64B3-5.002 Supervisor.
Qualifications and Responsibilities.

(1) Qualification. Degrees or semester hours of academic credit required in this section shall be obtained at a regionally accredited college or university or by foreign education equated pursuant to subsection 64B3-6.002(6), F.A.C.

(2) To be licensed as a supervisor, an applicant: shall be licensed or meet the requirements for licensure as a technologist; complete a one-hour educational course acceptable to the Board on human immunodeficiency virus and acquired immune deficiency syndrome or provide an affidavit that the course will be completed within six (6) months of licensure; and meet the requirements of one of the options set forth in subsection (3), below:

(3)(a) Microbiology, Serology/Immunology, Clinical Chemistry, Hematology, Immunohematology, Blood Banking (Donor Processing), Cytogenetics.

(f) Molecular Pathology.

<table>
<thead>
<tr>
<th>Education</th>
<th>Option</th>
<th>Training/Experience</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctoral Degree in Clinical Laboratory, Chemical or Biological Science with 24 semester hours of academic science including 6 semester hours of biological sciences and 6 semester hours of chemical sciences</td>
<td>1a</td>
<td>1 year of pertinent clinical laboratory experience in the specialty area in which licensure is sought, and 25 hours of Board-approved continuing education in supervision and administration or GS (ABB)</td>
<td>As required for technologist licensure.</td>
</tr>
<tr>
<td>Masters Degree in Clinical Laboratory, Chemical or Biological Science with 16 semester hours of academic science</td>
<td>2a</td>
<td>3 years of pertinent clinical laboratory experience, and 25 hours of Board-approved continuing education in supervision and administration or GS (ABB)</td>
<td>As required for technologist licensure.</td>
</tr>
<tr>
<td>Bachelors Degree with 16 semester hours of academic science with 16 semester hours of academic science</td>
<td>3a</td>
<td>5 years of pertinent clinical laboratory experience with at least 2 years experience at the Technologist level, and 25 hours of Board-approved continuing education in supervision and administration or GS (ABB)</td>
<td>As required for technologist licensure.</td>
</tr>
<tr>
<td>Bachelors Degree with 16 semester hours of academic science with 16 semester hours of academic science</td>
<td>3b</td>
<td>5 years of pertinent clinical laboratory experience with at least 2 years experience at the Technologist level</td>
<td>The Molecular Diagnostics examination given by ABB or CHS (ABHI). SMB (ASCP)</td>
</tr>
</tbody>
</table>

(4) The Board approved Supervision and Administration examinations, used in lieu of the required 25 hours of supervision and administration continuing education are:
(a) The Diplomate in Laboratory Management examination administered by the American Society for Clinical Pathology (ASCP);

(b) The Specialist in Blood Banking examination administered by ASCP for the specialties of Blood Banking and Immunohematology;

(c) The Specialist in Microbiology examination administered by ASCP for the specialty of microbiology;

(d) The Specialist in Cytotechnology examination administered by ASCP for the specialty of Cytology;

(e) The Specialist in Chemistry examination administered by ASCP for the specialty of Clinical Chemistry;

(f) The Specialist in Hematology examination administered by ASCP for the specialty of Hematology;

(g) The Certified Histocompatibility examination (CHS) administered by the American Board of Histocompatibility and Immunogenetics (ABHI);

(h) The Specialist in Andrology/Embryology examination administered by the American Board of Bioanalysis;

(i) The Specialist in Molecular Diagnostics examination administered by the American Board of Bioanalysis;

(j) The Generalist Supervisor examination administered by the American Board of Bioanalysis;

(k) The National Registry of Certified Chemists (NRCC) examinations.

(l) Specialist in Molecular Biology examination administered by ASCP for the specialty of molecular pathology.
64B3-5.003 Technologist.

(1) Technologist Qualifications. Degrees or semester hours of academic credit required in this section shall be obtained at a regionally accredited college or university or, if foreign education, equated pursuant to subsection 64B3-6.002(6), F.A.C. Applicants for technologist licensure in the categories of microbiology, serology/immunology, chemistry, hematology, immunohematology, histocompatibility, blood banking, cytology, cytogenetics, histology, molecular pathology, andrology and embryology shall complete a one hour educational course acceptable to the Board on human immunodeficiency virus and acquired immune deficiency syndrome or provide an affidavit that the course will be completed within six (6) months of licensure.


(3) In addition, at least one of the following requirements must be met for specific areas of licensure. In some cases there are multiple options for meeting the requirement.

(a) Microbiology, Serology/Immunology, Clinical Chemistry, Hematology, Immunohematology. A Generalist Technologist license includes the specialties of microbiology, serology/immunology, clinical chemistry, hematology, and immunohematology.

(c) Molecular Pathology.

