[Laboratories](#)

8 LABORATORY ACCREDITATIONS, CERTIFICATION & NORMAL VALUES

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REQUIREMENT & PURPOSE

Contains lab certifications (CAP, CLIA, etc.), lab normal ranges and CV of the laboratory director (when appropriate).

Lab accreditations certify qualifications of local or central laboratories to perform required study tests and support reliability of results of medical, laboratory, standardized procedures and other tests. Documents lab normal values and/or ranges that are used to interpret clinical test results. When required, the CV of the laboratory director details qualifications and competence to conduct tests for clinical trials.

NOTE: For research labs that test protocol specimens but do NOT report any subject-specific results for the diagnosis, treatment, prevention or assessment of the health of subjects, such certifications (CAP/CLIA) are not relevant. In this case, documentation that the lab director and/or personnel performing the tests have training and qualifications to assure ability to perform the tests as required by the protocol is required.

REFERENCE & GUIDANCE

- 21 CFR 58
- 21 CFR 312
- 42 CFR 493.3
- ICH GCP §4.2, 8.2.11, 8.2.12, 8.3.6, 8.3.7
- Certifications must be current
- Expired certifications should NOT be removed from this MF

CAP & CLIA Certification

Visit https://www.testmenu.com/ucsd to obtain the following information:

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  UC San Diego Links

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  Requisition Info

-

- Clinical Research Billing | CRB
- Human Research Protections Program | HRPP
- Office of Coverage Analysis Administration | OCAA
- Office of Contract & Grant Administration | OCGA

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Accreditation (CAP)

-
  Licensure

-
  ### CLIA Certification

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  Processing Links

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  Transfusion Medicine

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