



STEM CELL LABORATORY (STCL)



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EMMES Stability Data Integrity Verification JA1

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STCL-QA-008 JA1

EMMES STABILITY DATA INTEGRITY VERIFICATION

1. INTRODUCTION

- 1.1. This document describes the process by which a portion of the data, used to generate the annual stability report, will be verified in the STCL EMMES database against source documentation in the laboratory files.
- 1.2. A sample of the records, included in the data used to generate the annual stability report, will be selected to confirm the accuracy of the data that has been generated.

2. DEFINITIONS/ACRONYM

- 2.1. STCL Stem Cell Laboratory
- 2.2. QSU Quality Systems Unit

3. REQUIREMENTS

- 3.1. Requirements are described in the following document:
 - 3.1.1. A portion of the data used to generate the STCL Stability Annual Report. Source will be verified in the STCL EMMES database against source documentation in each respective laboratory file for accuracy.
 - 3.1.2. If corrections are found during the review process, the data in the STCL EMMES database will be corrected and a determination will be made, based on the correction rate, regarding whether or not a corrected report needs to be generated by the EMMES Corporation.

4. AUTHORIZATION

- 4.1. This data verification process will be initiated when the stability data, which is provided by the EMMES Corporation from data extrapolated from the STCL EMMES database, has been provided for the annual report.
 - 4.1.1. STCL QSU in August (+ / - one month) of each year.

5. PROJECT PLAN

- 5.1. The following team members will participate in the verification process:
 - 5.1.1. STCL staff
- 5.2. The team member will execute the review of all of the tests results used to populate data referenced in Table 8-1 in *STCL-QA-008 Stability Assessment of Clinical Products*.
- 5.3. Successful completion of data verification process will be captured on the printouts generated from the *Infusion Data* report and *Stem Cell Form* report printed from the STCL EMMES database (pre-verification of data and post-verification of data).

5.4. Corrections, if needed, will be made in the database in real time; a correction rate will be calculated and reflected in the STCL Annual Stability Report.

5.5. Validations are to be complete by:

5.5.1. May 31st

6. TESTING

- 6.1. For each of the ten (10) laboratory records that are randomly selected for verification, the Infusion Data and Stem Cell Form reports in the STCL EMMES database will be compared against the source documentation located in each respective laboratory file.
- 6.2. The Infusion Data and Stem Cell Form report forms should each be printed at the start of the verification process to show the original data. Once the Infusion Data and Stem Cell Form has been opened, select “Preferences” (*on the tab located at the top right of the screen*) then under the “Session Preferences”, select “Check to display the Audit History”). These actions will display the entire audit history for that report at the bottom of each report.
- 6.3. Once all of the source documentation has been reviewed for both the Infusion Data and Stem Cell Form reports, if errors are found, corrections should be made in the STCL EMMES database as soon as possible.
- 6.4. Once corrections have been made, the final report for both the Infusion Data and Stem Cell Form reports should be reprinted including the “Audit History” so there is documentation of the correction that was made, who made it, date/time of the correction, etc.
- 6.5. Once all of the applicable source documentation for the ten (10) laboratory files has been reviewed against the Infusion Data and Stem Cell Form reports, the total # of data fields reviewed for each report can be totaled along with the # of corrections in order to obtain the “correction rate” for this verification process.
- 6.6. If the number of corrections made is significant and could have a major effect on the final data that was used to generate the annual stability report, a corrected report should be requested from the EMMES Corporation (*once all of the corrections have been entered*).
- 6.7. See screenshots (*at the end of this document*) showing Infusion Data and Stem Cell Form reports and the audit histories at the bottom of each report so correction rate can be calculated.

7. TESTING REPORT

- 7.1. The correction rate calculated, when comparing the source documentation in the STCL EMMES database against the source documentation, will be included in the STCL Annual Stability Report.