<table>
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<tr>
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<th>Option</th>
<th>Training/Experience</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bachelor's Degree (or higher) with 16 semester hours of academic science</td>
<td>1</td>
<td>as required by certifying body</td>
<td>• MB (ASCP) or&lt;br&gt;• MT (AAB) Molecular Diagnostic examination&lt;br&gt;• CHT (ABHI)&lt;br&gt;• MDT (AMT)</td>
</tr>
<tr>
<td>as required by certifying body</td>
<td>2</td>
<td>One year pertinent clinical laboratory experience in molecular pathology</td>
<td>• MB (ASCP) or&lt;br&gt;• MT (AAB) Molecular Diagnostic examination or&lt;br&gt;• CHT (ABHI)&lt;br&gt;• MDT (AMT)</td>
</tr>
</tbody>
</table>
64B3-5.004 Technician.

(1) General Qualifications. Degrees or semester hours of academic credit required in this section shall be obtained at a regionally accredited college or university, or by foreign education equated pursuant to subsection 64B3-6.002(6), F.A.C. In order to be licensed as a laboratory technician, which includes the categories of microbiology, serology/immunology, chemistry, hematology, immunohematology, histology, molecular pathology, andrology and embryology, the applicant shall complete a one hour educational course acceptable to the Board on human immunodeficiency virus and acquired immune deficiency syndrome or provide an affidavit that the course will be completed within six (6) months of licensure.


(3) In addition, at least one of the following requirements must be met for specific areas of licensure. In some cases there are multiple options for meeting the requirement.

(a) Microbiology, Serology/Immunology, Clinical Chemistry, Hematology, Immunohematology.

(d) Molecular Pathology

<table>
<thead>
<tr>
<th>Education</th>
<th>Option</th>
<th>Training/Experience</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>High school diploma or high school equivalent</td>
<td>1</td>
<td>Licensed clinical laboratory technologist or technician in any specialty area</td>
<td>MLT (AAB) Molecular Diagnostic Examination</td>
</tr>
</tbody>
</table>
64B3-13.002 Responsibilities of Supervisors.

(1) The supervisor is responsible for fulfilling the responsibilities of the director as assigned and for monitoring compliance with all applicable regulations of the board and of the Department.

(2) In addition, the supervisor shall fulfill the following responsibilities:

(a) Performs the duties of a technologist in the specialty or specialties in which licensure is held, as needed.

(b) Assigns, if needed, performance of his or her direct supervision responsibilities to licensed technologists, however, the supervisor remains responsible for ensuring that direct supervision is properly performed. The assignment of responsibilities from the supervisor to the technologist must be written and specific.

(c) Evaluates the competency of technologists and technicians and assures that the staff maintain their competency to perform
test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff shall include:

1. Direct observation of routine test performance including patient preparation, if applicable, and specimen handling, processing and testing.
2. Monitoring the recording and reporting of test results.
3. Reviewing the intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
5. Assessment of test performance through testing previously analyzed specimens, through internal blind testing samples or through external proficiency testing samples.
6. Assessment of problem solving skills.

(d) Evaluates and documents the performance of individuals responsible for testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes have occurred, in which case, prior to reporting patient test results, the individuals performance must be reevaluated and documented to include the use of the new test methodology or instrumentation.

(e) Is accessible to clinical laboratory personnel at all times testing is performed and provides on-site telephone or electronic consultation to resolve technical problems in accordance with approved policies and procedures of the clinical laboratory.

(f) Provides day-to-day supervision of test performance by technologists and technicians.

(g) Ensures onsite direct supervision when testing is being performed by those technicians who are required to work under direct supervision.

(h) Monitors test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

(i) Assures that all remedial actions are taken whenever test systems deviate from the clinical laboratory’s established performance specifications.

(j) Ensures that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning.

(k) Provides orientation to all testing personnel.

(l) Identifies weakness in performance and takes necessary action to insure minimal acceptable performance.

(n) Establishes and maintains systems for the accession, identification, transport, storage and disposal of specimens adhering to internal and external policies and regulations including medico-legal custodial responsibilities.

(n) Determines the need for, selects, utilizes and evaluates referral services as appropriate to laboratory resources and/or priorities.

(o) Establishes protocols for performance of confirmatory and additional procedures as indicated.

(p) Establishes and maintains systems for the accession, identification, transport, storage and disposal of specimens adhering to internal and external policies and regulations.

(q) Devises a plan for management and scheduling of clinical laboratory personnel.

(r) Establishes and communicates short term goals and objectives for delivery of clinical laboratory services.

(s) Monitors compliance with institutional policies and regulations and standards of external agencies.

(t) Designs and/or implements a quality assurance program to monitor variables which affect the quality of clinical laboratory services.

