1. Background

The International Conference of Harmonization (ICH) E6 standard, *Good Clinical Practice: Consolidated Guidance*, accepted as regulatory guidance by the U.S. Food and Drug Administration (FDA), states:

The contents of a clinical trial protocol should generally include (6.1.7) Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial. *This information is also required according to FDA 21 CFR 312.53(c)(iv))*.

Sites and sponsors are required to keep documentation of (8.2.11) Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol. (To document normal values and/or ranges of the tests); (8.2.12) Medical/laboratory/technical procedures/tests: certification, or accreditation, or established quality control and/or external quality assessment, or other validation (where required), to document competence of facility to perform required test(s), and support reliability of results.

2. Name and Addresses of Laboratories

Stanford Anatomic Pathology and
Clinical Laboratories
300 Pasteur Drive, MC 5627
Pavilion E, Level 1, E12
Stanford, CA 94305

Stanford Clinical Lab at Hillview
3375 Hillview Avenue
Palo Alto, CA 94304

Stanford Cancer Center South Bay
2589 Samaritan Drive
San Jose, CA 95124

Stanford Clinical Lab at Redwood City
450 Broadway Street, Room L010624
Redwood City, CA 94063

3. Normal Values

The Stanford Clinical Laboratory does not provide lists of study-specific reference ranges for study teams (beginning November 2022). Please refer to School of Medicine *Clinical Laboratory Reference Ranges* (MEM-0) available on the CRQ website for more information.

4. Director CV and Medical License

To meet regulatory requirements, and in cooperation with Stanford University School of Medicine, the Clinical Laboratory at Stanford Health Care will provide the information described below. Because the clinical laboratory director is not directly engaged in individual research projects at Stanford, the director does not provide a curriculum vitae or medical license.

Note: If a request for the laboratory director's CV or license includes evidence of a regulatory requirement for these items, this best practice position will be evaluated.

5. Clinical Laboratory Licenses and Certifications

Stanford Health Care (SHC) licenses and CLIA certifications are available from the Stanford Pathology & Laboratory Medicine website, or via request forms available on websites in the School of Medicine.

Note: There may be occasional delays uploading renewed license or certification documents to the website. During the re-accreditation process, no additional communication will be posted or provided to third parties.

6. Resources

- E6(R2) Good Clinical Practice: Integrated Addendum (FDA website)
- 21 CFR 312 Investigational New Drug Application (FDA website)
- Spectrum, Stanford Center for Clinical & Translational Research & Education
- School of Medicine *Clinical Laboratory Reference Ranges* (MEM-011) available on the Clinical Research Quality website.
- Stanford Health Care, Pathology & Laboratory Medicine (www.stanfordlab.com)