Wake Forest Baptist Medical Center	Correction of Laboratory Records (QC log, Temperature logs, etc.)	Dept:	Pathology
		Effective Date:	Jan 17, 2019
		Revised Date:	
		Contact:	Lab Compliance, QA, Safety
Name & Title: CLIA Laboratory Director		Date:	1/21/19
Signature:			

1) **General Policy Statement:** The Department of Pathology laboratory sections follow a standard policy for the management and correction of laboratory records, including quality control data, temperature logs, and intermediate test results or worksheets.

   a. **Purpose:** The purpose of this policy is to ensure that corrections made to any laboratory records are performed consistently and occur in a manner that is both legible and indelible. Corrections should be made in accordance with CAP Standard GEN.20450.

   b. **Responsible Department/Scope:**
      i. Procedure owner/Implementer: Department of Pathology
      ii. Procedure prepared by: Laboratory Compliance, QA and Safety
      iii. Supervision: CLIA Lab Director, Section Medical Director, Section Manager/Assistant Manager, Laboratory Compliance/QA
      iv. Implementation: CLIA Lab Director, Section Medical Director, Section Manager/Assistant Manager, Laboratory Staff

2) **Procedure:**
   a. All changes to laboratory records must be legible and indelible (use of pencils are prohibited).

   b. Original (erroneous) entries must be visible (i.e., erasures, white and correction fluid are unacceptable) or accessible (example: audit trail for electronic records).

   c. Use of a single, horizontal line to strike through the original (erroneous) entry is preferred.

   d. Corrected data, including the identity of the person changing the record and when the record was changed, must be accessible to audit. This requirement does not apply to changes to patient reports (refer to GEN.41310).

   e. Corrections or changes to records should be noted by the Section Manager/Section Medical Director during the monthly QA review process. If

reason for correction/change was other than a minor error, implementation of a CAPA review may be necessary.

3) **Review/Revision/Implementation:**
   - All procedures must be reviewed at least every 2 years.
   - Procedure will be housed in the Department of Pathology.

4) **Related Procedures:** None

5) **References:**
CAP Standard GEN.20450

6) **Attachments:** None

7) **Revised/Reviewed Dates and Signatures:**

8) Review Date	Revision Date	Signature