(u) Prepares and periodically updates policy and procedure manuals.

(v) Establishes and evaluates the preventive maintenance program for instrumentation and equipment.

(w) Establishes and periodically evaluates safety measures in accordance with internal and external regulations.

(x) Evaluates and selects chemicals, biologicals and radionucleotides for clinical use and establishes monitoring systems for handling, processing, and storing these supplies and reagents.

(y) Designs a plan for administration of education programs in the clinical laboratory sciences for a variety of settings including academic, clinical, alternate site, exclusive use, in-service, and continuing education.

(z) Designs research in the clinical laboratory sciences by obtaining and utilizing resources and by reporting results as appropriate.

(aa) In the specialty of Cytology, in addition to the above responsibilities, the supervisor shall, if responsible for screening
cytology slide preparations, document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24 hour period to screening of cytology slides. The supervisor shall be responsible for and be required to provide this information to any laboratory for which the individual screens slides.

Rulemaking Authority 483.805(4) FS. Law Implemented 483.813, 483.823, 483.825 FS. History—New 12-6-94, Amended 3-28-95, Formerly 590-13.002, Amended 4-10-01, 4-7-02, 10-1-19.

64B3-13.003 Responsibilities of Technologists.
(1) The technologist is responsible for fulfilling the responsibilities of the supervisor, as assigned. The assignment of responsibilities must be written and specific.
(2) In addition the technologist shall fulfill the following responsibilities.
   (a) Performs only those tests authorized by the director.
   (b) Follows the clinical laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.
   (c) Maintains records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens.
   (d) Adheres to the clinical laboratory's quality control policies, documents all quality control activities, instrument and procedural calibrations and maintenance performed in accordance with the clinical laboratory's approval policies and procedures.
   (e) Follows the clinical laboratory's established policies and procedures whenever test systems are not within the clinical laboratory's defined acceptable levels of performance.
   (f) Is capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify a supervisor or director.
   (g) Documents all corrective action taken when test systems deviate from the laboratory's established performance specifications.
   (h) Exercises professional judgment in evaluation, specimen integrity, result accuracy and inter-result validity and takes corrective action as necessary. Such corrective action shall include specimen rejection, recollection, and/or retesting using the same or alternate methods and/or utilizes other skills associated with the practice of clinical laboratory science to ensure validity and accuracy of testing at all times taking care not to compromise patient care with excessive rejections, recollections or delays. If in their judgment a specimen is compromised, the technologist shall include an appropriate disclaimer statement in the report indicating the potential compromised nature of the result and why.
   (i) Participate in proficiency testing samples and ensure that these samples are tested in the same manner as patient specimens.
   (j) In the specialty of Cytology, in addition to the above responsibilities, the technologist shall:
      1. Document slide interpretation results of each gynecologic and non-gynecologic cytology case he or she examined or reviewed, and the clinical laboratory's policies and procedure.
      2. Document for each 24 hour period the total number of slides examined or reviewed.
      3. Document the number of hours spent examining slides in each 24 hour period.

Rulemaking Authority 483.805(4), 483.823 FS. Law Implemented 483.813, 483.823, 483.825 FS. History—New 12-6-94, Amended 3-28-95, 7-12-95, 12-4-95, Formerly 590-13.003, Amended 4-10-01, 4-7-02, 10-1-19.

64B3-13.004 Responsibilities of Technicians.
The technician shall:
(1) Perform tests classified as highly complex pursuant to 42 CFR §493.17 as published on October 1, 2007, incorporated by reference herein, only when under the direct supervision of a licensed technologist, supervisor, or director unless the technician meets the minimum qualifications set forth in 42 CFR §493.1489 as published on October 1, 2007, incorporated by reference herein and the requirement contained in rule 64B3-5.004, P.A.C.
(2) Perform only those tests authorized by the director.
(3) Follow the clinical laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.
(4) Notify a licensed technologist or supervisor whenever test systems are not within the clinical laboratory's defined acceptable levels of performance.
(5) Participate in proficiency testing samples and ensure that these samples are tested in the same manner as patient specimens.
(6) Adhere to the clinical laboratory’s quality control policies and document quality control activities, instrument and procedural calibrations and maintenance performed.

(7) Be capable of identifying problems that may adversely affect test performance or reporting of test results and immediately notify a licensed technologist or supervisor.

(8) Document all corrective actions taken when test systems deviate from the clinical laboratory’s established performance specifications.

(9) Follow the directives of directors, supervisors or technologists while exercising their duties and responsibilities.

Rulemaking Authority 483.805(4) FS. Law Implemented 483.813, 483.823, 483.825 FS. History–New 12-6-94, Amended 3-28-95, 7-12-95, Formerly 59O-13.004, Amended 1-27-00, 9-27-00, 4-7-02.