Good Clinical Laboratory Practices (GCLP): Correction of Records

UNIVERSITY *of* WASHINGTON

Learning Objectives:

After completion of this training module staff will be able to:

- **Demonstrate knowledge of the different licensing and accrediting agencies that provide oversight for TSL.**
- **Determine whether or not a record correction was completed according to good clinical laboratory practices.**

TSL Accrediting/Licensing Agencies Standards & Regulations

- CAP (College of American Pathologists)
  - Laboratory General Checklist
- CMS (Centers for Medicare Services)
  - 42 CFR Part 493 - Laboratory Requirements
- FDA (Food and Drug Administration)
  - 21 CFR Part 200 – Laboratory Records
  - 21 CFR Part 600 – Biological Products

All of these organizations have standards (CAP) and Regulations (CMS & FDA) that hold laboratories accountable and ensure patient safety through good laboratory practices.

Standards & Regulations for Correction of Records

- CAP: GEN.20450 Correction of Laboratory Records
- CMS: 42 CFR 493.1105 Standard: Retention Requirements
- FDA: 21 CFR 211.194 Laboratory Records

GEN.20450 Correction of Laboratory Records

- The laboratory makes corrections to laboratory records (eg, quality control data, temperature logs, and intermediate test results or worksheets) using appropriate techniques.
  - Laboratory records and changes to such records must be legible and indelible. The techniques used must meet the following criteria:
    - Original (erroneous) entries must be visible (ie, erasures and correction fluid or tape are unacceptable) or accessible (eg, audit trail for electronic records).
    - Corrected data, including the identity of the person changing the record and when the record was changed, must be accessible to audit.

CMS: 42 CFR 493.1105 Standard: Retention Requirements

- (3) *Analytic systems records.* Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in §§ 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:
  - (i) Records of test system performance specifications that the laboratory establishes or verifies under § 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.
  - (ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v) and (d).

FDA: 21 CFR 211.194 Laboratory Records

- Records shall be maintained that include, but are not limited to, the following when applicable:
  - Donor records
  - Processing records
  - Storage and distribution records
  - Compatibility test records
  - Quality control records
  - General Records

What do these standards and regulations mean?

- All laboratory records have specific retention periods, part of retention is ensuring that all parts of the record are retained including the initial documentation if corrected, and the correction.
- Documentation written on any of these records must be done with indelible ink.
- When correcting written documentation, the original documentation must still be legible after correction.
- Corrections must include a way to identify the corrector and the date that the correction was made.

How can we meet the requirements for these standards and regulations?

When making a correction:

Do:

- Draw a single line through incorrect text.
- Document your Tech ID
- Document the date of correction

*If there is not room in the field you are correcting for your tech code and the date, you may use the space at the bottom of the document or on the back of the document and write “Correction to (field you are correcting) on (date) by (tech ID).”

Do NOT:

