used if such use can be threatening to the health or life of human beings. Always refer to the information provided by the CliniMACS plus Instrument or the CliniMACS Manual.

The Software is provided on an "as is" basis without any warranty. To the fullest extend permitted by applicable law, Miltenyi Biotec expressly disclaims all warranties, conditions and other terms of any kind, whether express or implied, including, but not limited to any implied term of merchantability, accuracy, satisfactory quality, or fitness for a particular purpose, Miltenyi Biotec makes no warranty or representation that (i) the Software will be secure or error-free, and (ii) the results that may be obtained from the use of the Software will be accurate or reliable.

Always refer to the CliniMACS Manual!

print date: 12/20/2012

STCL-PRO-038 JA3 3 Separation Planner V2.40 STCL, DUMC Durham, NC

#### Signature Manifest

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Title: Separation Planner V2.40

#### STCL-PROC-038 JA3 Separation Planne

Au	thor	Api	prov	val

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 Dec 2012, 04:28:36 PM	Approved

#### **Manager Approval**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		21 Dec 2012, 04:28:59 PM	Approved

#### **Medical Director Approval**

Name/Signature	Title	Date	Meaning/Reason	
Joanne Kurtzberg (KURTZ001)		21 Dec 2012, 07:20:36 PM	Approved	

#### QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG00	6)	23 Dec 2012, 04:54:45 PM	Approved

#### **Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		14 Jan 2013, 04:27:35 PM	Approved

#### Notification

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		14 Jan 2013, 04:27:35 PM	Email Sent
Sharon Hartis (SH259)		14 Jan 2013, 04:27:35 PM	Email Sent
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System Administrator (SYSADMIN)		14 Jan 2013, 04:27:35 PM	Email Sent