

STEM CELL LABORATORY (STCL)



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| DOCUMENT TITLE: |
| EMMES Stability Data Integrity Verification JA1 |
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| DOCUMENT NOTES: |
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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).

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- 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

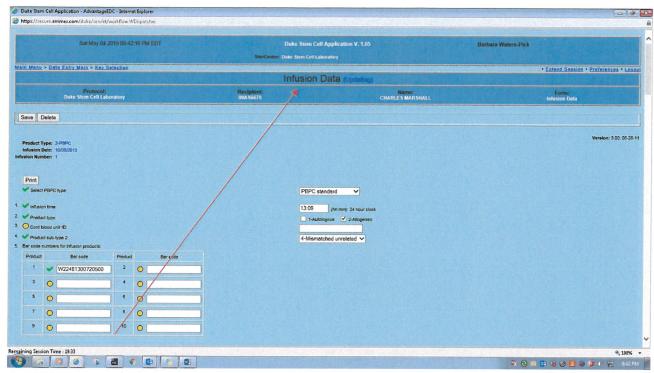
- 6.1. For each of the ten (10) laboratory records that are randomly selected for verification, the *Infusion Data* and *Stem Cell Form* reports in the STCL EMMES database will be compared against the source documentation located in each respective laboratory file.
- 6.2. The <u>Infusion Data</u> and <u>Stem Cell Form</u> report forms should each be printed at the start of the verification process to show the original data. Once the <u>Infusion Data</u> and <u>Stem Cell Form</u> has been opened, select "<u>Preferences</u>" (on the tab located at the top right of the screen) then under the "<u>Session Preferences</u>", select "<u>Check to display the Audit History</u>"). 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 <u>Infusion Data</u> and <u>Stem Cell Form</u> 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 <u>Infusion Data</u> and <u>Stem Cell Form</u> 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 <u>Infusion Data</u> and <u>Stem Cell</u>
 <u>Form</u> reports and the audit histories at the bottom of each report so correction rate can be calculated.

7. TESTING REPORT

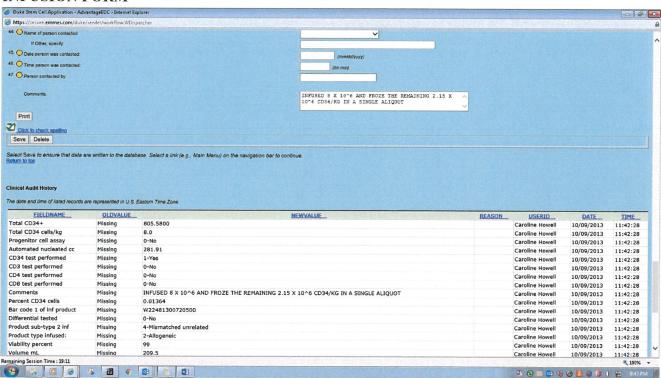
7.1. The correction rate calculated, when comparing the source documentation in the STCL EMMES database against the source documentation, will be included in the STCL Annual Stability Report.

8. RELATED DOCUMENTS

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

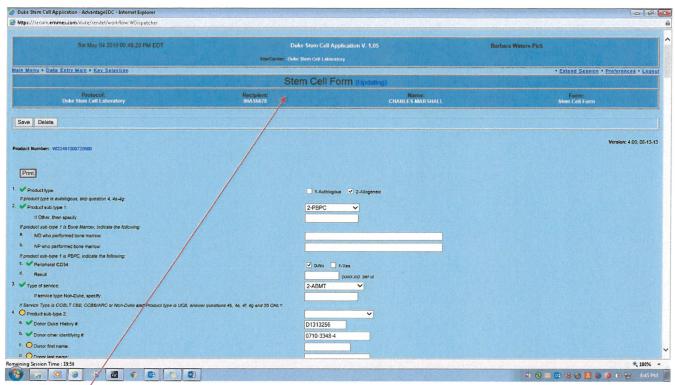


INFUSION FORM

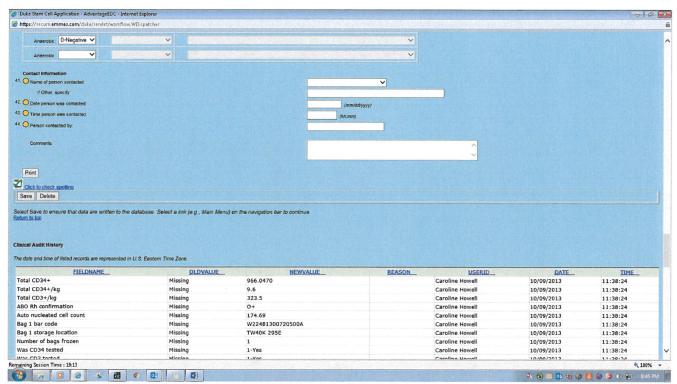


AUDIT HISTORY

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STEM CELL FORM



AUDIT HISTORY

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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

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All dates and times are in Eastern Time.

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Document Release

| Name/Signature | Title | Date | Meaning/Reason |
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