Lab Documents

Lab Documents

Requirements

- Current Lab Certification (e.g. CLIA, CAP)
- Normal Lab/Reference Values

Tips / Additional Information

- Keep updated lab documents to document the competency of all lab facilities being utilized, and to support the reliability of test results.
- If lab documents are filed electronically or separately, include a signed and dated note to file indicating the location.
- Research laboratories typically do not have lab certifications (e.g. CLIA, CAP). In the case of research laboratories, ensure that the research lab reference values are on file.
- CLIA and all other licensure for all UCLA labs can be found here: UCLA Clinical Laboratories Licensing & Accreditation Documents
- You will also need the CV of the lab manager for your regulatory binder. Please contact UCLA Pathology & Laboratory Medicine to obtain a copy.
- Reference values: UCLA Health Laboratory Test Directory

Applicable GCP Sections:

- 8.2.11
- 8.2.12
- 8.2.14
- 8.3.6
- 8.3.7

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