KAISER PERMANENTE®

DOCUMENT NUMBER:	SCPMG-PPP-0151
DOCUMENT TITLE:	Documentation and Error Correction for Laboratory Records
DOCUMENT NOTES:	

LOCATION:	SCPMG-rel	**VERSION:**	01
DOC TYPE:	Quality Mgmt System	**STATUS:**	Release

EFFECTIVE DATE:	17 May 2017	**NEXT REVIEW DATE:**	17 May 2019
RELEASE DATE:	17 May 2017	**EXPIRATION DATE:**	

AUTHOR:	K083442	**PREVIOUS NUMBER:**	
OWNER:	SCPMG Quality Systems Ldr	**CHANGE NUMBER:**	SCPMG-CR-0319

Documentation and Error Correction for Laboratory Records

Purpose

This procedure describes how to document laboratory work for written records, as well as how to document error correction on records.

Policy

- All work performed is recorded legibly. Work is recorded in such a manner that another individual, competent in the same field, may interpret the work solely from the description written without additional explanation.
- Observations and calculations are to be clearly and permanently recorded at the time they are made (concurrent documentation).
  - Work that is not documented concurrently must be identified as a late entry or as an addendum with current date/time.
- Entries contain a date, and initials/signature of person creating the record.
- Entries are made in indelible blue or black ink. Space not used (e.g., no testing performed on that day) is indicated as specified in the legend on the form. If no legend exists, annotate the form to include the abbreviation used. Example: N/A = Not Applicable, or NT = Not Tested
- Corrections are made by drawing a single line through the incorrect entry, entering the correct information; initial and date the change.
  - The original entry must not be obliterated and should remain legible.
- Records or documents must be kept for the appropriate timeframe per the policy *Retention of Laboratory Records and Materials*. Records within the retention guideline must not be discarded without explanation.
- Examples of unacceptable documentation or error correction include:
  - Ditto marks, arrows, or continuation lines instead of entering data
  - A stamp in lieu of a handwritten signature
  - White-out or any similar product, blacking out with marker
  - Erased entry
  - Write over
- Use of scrap paper, Post-it notes or any similar product that would intentionally record raw data on non-official records is prohibited.
- Use form legend when using abbreviations on records.

Scope

This procedure applies to all Laboratory staff, supervisors, and managers related to the management of all laboratory records.

Special safety precautions

Refer to the safety manual for general safety requirements.

Continued on next page

Documentation and Error Correction for Laboratory Records,
Continued

Definitions

- Electronic Record – An electronic record is information recorded in a form that only a computer can process. Electronic records include numeric, graphic and textual information.
- Form – A form is a document with a fixed arrangement of captioned spaces designed for entering and extracting prescribed information. Forms become a record once filled out.
- Non-record – Non-records are copies of memoranda or letters sent to an office or an employee for information only and for whose filing or maintenance no one in the office is responsible.
- Quality records – Quality records include the following: laboratory operating procedures, preventive maintenance charts, quality control (QC) charts, internal audit reports, management reviews, corrective and preventive actions.
- Records – Records are materials created or received by a department and that are preserved as evidence of the activities of the department or for its information value. Records include reports, correspondence, diaries, quality records and technical records.
- Technical records – Technical records are accumulations of data and information which result from carrying out tests or calibrations and which indicate whether specified quality or process parameters are achieved. Technical records include forms, worksheets, control graphs, inspection reports, and test reports.

Documentation

Follow these steps for documentation.

Step	Action
1	Where documents require the entry of data, enter the data clearly and legibly with indelible blue or black ink.
2	• Make data entries or complete records at the time each action is taken or document as a late entry. Temperatures and other observations that may change over time may not be entered as a late entry. • If there are missing entries at the time of record review, the empty field should be circled. Multiple missing entries should be investigated and corrective or preventive action taken. If necessary, make photocopies of missing entries to be used for corrective or preventive action.

Continued on next page

Documentation and Error Correction for Laboratory Records,
Continued

Documentation, continued

Step	Action
3	Do not leave spaces for handwritten entries blank. Space not used (e.g., no testing performed on that day) is indicated as specified in the legend on the form. If no legend exists, annotate the form to include the abbreviation used. Example: N/A = Not Applicable, or NT = Not Tested

Omission of Documentation

Follow these steps correcting the omission of documentation.

Step	Action
1	Omission of documentation can be corrected as late entry or an addendum to the document with current date and/or time as indicated. It is considered falsification of records to go back and complete or to fill-in the blanks.
2	Late entry is allowed only when there is supporting information to validate the entry.
3	Late entry is allowed within the designated time frame and is at the discretion of department administrator.
4	Operating departments are encouraged to have frequent monitoring to assure that documentation is complete and timely. Examples include shift-to-shift review or daily peer review.

Continued on next page

Documentation and Error Correction for Laboratory Records, Continued

Error correction

Follow these steps for error correction.

Step	Action
1	Verify the written error before making the correction. • The person making the correction must be knowledgeable of the incident and authorized by training to make the change. • All changes that would change the intent or substance of the original documentation must have supervisor approval.
2	• Make corrections of daily temperatures or preventive maintenance on the Action Log or in the space marked accordingly. • Draw one line across the incorrect data, place an asterisk (*) next to the incorrect entry, and document the data correction on the form appropriately.
3	Make clear corrections of QC records on the form when possible. • If the correction cannot be made clearly, then draw one line across the incorrect data and place an asterisk (*) next to the incorrect data entry. • Document the correction and any additional details on the form appropriately.
4	Make any correction on the manual records only by drawing a line through the original entry, so as not to obliterate that record, and then writing the corrected entry with an initial and date of the person making the correction.

Non-controlled documents

The following non-controlled documents support this procedure:

- J. Ezzelle, I. R. Rodriguez-Chavez, J. M. Darden, M. Stirewalt, N. Kunwar, R. Hitchcock, T. Walter, and M. P. D'Souza. *Guidelines on Good Clinical Laboratory Practice*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2213906/?tool=pubmed , downloaded July 5, 2010.
- *Good Documentation Practice*, Wikipedia, https://en.wikipedia.org/wiki/Good_documentation_practice , downloaded May 30, 2017.

Signature Manifest

Document Number: SCPMG-PPP-0151 **Revision:** 01

Title: Documentation and Error Correction for Laboratory Records

All dates and times are in Pacific Standard Time.

Doc & Error Correction for Lab Rec

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
Maureen Ahler (K083442)	Quality Systems Leader	06 May 2017, 10:27:47 PM	Approved
Fred Ung (K057175)	SCPMG LABORATORY QCD	09 May 2017, 09:53:39 AM	Approved

Final Approval

Name/Signature	Title	Date	Meaning/Reason
David Quam (P092597)	Rgnl Mg Admn-Pmg Executive	12 May 2017, 01:51:58 PM	Approved
Gary Gochman (P091953)	SCPMG Laboratories AP Dir	17 May 2017, 12:11:44 PM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Maureen Ahler (K083442)	Quality Systems Leader	17 May 2017, 02:33:36 PM	Approved

Documentation and Error Correction for Laboratory Records

Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
Janice M. Wolf	7.16.18
Name: Janice M. Wolf **Operations Director, Area Laboratory**	
	7/16/18
Name: Sony Wirio, MD **CLIA Laboratory Director**	