

CLIA QUALIFICATIONS OF LABORATORY MANAGEMENT

- St. Joseph Medical Center Tacoma, WA
 St. Clare Hospital Lakewood, WA
 St. Elizabeth Hospital Enumclaw, WA
 St. Francis Hospital Federal Way, WA
 St. Anthony Hospital Gig Harbor, WA
 PSC

PURPOSE

It is FHS Laboratory policy that the qualifications and responsibilities as defined by CLIA 88 are met for all testing personnel and that key roles filled by lab management are identified in areas with high complexity testing.

CLIA 88 POSITIONS and FHS LAB MANAGEMENT OF HIGH COMPLEXITY TESTING

Medical Laboratory Director

Linda Burkhardt, M.D. is the Medical Director for St. Anthony, St. Clare, St. Elizabeth, St. Francis, and St. Joseph Laboratories. She is a doctor of medicine and is a board certified in anatomic/clinical pathology.

Technical Supervisor

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis. At a minimum a bachelor's degree in laboratory science and 4 years of experience is required.A

Section	Technical Supervisor	Qualification	Experience
Anatomic Pathology	Linda Burkhardt	M.D., Pathologist	Pathologist
Chemistry	Nuria Adem Jezelin Temporosa Sally Kramer Cecil Dunn Roberta Dutcher	BS, MT	>4 yrs of laboratory training or experience, or both, in high complexity testing within the specialty
Microbiology, Parasitology	Claudia Willis	BS Microbiology, MSM	>4 yrs of laboratory training or experience, or both, in high complexity testing within the specialty
Hematology and Coagulation	Nuria Adem Jezelin Temporosa Sally Kramer Cecil Dunn Roberta Dutcher	BS, MT	>4 yrs of laboratory training or experience, or both, in high complexity testing within the specialty
Immunoematology	Katie Wilkinson, Teri Emerson	M.D., Pathologist MT, SBB	Pathologist >4 yrs of laboratory training or experience, or both, in high complexity testing within the specialty

Urinalysis	Claudia Willis Jezelin Temporosa Sally Kramer Cecil Dunn Roberta Dutcher	BS Microbiology, MSM	>4 yrs of laboratory training or experience, or both, in high complexity testing within the specialty
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General Supervisors

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provide day-to-day supervision of testing personnel and reporting of test results. In the absence of the lab medical director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. At a minimum an Associate degree and 2 years of lab experience is required.

Facility	General Supervisor	Qualification	
St. Elizabeth Hospital	Joanne Walsh	BS, MT	Qualify as testing personnel under Sec. 493.1489(b)(2); and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing
St. Anthony Hospital Laboratory	Cecil Dunn Jackie Hilyard	BS, MT	Qualify as testing personnel under Sec. 493.1489(b)(2); and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing
St. Clare Hospital Laboratory	Jezelin Temporosa Gary Meyer	BS, MT	Qualify as testing personnel under Sec. 493.1489(b)(2); and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing
St. Francis Hospital Laboratory	Sally Kramer Hildy Sulski Anne Tuttle	BS, MT	Qualify as testing personnel under Sec. 493.1489(b)(2); and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing
St. Joseph Medical Center Laboratory	Carla Herl Claudia Willis Teri Emerson Rebecca Arguelles	BS, MT BS, MT BS, MT, SBB Pathologist's Asst	Qualify as testing personnel under Sec. 493.1489(b)(2); and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing

TECHNICAL SUPERVISOR AND GENERAL SUPERVISOR RESPONSIBILITIES


<p>Tech Supervisor Responsibilities</p>	<p>The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.</p> <p>(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and</p> <p>(b) The technical supervisor is responsible for--</p> <p>(1) Selection of the test methodology that is appropriate for the clinical use of the test results;</p> <p>(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;</p> <p>(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;</p> <p>(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;</p> <p>(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;</p> <p>(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>
<p>General Supervisor Responsibilities</p>	<p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>(a) The general supervisor--(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;</p> <p>(2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under Sec. 493.1489;</p> <p>(3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under Sec. 493.1489(b)(5); and</p> <p>(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.</p> <p><u>The lab director or technical supervisor may delegate to the general supervisor:</u></p> <p>Providing orientation to all testing personnel; and annually evaluating and documenting the performance of all testing personnel.</p>

TECHNICAL SUPERVISOR COMPETENCY DELEGATION

The Technical Supervisor is responsible for evaluating the competency of all testing personnel and assuring staff competency to perform the testing. At Franciscan Health System Laboratories, competency assessment may be delegated to staff that meet the educational requirements to qualify under CLIA as a Technical Supervisor or General Supervisor.

Testing Personnel

All testing personnel meet the personnel qualifications and responsibilities as defined by CLIA 88 for the testing they will perform. The CLIA 88 qualifications of potential technical candidates are evaluated prior to hiring and copies of their diploma or transcript, and certifications are maintained.

DOCUMENT APPROVAL Purpose of Document / Reason for Change:		
Added technical supervisor delegation to Med Tech Coordinators or Lead Tech; updated names. Added St Elizabeth manager. Added task delegation details from medical director to technical supervisor and general supervisor		
<input type="checkbox"/> No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.		
Committee Approval Date	<input type="checkbox"/> Date: 8/29/13 <input type="checkbox"/> N/A – revision of department-specific document which is used at only one facility	Medical Director Approval (Electronic Signature)  8/27/13