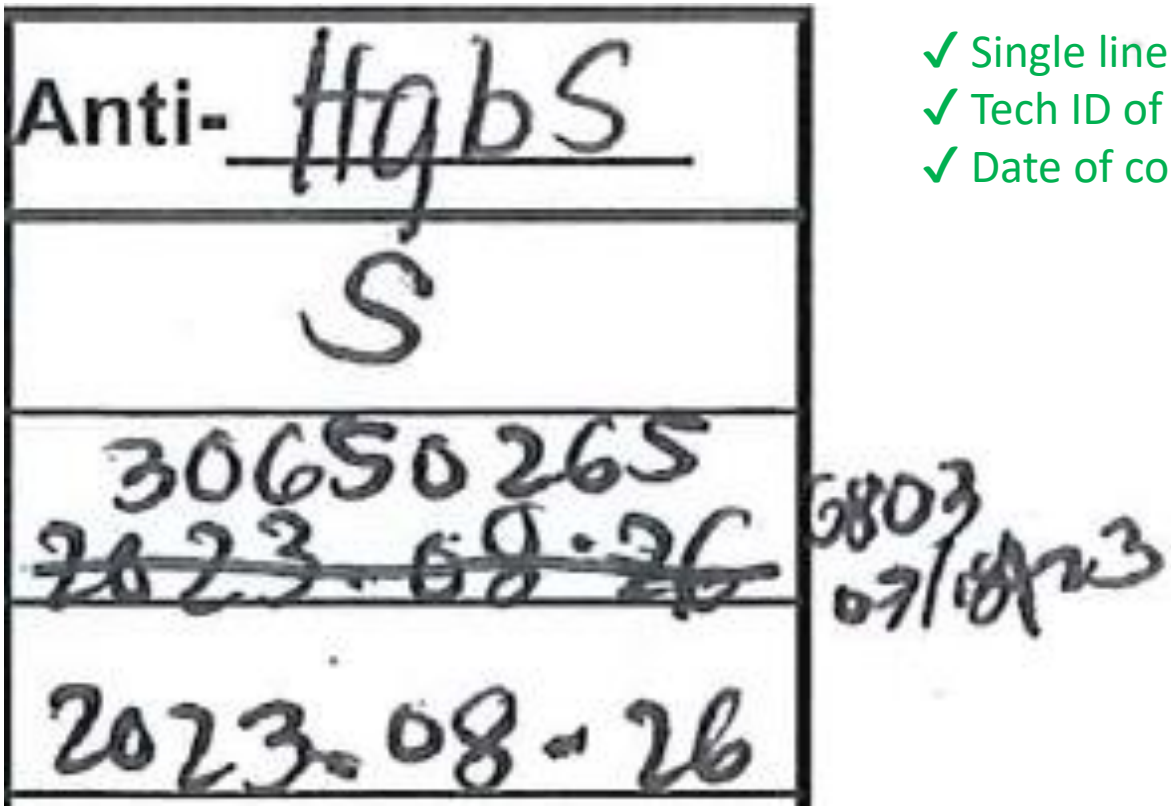
- Cross out information with a scribble or by writing over the incorrect text.
- Make any corrections without documentation of your Tech ID and the date of correction
- Use whiteout or correction tape.

How can we meet the requirements for these standards and regulations? (Continued)

When performing documentation on a laboratory record:

- Use only laboratory provided pens and sharpies to prevent bleeding or smearing of ink.
- Do not perform any documentation in pencil or erasable pen.
- Use sharpie to perform any required documentation on blood component labels or rad-sure irradiation stickers.

Example 1 of an appropriate record correction:



- ✓ Single line through incorrect text
- ✓ Tech ID of corrector
- ✓ Date of correction

Example 2 of an appropriate record correction:

Cell Washer		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
SN 0003785	Inspect Tubing (✓)	✓																														
Saline Volume (54-59 mL)		~~56~~ 55																														
SN 0003799	Inspect Tubing (✓)																															
Saline Volume (54-59 mL)																																
SN 0003789	Inspect Tubing (✓)																															
Saline Volume (54-59 mL)																																
SN 0003791	Inspect Tubing (✓)																															
Saline Volume (54-59 mL)																																
SN 0003782	Inspect Tubing (✓)																															
Saline Volume (54-59 mL)																																
SN 0003800	Inspect Tubing (✓)																															
Saline Volume (54-59 mL)																																
SCALE		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Weight	Range																															
20g	19.99-20.01g																															
500g	499.99-500.01g																															
Calibration performed when out of range (✓)																																
Staff Initials																																
Daily Review																																

