

REGISTERED/LICENSED LABORATORY SELF ASSESSMENT CHECKLIST

REGISTERED LABORATORIES:

Physician's Private Practice: Performs waived & non-waived testing.

LICENSED LABORATORIES:

Independent Laboratories that serve the general public: Performs waived & non-waived testing.

DIRECTOR QUALIFICATIONS:

REGISTERED LABORATORY: Physicians license + 1 year of experience of directing a non-waived lab or 20 CME credits regarding the duties of a laboratory director.

EFFECTIVE 01/30/08: ALL REGISTERED LABORATORY DIRECTORS MUST QUALIFY & OBTAIN THE DIRECTOR LICENSE.

**LICENSED LABORATORY: Physician,
Board Certified in Anatomic and Clinical Pathology, or
Ph.D., Board Certified: American Board of Medical Microbiology;
American Board of Clinical Chemistry;
American Board of Bioanalysis;
American Board of Medical Laboratory Immunology; or
American Board of Medical Genetics**

**THE DIRECTOR MAY NOT DIRECT MORE THAN FIVE LABORATORIES
NOT INCLUDING EXEMPT (WAIVED) LABS.**

DIRECTOR SHALL: (NRS 652.180)

- Select and supervise all laboratory procedures. (Assure the Director has reviewed and signed all policies and validation of each Methodology.)
- Responsible for all testing and all subordinates.
- Maintain records: Pathology = 10 years
Blood bank & Cytology = 5 years
All other specialties/sub-specialties = 2 years

EXAMINATION OF SPECIMENS (NRS 652.190)

- Requested by an authorized person and
- Reported to the authorized persons

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MEDICAL LABORATORIES.**

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SAFETY (NAC 652.280 & NAC 652.290)

- Policies developed, implemented and enforced, to direct protect the staff,
- Monitor and record temperatures consistent with manufacturer's requirements,
- Eyewash must be available near testing area, showers when necessary.
- Decontaminate or double bag bio hazardous material
- Dispose of sharps in a puncture proof container
- Sterilize "reusable" needles according to procedure

TESTING PROCEDURES AND RESULTS: NAC 652.282

- Accuracy, precision, sensitivity, linearity, calibration for each test method.
- Establish normal values and reportable range
- Adequate methodology
- Validation for each method approved by the Director.
- Comprehensive quality control program.
- Develop and implement a comprehensive Quality Assurance Program which includes pre-analytic, analytic and post-analytic review.
- Perform tests according to Director approved procedure and in accordance with regulations.
- Reports to contain pertinent information to interpret results.
- Remedial action must be taken and documented.
- All patient results must be evaluated for accuracy and repeat testing when necessary.

PROFICIENCY TESTING: NAC 652.284

- Develop policy for PT samples
- Test specimens exactly as you test your patients
- Return results within specified time
- Evaluate results with staff
- Perform corrective action for all results less than 100%
- Failure in 2 of 3 events mandates cease testing and must notify BLC

PERSONNEL: NAC 652.286

- Director must assure sufficient number of personnel,
- With appropriate education and training,
- Must develop policies for assuring personnel competency,
- Document competency assessment prior to testing for each test performed,
- Director must approve the procedure manual,
- Job descriptions must be available for all technical personnel,

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- Establish the amount of supervision required to perform each test and report the results,
- General Supervisor must be on the premises during all routine hours of operation for all licensed laboratories

TEST REQUEST: NAC 652.300

- Verbal request must be followed by a written request within 30 days
- Each request must contain:
 - The full name and number to identify the person,
 - The name of the license physician who ordered the test,
 - The date and time the specimen was collected,
 - The test to be performed.

TEST RECORDS: NAC 652.310

- Lab must maintain daily accession log which contains:
 - Accession number of the specimen.
 - The date/time the specimen was received by the laboratory.
 - The condition of the specimen.
 - The date the specimen was tested.
 - The identity of the person who performed the test.

TEST REPORT: NAC 652.340

- The report must contain:
 - The name and address of the laboratory where the test was performed,
 - The date and time the specimen was received in the laboratory,
 - The condition of the specimen if unsatisfactory for testing,
 - The result of the test and the date of the test
 - Labs must maintain an exact duplicate of the report for the required period of time.

GENERAL SUPERVISOR QUALIFICATIONS:

Medical Technologist + 3 years of experience
Masters Degree (Science) + 2 years of experience
Ph.D. (Science) + 1 year of experience

**NO PATIENT TESTING IS TO BE PERFORMED PRIOR TO
SURVEY.**

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