

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: <u>UCLA Clinical Laboratories Licensing & Accreditation Documents</u>
- You will also need the CV of the lab manager for your regulatory binder. Please contact <u>UCLA Pathology & Laboratory Medicine</u> to obtain a copy.
- Reference values: <u>UCLA Health Laboratory Test Directory</u>

Applicable GCP Sections:

- <u>8.2.11</u>
- <u>8.2.12</u>
- <u>8.2.14</u>
- <u>8.3.6</u>
- <u>8.3.7</u>

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