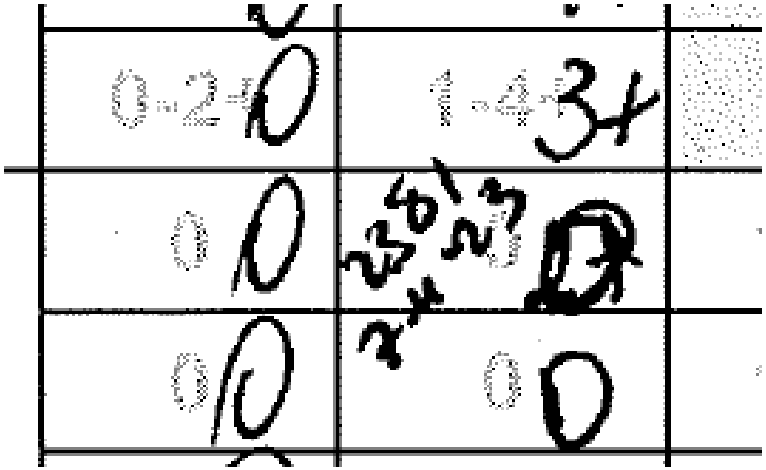
✓ = Performed/Acceptable NIS= Not in Service

*Correction to 7/1 SN 00037885 saline volume by TR06030 on 7/1/2023.

✓ Single line through incorrect text

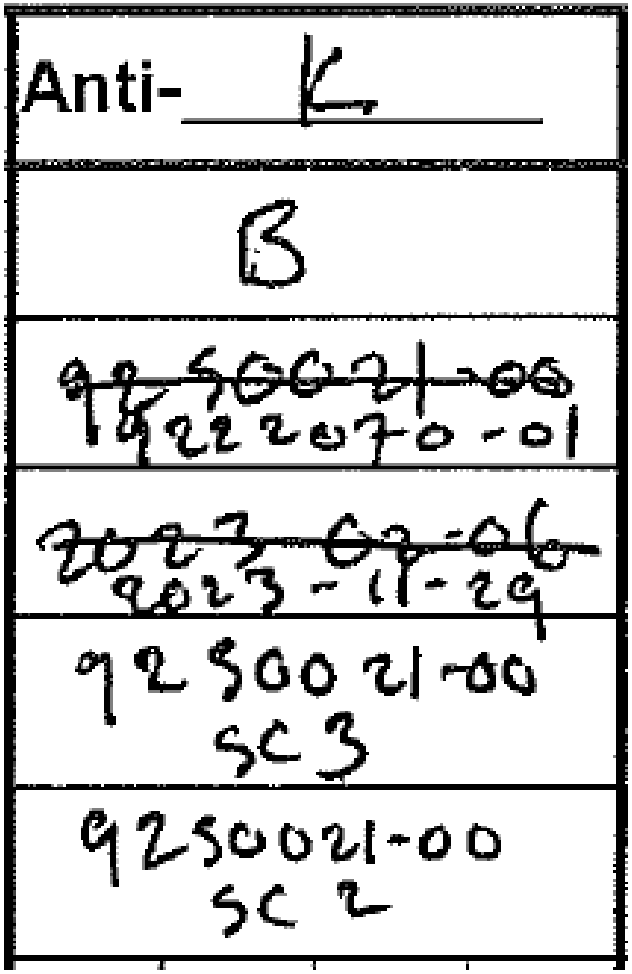
✓ Field corrected, Tech ID of corrector, and date of correction noted at bottom of form due to lack of space

Example 1 of an inappropriate record correction:



✗ Original text written over making it illegible
✓ Tech ID of corrector
✓ Date of correction

Example 2 of an inappropriate record correction:



✓ Single line through incorrect text
✗ Missing Tech ID of corrector
✗ Missing Date of correction

References:

- Code of Federal Regulations, Title 21, Part 606 https://www.ecfr.gov/current/title-21/part-606
- Code of Federal Regulations, Title 21, Part 211 https://www.ecfr.gov/current/title-21/part-211
- Code of Federal Regulations, Title 42, Part 493 https://www.ecfr.gov/current/title-42/part-493
- College of American Pathologists. Laboratory General Checklist. Northfield, IL: College of American Pathologists; 2022

Review Complete! Please make sure to document review in MTS.

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