# Applicable Laboratory(s)):

[x]  North Carolina Baptist Hospital (NCBH)

[ ]  Lexington Medical Center (LMC)

[ ]  Davie Medical Center (DMC)

[ ]  Wilkes Medical Center (WMC)

[ ]  High Point Medical Center (HPMC)

[ ]  Westchester

[ ]  Clemmons

# Policy Purpose

The purpose of this policy is to describe how to consistently correct errors when they occur on various reports, documents and electronic records.

# Scope

This policy applies to Blood Bank Staff and Management.

# Definitions

1. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH.  A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
2. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.

**Sections:**

1. Manual Corrections
2. Correction of electronically reported test results / interpretations

 C. Electronic Worksheet Corrections

D. Recording Corrections Made by Other Laboratories or Outside the Medical Center

**POLICIES**

1. Only BLACK ink will be used on manual requisitions, records, charts.

2. No gel or felt-tip pens for documenting results (Exception: Liquid nitrogen storage).

3. Ink should be indelible to the conditions with which it comes in contact.

4. No blanks should be left on labels; N/A should be used to fill label blanks.

5. No white-out or correction tape of any kind should be used to cover incorrect manual entries.

6. Changes to records shall be controlled

6.1. The date of changes and the identity of the individual changing the record shall be documented, and this information shall be maintained for the retention period of the original record.

6.2 Overwrites are not allowed; for example making one number into another by writing over the original information.

6.2. Record changes shall not obscure previously recorded information.

a. Manual corrections to documented results shall be made with one line drawn through the incorrect result / interpretation.

b. Results shall not be “blacked out” or “scribbled out” with ink or marker.

c. Correction tape or white out to cover any error shall not be used.

d. Protocols and procedures cannot be changed except by manager or designee.

7. Errors that result in a change of patient cell dosage shall be reported to the SCTCT laboratory medical director, the SCTCT Program director, and the nurse coordinators immediately.

8. Errors made by other laboratories on reports received by the BB/SCTCT lab will be corrected by the reporting lab. BB/SCTCT lab must document the changes made by the other laboratories.

9. An Occurrence Report must be filled out and submitted to management when any electronic results are changed or corrected.

*Refer to BB-FORMS-0120: Quality Assurance Exception Report*

10. Any results / interpretations that are incorrect and that reach the patient’s chart or permanent record (EPIC) incorrectly must be reported on an Occurrence Report and in the RL6 system when corrections and/or modifications are made. If the result did NOT reach the patient’s chart (only BB LIS affected) an RL6 is not necessary.

*Refer to BB-FORMS-0120: Quality Assurance Exception Report*

*Refer to BB-SOP-0077: RL6 Procedure*

11. Errors involving patients and/or products will be assessed by management on a case by

case basis to determine whether the incident requires FDA reporting.

12. Upon discovery, nonconforming products, components, tissue, derivatives, critical materials, and services shall be evaluated and their disposition determined.

13. Any adverse events or fatalities that occur as result of an error shall be reported to management and the department medical director. Refer to the Quality Plan Manual: There is a process that involves layers of department notification if a mortality event occurs. The laboratory medical director and laboratory administrator will be notified immediately. This notification will be escalated to the appropriate medical center departments. An RL6 will be written with appropriate harm score. The laboratory medical director will notify any outside agencies (if needed). FDA notification (if needed) will be notified as soon as possible within 7 days and a report generated within 14 days.

