STEM CELL LABORATORY (STCL)

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DOCUMENT TITLE:

Corrected Results - Monitoring, Reporting and Remediation

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STCL-GEN-019
Corrected Results - Monitoring, Reporting and Remediation

1. PURPOSE:

1.1. To ensure that all laboratory results that need correction or modification after release from the lab are detected and corrected in a timely and consistent manner to allow opportunity for prompt changes in patient management strategies, if needed.

1.2. To minimize the probability of recurrence of laboratory reporting errors.

2. INTRODUCTION:

2.1. Each laboratory will monitor test result reporting accuracy.

2.2. Errors will be corrected in Beaker (Maestro Care) if results were reported in Beaker.

2.3. Corrected results will include the reason for the correction and, as necessary, a comment explaining the nature of the changed result.

2.4. Any corrections that cause a change in the meaning or fundamental interpretation of a result will require an investigation to be performed. The laboratory will document the results of the investigation in the SRS system RL Solutions.

2.5. Further, laboratories must communicate errors that cause a change in patient result meaning directly to the responsible healthcare provider.

3. SCOPE AND RESPONSIBILITES:

3.1. The Stem Cell Laboratory Medical Director, Manager, and applicable STCL personnel who enter laboratory results in EPIC are responsible for ensuring the requirements of this procedure are successfully met.

4. DEFINITIONS /ACRONYMS

4.1. Corrected Result – A change in a test result after the result has been verified and released to the responsible healthcare provider.

4.2. SRS Safety Reporting System RL Solutions

4.3. STCL Stem Cell Laboratory

4.4. DUHS Duke University Health System

4.5. N/A Not Applicable

5. MATERIALS

5.1. N/A

6. EQUIPMENT

6.1. N/A

7. SAFETY

7.1. N/A

8. PROCEDURE

8.1. Error detection system:

8.1.1. STCL personnel who are assigned to manually enter lab results in EPIC, will double check the results reflected on the hand-written documents/worksheets to ensure that the information entered in EPIC is accurate. Since a second qualified employee is not always available, results must be double-checked by the same technologist to ensure accuracy before verifying those results.

8.1.2. Methods of review may include review of results by a (second) qualified person prior to release from the laboratory, review of unusual results (*when appropriate*), review of a percentage of previously released results or a review of known reporting problem areas.

8.1.3. Significant clerical and analytical errors must be corrected in EPIC in a timely manner to ensure patient care is not compromised.

8.1.4. The laboratory will review Corrected Result Reports on a monthly basis.

8.2. Error correction documentation process:

8.2.1. Incorrect results that have been verified in Beaker must be corrected using the "Result Correction Authorization" function. Refer to "*Correct a Verified Result" in the MaestroCare Quick Start Guide Beaker Clinical Pathology.*

8.2.2. All revised reports must clearly be identified as revised and the original and corrected results must remain available to the patient's provider.

8.2.3. The corrected report must include the original result and the corrected result and any comments associated with the change in the results.

8.3. Error notification process:

8.3.1. For results that cause a change in patient result meaning, the STCL communication methods include, but are not limited, to phone call, in-basket message, e-mail, text page, or a corrected result report. Comments associated with the corrected report should include the name of the person notified of the change, which mode of communication was used, the date, and time of the notification (*ie. "Dr. Smith was notified of corrected result for CD34+ cells/kg via e-mail on 1/15/2018 @ 14:15").*

8.3.2. For results that do NOT cause a change in patient result meaning, the STCL can include a chartable comment attached to the patient result when making that correction.

8.4. Error investigation system and documentation process:

8.4.1. The laboratory manager, MLS Specialist, or MLS, Advanced will review all result corrections made by the STCL each month.

8.4.2. An investigation is performed and the findings of that investigation documented on the report. Appropriate action is taken. Documentation should be saved and available for two (2) years.

8.5. SRS Filing:

8.5.1. The STCL technologist performing the correction will be required to submit a SRS report through RL Solutions regarding result changes when any of the following is true:

8.5.1.1. The correction changes the fundamental interpretation or meaning of the result (*ie. positive to negative, present to absent, a qualitative result within normal range to abnormal or critical or the converse of any of these*).

8.5.1.2. Action was taken by a member of the patient's care team, based on a result that was subsequently changed and, given the revised result, the action taken was no longer appropriate.

8.5.1.3. Appropriate treatment was delayed based on the incorrect result.

8.5.2. The documentation in RL Solutions should include a description of what happened, identification of the factors that contributed to the error, what remediation is required, a determination of the relative risk of recurrence, establishment of a monitoring system and determination of the degree of harm to the patient.

8.6. **Director Review**:

8.6.1. It is the responsibility of each laboratory director or designee to review corrected results on a monthly basis.

8.6.2. Beaker Report is provided to the lab manager on a monthly basis on the shared Clinical Laboratories drive.

8.6.3. In addition, corrected results will be reviewed on a quarterly basis at the laboratory specific Director's meeting.

9. RELATED DOCUMENTS/FORMS

9.1. Corrected Results (LTR79502)

9.2. MaestroCare Quick Start Guide Beaker Clinical Pathology

10. REFERENCES

10.1. N/A

11. REVISION HISTORY

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01	B. Waters-Pick	New Document

Signature Manifest

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