

Title: Quality Correction of Laboratory Records Policy (Multi Site Labs)

Published Date: 10/01/2025

Last Review / Revised Date: 10/01/2025

Document Type:

☒ Policy ☐ Procedure ☐ Guideline ☐ Other

Content Applies to Patient Care:

☒ Adults ☒ Pediatrics (Under 18) ☐ N/A

Scope: ☐ Enterprise

☐ Division(s):

☐ Area Name:

☒ Entity Name: Multi Site Labs

☒ Department Name: Quality

I. 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.

II. SCOPE

This policy applies to all learners, employees, and faculty in the Department of Laboratory Medicine and Pathology at Atrium Health Wake Forest Baptist Medical Center.

III. DEFINITIONS/ABBREVIATIONS

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.

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 (NC Baptist Hospital), Lexington Medical Center (Lexington), Davie Medical Center (Davie), Wilkes Medical Center (Wilkes), High Point Medical Center (High Point), and Lab at Clemmons.

IV. POLICY

A. All laboratory records, e.g., quality control data, temperature logs, and intermediate test results or worksheets, must comply with the following guidelines:

Quality Correction of Laboratory Records Policy (Multi Site Labs)

1. All changes to laboratory records must be legible and indelible (use of pencils is prohibited).
2. Original (erroneous) entries must be visible and accessible for auditing; erasures and correction fluid or tape are unacceptable.
3. Corrections to handwritten or printed material should be made with a **single, horizontal strikethrough** of the original (erroneous) entry.
4. Corrected data, including the identity of the person changing the record and when the record was changed, i.e., initials and date, must be accessible to audit. This requirement does not apply to changes to patient reports (refer to GEN.41310, Corrected Reports).
5. Corrections or changes to records should be noted by the Section Manager/Section Medical Director during the monthly QA review process. If the reason for correction/change was anything other than a minor error, implementation of a CAPA review may be necessary.

V. **CROSS REFERENCES**

Not Applicable

VI. **RESOURCES AND REFERENCES**

College of American Pathologists, Lab General Checklist (12/26/2024)

- GEN.20450
- GEN.41310

VII. **ATTACHMENTS**

Not Applicable