



## STEM CELL LABORATORY (STCL)



**DOCUMENT NUMBER:** STCL-SOP-052 FRM1

**DOCUMENT TITLE:**

Progenitor Cell Assay Form

**DOCUMENT NOTES:**

Document required for the BLA.

### Document Information

**Revision:** 03

**Vault:** STCL-Processing-rel

**Status:** Release

**Document Type:** SOPs

### Date Information

**Creation Date:** 07 Feb 2013

**Release Date:** 15 Feb 2013

**Effective Date:** 15 Feb 2013

**Expiration Date:**

### Control Information

**Author:** WATE02

**Owner:** WATE02

**Previous Number:** 9D.212

**Change Number:** STCL-CCR-115

DUKE UNIVERSITY MEDICAL CENTER STEM CELL LABORATORY  
PROGENITOR CELL ASSAY FORM

Bar code
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Date Collected: \_\_\_\_\_

Date Received: \_\_\_\_\_

Segment volume (if thawed) \_\_\_\_\_

Source: \_\_\_\_\_

Cell Count per ml  $\times 10^5$  \_\_\_\_\_  $\frac{\text{_____} \times 10^5}{1} \frac{2.5 \times 10^5}{X} = \text{_____} \mu\text{l needed}$

Source: \_\_\_\_\_

Cell Count per ml  $\times 10^5$  \_\_\_\_\_  $\frac{\text{_____} \times 10^5}{1} \frac{2.5 \times 10^5}{X} = \text{_____} \mu\text{l needed}$

Calculation by Tech Study ID #: \_\_\_\_\_

Plating by Tech Study ID #: \_\_\_\_\_

Results:

Cells Plated per Well	GM	GEMM	BFUE	Read by	Date	Checked by

Comments:

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**TNCC:**

**GM**

$$\frac{\quad}{1.25 \times 10^4} \times \frac{\quad}{\quad \times 10^9} = \quad \times 10^5$$

**GEMM**

$$\frac{\quad}{1.25 \times 10^4} \times \frac{\quad}{\quad \times 10^9} = \quad \times 10^5$$

**BFU-E**

$$\frac{\quad}{1.25 \times 10^4} \times \frac{\quad}{\quad \times 10^9} = \quad \times 10^5$$

Reviewed by: \_\_\_\_\_

(Technologist's Name)

Date Reviewed: \_\_\_\_\_

Field	Requirement
Barcode	Enter barcode of the unit
Date collected	Enter date collected
Date received	Enter date received into lab
Source	Enter UCB. A second source field is listed in case the assay needs to be repeated.
Cell Count per ml $\times 10^5$	Enter cell count per ml
# of uls needed	Enter the total # of uls needed to perform the assay (based on the cell count per ml) using the formula provided.
Calculation by Tech Study ID	Study ID of tech performing calculations
Plating by Tech Study ID #:	Study ID of tech responsible for plating the cells
Results	Enter results of assay. Results will be recorded in triplicate. The average result will also be provided below for GM, GEMM, and BFUE colonies.
Comments	Enter any comments applicable to this assay.
TNCC (Back Page)	Record the TNCC in the entire UCB unit
GM / $1.25 \times 10^4$ (Back Page)	Record the average # of GM colonies (reported on the 1 <sup>st</sup> page) / $1.25 \times 10^4$ . (Record the number of GEMM & BFUE colonies as well).
Solving for "x" / TNC $\times 10^9$ (Back Page)	Solve for "x" being the "# of colonies" in the entire UCB unit (Do the same calculation for GEMM & BFUE)
Total # of GM, GEMM, and BFUE colonies ( $\times 10^5$ ) in the entire UCB unit	Transcribe these results onto the Graft Characterization Form which will be manually entered in the CCBB Emmes Database.
Reviewed by:	Technologist's name who reviewed the calculations.
Date Reviewed:	Enter the date the calculations were reviewed by the technologist.

DUKE UNIVERSITY MEDICAL CENTER STEM CELL LABORATORY  
PROGENITOR CELL ASSAY FORM

Bar code

Date Collected: 1-31-05Date Received: 2-1-05

Segment volume (if thawed) \_\_\_\_\_

Source: UCBCell Count per ml  $\times 10^5$  665

$$\frac{665}{1} \times 10^5 \frac{2.5 \times 10^5}{X} = 3.8 \mu\text{l needed}$$

Source: \_\_\_\_\_

Cell Count per ml  $\times 10^5$  \_\_\_\_\_

$$\frac{\quad}{1} \times 10^5 \frac{2.5 \times 10^5}{X} = \quad \mu\text{l needed}$$

Calculation by Tech Study ID #: 104Plating by Tech Study ID #: 0119

Results:

Cells Plated per Well	GM	GEMM	BFUE	Read by	Date	Checked by
$1.25 \times 10^4$	10 12 11	1 0 1	19 17 18	0119	2-15-05	NA
	11	0.7	18			

Comments:

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**TNCC:**  $14.29 \times 10^8$

**GM**

$$\frac{11}{1.25 \times 10^4} \times \frac{X}{1.429 \times 10^9} = 12.6 \times 10^5$$

**GEMM**

$$\frac{0.7}{1.25 \times 10^4} \times \frac{X}{1.429 \times 10^9} = 0.8 \times 10^5$$

**BFU-E**

$$\frac{18}{1.25 \times 10^4} \times \frac{X}{1.429 \times 10^9} = 20.6 \times 10^5$$

Reviewed by: Super STCL Tech

(Technologist's Name)

Date Reviewed: 02/15/2005

**Signature Manifest****Document Number:** STCL-SOP-052 FRM1**Revision:** 03**Title:** Progenitor Cell Assay Form

All dates and times are in Eastern Time.

**STCL-SOP-052 FRM1 Progenitor Cell****Author Approval**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		11 Feb 2013, 02:24:58 PM	Approved

**Medical Director Approval**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		11 Feb 2013, 06:27:05 PM	Approved

**QA Approval**

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		11 Feb 2013, 08:50:14 PM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		13 Feb 2013, 04:17:37 PM	Approved

**Notification**

Name/Signature	Title	Date	Meaning/Reason
Sharon Hartis (SH259)		13 Feb 2013, 04:17:38 PM	Email Sent
Linda Sledge (SLEDG006)		13 Feb 2013, 04:17:38 PM	Email Sent
System Administrator (SYSADMIN)		13 Feb 2013, 04:17:38 PM	Email Sent
Barbara Waters-Pick (WATE02)		13 Feb 2013, 04:17:38 PM	Email Sent

**Review: STCL-SOP-052 FRM1 03****Review**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		23 Dec 2014, 05:31:32 PM	Reviewed
Joanne Kurtzberg (KURTZ001)		11 Jan 2015, 04:58:28 PM	Reviewed
Sharon Hartis (SH259)		13 Jan 2015, 03:06:45 PM	Reviewed
Betsy Jordan (BJ42)		13 Jan 2015, 03:18:19 PM	Reviewed
John Carpenter (JPC27)		13 Jan 2015, 05:41:46 PM	Reviewed