# Procedure

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: None

**I. MANUAL CORRECTIONS**

| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | **Draw a single line through the incorrect result / interpretation.** Laboratory |
| **2.0** | **Document the CORRECT result / interpretation clearly above or below the incorrect result / interpretation***Blood Bank*Laboratory |
| **3.0** | **Record date of correction next to the incorrect result / interpretation.** *Blood Bank 6/6/2024*Laboratory  |
| **4.0** | **Record initials of person recording error message next to the incorrect result.** *Blood Bank 6/6/2024 CSW*Laboratory  |
| **5.0** | **See additional example, Attachment 1.** |

**II. CORRECTION OF ELECTRONICALLY REPORTED TEST RESULTS/ INTERPRETATIONS**

| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | **Correct any manually recorded results on requisition / equivalent as necessary.*** 1. Refer to *Section I. Manual Corrections*.
 |
| **2.0** | **Access the specific test order in BOP.** |
| **3.0** | **Enter the patient’s MRN and select.****3.1 Select the correct accession number.**  |
| **4.0** | **Review BAD file.** |
| **5.0** | **Click on Test Result to be corrected.** 5.1 Place cursor in the test field.5.2 Enter correct results (may be in the reaction grid if applicable).5.3 Review modified test results / interpretations for accuracy.5.4 Respond to any exceptions.5.5 Review information for completeness and clarity.5.6 Save result5.7 Sunquest will send the corrected report comment to Beaker.5.8 Sunquest will send the NEW interpretation and the PREVIOUS interpretation to Beaker. 5.9 If Interpretation is changed then proceed to step 6.5.10 If interpretation is NOT changed then stop. |
| **6.0** | **Notify a member of the clinical team (nurse or physician) of the corrected interpretation when it will impact the treatment of the patient (i.e. correction that changes DAT interpretation, or blood availability).**6.1 Document who was notified on QA and in Sunquest using the BCALL test. Example: “DAT corrected result of positive called to John Smith, RN by Christina Warren 6/6/24”6.2 Override exception for result modification using appropriate Reason Code LIE = Logged in Error CLERR = Clerical Error INCT = Incomplete Testing BBR= Blood Bank Reason: if this reason is being used you MUST free text a  comment explaining the reason. 6.3 Save |
| **7.0** | **Do RL6 and Quality Assurance Exception report.** |

**III. ELECTRONIC WORKSHEET CORRECTIONS**

| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | **Correct the electronic worksheet electronically and reprint.** * 1. Do not destroy the original worksheet.
 |
| **2.0** | **Circle the corrected result on all copies.**  |
| **3.0** | **Record the message: *Corrected Results, See Error Results* on the Corrected Report.**  |
| **4.0** | **Record the message: *Error Results, See Corrected Results* on the Incorrect Report.**  |
| **5.0** | **Record date and time of correction.**  |
| **6.0** | **Record initials of person recording corrected result message.** |
| **7.0** | **Complete QA Exception Report explaining the reason for the correction.**  |
| **8.0** | **When results are charted, complete an RL6 report.** |
| **9.0** | **See example, Attachment 2.** |

**IV. RECORDING CORRECTIONS MADE BY OTHER LABORATORIES OR**

 **OUTSIDE THE MEDICAL CENTER**

| **STEPS** | **INSTRUCTIONS** |
| --- | --- |
| **1.0** | **The laboratory that had the error will enter a corrected report according to their procedure.** * 1. Do not destroy any original reports.
 |
| **2.0** | **Circle the corrected result on all copies.**  |
| **3.0** | **Record the message: *Corrected Results, See Error Results* on the Corrected Report.**  |
| **4.0** | **Record the message: *Error Results, See Corrected Results* on the Incorrect Report.**  |
| **5.0** | **Record date of correction.** |
| **6.0** | **Record initials of person recording corrected result message.** |
| **7.0** | **Complete QA Exception Report explaining the reason for the correction.**  |
| **8.0** | **When results are charted, complete an RL6 report.** |

# Literature References:

21 CFR 211.100

*Standards for Blood Banking and Transfusion Services.* AABB, Revised periodically

FACT Cellular Therapy Standards, D12.1.2.2, Revised periodically

# Related Policies/Procedures in Navex:

# Attachments/Linked Documents in Title 21:

Attachment 1. Correction of Manual Results

Attachment 2. Correction of Electronic Worksheets

# Revision Dates: Review Change Summary as Represented in Title 21.