|  |  |  |  |
| --- | --- | --- | --- |
| H:\logo.png | **Correction of Laboratory Records****(QC Log, Temperature Logs)** | **WFHN** | **Lab Services-Catawba**  |
| **Effective Date:** | **2/3/20** |
| **Revised Date:** |  |
| **Contact:** | **Sandra Johnston** |
| **Approval Signature:**  | **Date:** |  |
| **Typed Name and Title: Dr. Toby Foster, MD., Laboratory Director**  |

**General Policy/Procedure Statement:**

The Department of Laboratory Compliance follow a standard policy for the management of correction of laboratory records, including quality control data, temperature logs and intermediate test results or worksheet.

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.

**Procedure:**

1. All changes to laboratory records must be legible and indelible (use of pencils are prohibited). Only use blue or black ink in laboratory.
2. Original (erroneous) entries must be visible (i.e. erasures, white and correction fluid are unacceptable) or accessible (example: audit trail for electronic records.
3. Use of a single, horizontal line to strike through the original (erroneous) entry is preferred. Initial the strike –through.
4. Corrected data, including the identity of the person changing the record and when the record was changed, must be accessible to audit.
5. Corrections or changes to records must be noted by the technical consultant or 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.

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

**Review/Revision/Implementation:**

All procedure must be reviewed annually. All new procedures as well as those that have major revisions must be signed by the Laboratory Director. Review/sign off can be completed by the designated manager in the following circumstances: Annual review and minor document revisions.

**Revised/Reviewed Dates and Signatures**

|  |  |  |
| --- | --- | --- |
| **Review Date** | **Revision Description** | **Signature** |
|  |  |  |
|  |  |  |
|  |  |  |