8. RELATED DOCUMENTS

- 8.1. STCL-QA-008 Stability Assessment of Clinical Products

Duke Stem Cell Application - AdvantageEDC - Internet Explorer
 https://secure.emmes.com/duke/send/workflow.WDispatcher

Sat May 04 2019 08:42:16 PM EDT Duke Stem Cell Application V. 1.05 Barbara Waters-Pick
 Site Center: Duke Stem Cell Laboratory

Main Menu > Data Entry Main > Key Selection Extend Session Preferences Logout

Infusion Data (Updating)

Protocol: Duke Stem Cell Laboratory Recipient: 00A56676 Name: CHARLES MARSHALL Form: Infusion Data

Save Delete

Product Type: 2-PBPC
 Infusion Date: 10/09/2013
 Infusion Number: 1

Print
 Select PBPC type

1. ☒ Infusion time
 2. ☒ Product type
 3. ☐ Cord blood unit ID
 4. ☒ Product sub-type 2
 5. Bar code numbers for infusion products

PBPC standard
 13:00 (hh:mm) 24 hour clock
☐ 1-Autologous ☒ 2-Allogeneic
☐ 3-Mismatched related ☒ 4-Mismatched unrelated

Product	Bar code	Product	Bar code
1	<input checked="" type="checkbox"/> W22481300720500	2	<input type="checkbox"/>
3	<input type="checkbox"/>	4	<input type="checkbox"/>
5	<input type="checkbox"/>	6	<input type="checkbox"/>
7	<input type="checkbox"/>	8	<input type="checkbox"/>
9	<input type="checkbox"/>	10	<input type="checkbox"/>

Version: 3.00; 05-28-11

Remaining Session Time: 19:33

INFUSION FORM

Duke Stem Cell Application - AdvantageEDC - Internet Explorer
 https://secure.emmes.com/duke/send/workflow.WDispatcher

44. ☒ Name of person contacted:
 If Other, specify:

45. ☐ Date person was contacted: (mm/dd/yyyy)

46. ☐ Time person was contacted: (hh:mm)

47. ☐ Person contacted by:

Comments:
 INFUSED 8 X 10⁶ AND FROZE THE REMAINING 2.15 X 10⁶ CD34/KG IN A SINGLE ALIQUOT

Print
 Click to check spelling

Save Delete

Select Save to ensure that data are written to the database. Select a link (e.g., Main Menu) on the navigation bar to continue.
[Return to top](#)

Clinical Audit History
 The date and time of listed records are represented in U.S. Eastern Time Zone.

FIELDNAME	OLDVALUE	NEWVALUE	REASON	USERID	DATE	TIME
Total CD34+	Missing	805.5800		Caroline Howell	10/09/2013	11:42:28
Total CD34 cells/kg	Missing	8.0		Caroline Howell	10/09/2013	11:42:28
Progenitor cell assay	Missing	0-No		Caroline Howell	10/09/2013	11:42:28
Automated nucleated cc	Missing	281.91		Caroline Howell	10/09/2013	11:42:28
CD34 test performed	Missing	1-Yes		Caroline Howell	10/09/2013	11:42:28
CD3 test performed	Missing	0-No		Caroline Howell	10/09/2013	11:42:28
CD4 test performed	Missing	0-No		Caroline Howell	10/09/2013	11:42:28
CD8 test performed	Missing	0-No		Caroline Howell	10/09/2013	11:42:28
Comments	Missing	INFUSED 8 X 10 ⁶ AND FROZE THE REMAINING 2.15 X 10 ⁶ CD34/KG IN A SINGLE ALIQUOT		Caroline Howell	10/09/2013	11:42:28
Percent CD34 cells	Missing	0.01364		Caroline Howell	10/09/2013	11:42:28
Bar code 1 of Inf product	Missing	W22481300720500		Caroline Howell	10/09/2013	11:42:28
Differential tested	Missing	0-No		Caroline Howell	10/09/2013	11:42:28
Product sub-type 2 Inf	Missing	4-Mismatched unrelated		Caroline Howell	10/09/2013	11:42:28
Product type infused:	Missing	2-Allogeneic		Caroline Howell	10/09/2013	11:42:28
Viability percent	Missing	99		Caroline Howell	10/09/2013	11:42:28
Volume mL	Missing	209.5		Caroline Howell	10/09/2013	11:42:28

Remaining Session Time: 19:11

AUDIT HISTORY

STCL-QA-008 JA1 EMMES Stability Data Integrity Verification
 Stem Cell Laboratory, DUMC
 Durham, NC

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Duke Stem Cell Application - AdvantageEDC - Internet Explorer
 https://secure.emmes.com/duke/server/workflow/WD:dispatcher

Sat May 04 2019 06:45:20 PM EDT Duke Stem Cell Application V: 1.05 Barbara Waters-Pick
 Site/Center: Duke Stem Cell Laboratory

Main Menu > Data Entry Main > Key Selection Stem Cell Form (Updating) Extend Session Preferences Logout

Protocol: Duke Stem Cell Laboratory Recipient: H0A50578 Name: CHARLES MARSHALL Form: Stem Cell Form

Save Delete

Product Number: W22481300720500 Version: 4.00; 06:13:13

Print

1. ☒ Product type:
 If product type is autologous, skip question 4, 4a-4g.

2. ☒ Product sub-type 1:
 If Other, then specify:
 If product sub-type 1 is Bone Marrow, indicate the following:
 a. MD who performed bone marrow:
 b. NP who performed bone marrow:
 If product sub-type 1 is PBPC, indicate the following:
 c. ☒ Peripheral CD34:
 d. Result:
 3. ☒ Type of service:
 If service type Non-Duke, specify:
 If Service Type is COBLT/CSE, COBBI/ARG or Non-Duke and Product type is UCB, answer questions 4b, 4c, 4f, 4g and 35 ONLY.

4. ☐ Product sub-type 2:
 e. ☒ Donor Duke History #:
 f. ☒ Donor other identifying #:
 g. ☐ Donor first name:
 h. ☐ Donor last name:

☐ 1-Autologous ☒ 2-Allogeneic
 2-PBPC
☒ No ☐ Yes
 2-ABMT
 D1313256
 0710-3348-4

Remaining Session Time: 19:56

STEM CELL FORM

Duke Stem Cell Application - AdvantageEDC - Internet Explorer
 https://secure.emmes.com/duke/server/workflow/WD:dispatcher

Anaerobic: O-Negative
 Anaerobic:

Contact Information
 41. ☐ Name of person contacted:
 If Other, specify:
 42. ☐ Date person was contacted:
 43. ☐ Time person was contacted:
 44. ☐ Person contacted by:
 Comments:

Print
 Click to check spelling
 Save Delete

Select Save to ensure that data are written to the database. Select a link (e.g., Main Menu) on the navigation bar to continue.
[Return to top](#)

Clinical Audit History
 The date and time of listed records are represented in U.S. Eastern Time Zone.

FIELDNAME	OLDVALUE	NEWVALUE	REASON	USERID	DATE	TIME
Total CD34+	Missing	966.0470		Caroline Howell	10/09/2013	11:38:24
Total CD34+/kg	Missing	9.6		Caroline Howell	10/09/2013	11:38:24
Total CD3+/kg	Missing	323.5		Caroline Howell	10/09/2013	11:38:24
ABO Rh confirmation	Missing	O+		Caroline Howell	10/09/2013	11:38:24
Auto nucleated cell count	Missing	174.69		Caroline Howell	10/09/2013	11:38:24
Bag 1 bar code	Missing	W22481300720500A		Caroline Howell	10/09/2013	11:38:24
Bag 1 storage location	Missing	TW40K 295E		Caroline Howell	10/09/2013	11:38:24
Number of bags frozen	Missing	1		Caroline Howell	10/09/2013	11:38:24
Was CD34 tested	Missing	1-Yes		Caroline Howell	10/09/2013	11:38:24
Was CD34 tested	Missing	1-Yes		Caroline Howell	10/09/2013	11:38:24

Remaining Session Time: 19:13

AUDIT HISTORY

STCL-QA-008 JA1 EMMES Stability Data Integrity Verification
 Stem Cell Laboratory, DUMC
 Durham, NC

The STCL EMMES database parameters being verified, may include, but are not limited to:

- Patient ID
- Product Number
- Product Type
- Date of collection
- Pre-Thaw Viability
- Pre-Thaw TNCC (x 10e8)
- Number of bags
- Product Barcode
- Product Type infused
- Infusion Date
- Infusion Number
- Product Age
- Product type infused
- Barcode 1, etc, infused
- Products infused?
- Type of Thaw?
- Post Thaw Viability
- Post Thaw TNCC (x 10e8)
- TNCC % Recovery
- Total CD34 (x 10e6)
- Total CFU-GM (x 10e5)
- Total CFU-GEMM (x 10e5)
- Total CFU-BFUE (x 10e5)
- Total CFU colonies (x 10e5)
- Aerobic Sterility Results
- Anaerobic Sterility Results

Signature Manifest**Document Number:** STCL-QA-008 JA1**Revision:** 01**Title:** EMMES Stability Data Integrity Verification JA1

All dates and times are in Eastern Time.

STCL-QA-008 JA1 EMMES Stability Data Integrity Verification**Author**

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