

Dear Director of a Licensed or Registered Laboratory:

The Division of Public and Behavioral Health (DPBH) has developed this document to assist your laboratory in assessing how it meets the regulatory requirements for Medical Laboratories (NAC Chapter 652).

Self-Assessment Instructions:

1. Conduct a thorough review of the premises and operation of your laboratory.
2. Complete the self-assessment by following these instructions:
 - Review the regulatory requirements below to assess if your laboratory is in compliance.
 - Check “Yes” column: If laboratory is in compliance at the time self-assessment is completed.
 - Check “No” column: If laboratory is not in compliance at the time self-assessment is completed. In remarks sections note the corrective actions being taken to correct the problem **and** the date it will be corrected by. Corrective actions must be completed and dated within 60 days of self-assessment completed date.
 - Check the box at the end indicating the Laboratory Director has reviewed and approved the self-attestation report.
 - Write in the name, title, email and phone number of the individual submitting the Self-Assessment.
 - Submit the completed assessment electronically to nenita@nphf.org, via fax to 775-684-1073 or via hard copy to:

Division of Public and Behavioral Health
Medical Laboratories Unit
727 Fairview Drive, Suite E
Carson City, NV 89701

This does not prohibit the Division from conducting an on-site inspection or complaint investigation of your laboratory.

Please direct any questions regarding this document to Leticia Metherell at 775-684-1045 or Vickie Estes at 775-684-1060.

**MEDICAL LABORATORY SELF-ASSESSMENT
 LICENSED AND REGISTERED LABORATORIES
 (moderate and high complexity testing)**

Name of Laboratory: _____ License #: _____

CMS Provider # (if applicable): _____ Name of Laboratory Director: _____

Date Self-Assessment Completed: _____ Corrective Actions: Latest Completed by Date: _____

NAC/TAG	Regulatory Requirement	Yes	No	Remarks
NAC/TAG	POINT OF CARE TESTING	Yes	No	Remarks
NAC652.344(1) L0006 - Point-of-Care Testing	A point-of-care testing device must be used: 1. In accordance with the testing management system and programs of quality control and quality assurance established by the laboratory performing the point-of-care test;			
NAC652.344(2) L0007 - Point-of Care Testing	A point-of-care testing device must be used: 2. In accordance with the instructions of the manufacturer of the device;			
NAC652.344(3) L0008 - Point-of Care Testing	A point-of-care testing device must be used: 3. By qualified personnel under the supervision of a director.			

NAC 652.346 L0009 - Point-of-Care Testing Personnel	Point-of-care testing device: Persons qualified to use. To be qualified to use a point-of-care testing device, a person must be licensed or certified as a: 1. Director; 2. General supervisor; 3. Clinical laboratory technologist; 4. Medical technician; 5. Blood-gas technologist; 6. Blood-gas technician; 7. Technologist; 8. Technician; or 9. Point-of-care test analyst.			
NAC/TAG	LAB DIRECTOR DUTIES	Yes	No	Remarks
NAC652.280(1) L0011 - Lab Director Duties: Health & Safety	A director shall ensure that: 1. Policies and procedures are established and enforced to ensure the health, welfare, and safety of the personnel of the laboratory and visitors.			
NAC652.280(2)(a)(b) L0012 - Lab Director Duties: Health & Safety	A director shall ensure that: 2. The physical premises and environmental conditions of the laboratory: (a) are appropriate for the testing performed. (b) Provide a safe environment in which employees are protected from biological, chemical and physical hazards.			
NAC652.280(3) L0013 - Director Duties: Health & Safety	A director shall ensure that: 3. The laboratory is adequately ventilated, with temperatures controlled within the requirements of the tests performed.			
NAC652.280(4) L0014 - Lab Director Duties: Health & Safety	A director shall ensure that: 4. Showers and eyewashes are provided where necessary for safety.			

NAC652.282(1) L0016 - Lab Director Duties: Procedure & Results	A director shall ensure that: 1. The testing systems developed and used for each of the tests performed in the laboratory result in services of high quality for the analytic phase of each test and any activities conducted before and after that phase.			
NAC652.282(2) L0017 - Lab Director Duties: Procedures & Results	A director shall ensure that: 2. Acceptable levels of analytical performance are established and maintained for each testing system.			
NAC652.282(3) L0018 - Lab Director Duties: Procedures & Results	A director shall ensure that: 3. The methodology selected for each test yields results of a sufficient quality to provide for the care of patients.			
NAC652.282(4) L0019 - Lab Director Duties: Procedures & Results	A director shall ensure that: 4. The procedures used for the verification of testing methods are adequate to determine the accuracy, precision and other pertinent characteristics of performance for those methods.			
NAC652.282(5) L0020 - Lab Director Duties: Procedures & Results	A director shall ensure that: 5. Testing is performed in such a manner as required by federal and state statute and regulation, and any policies and protocols adopted by the laboratory.			

NAC652.282(7) L0022 - Lab Director Duties: Procedures & Results	A director shall ensure that: 7. Programs of quality control and quality assurance are established and maintained to ensure the quality of the laboratory's services and to identify any failure of quality when it occurs, and that records of such programs are maintained by the laboratory for at least 2 years.			
NAC652.282(8)(a) L0024 - Lab Director Duties: Procedures & Results	A director shall ensure that: 8. Whenever there is a significant deviation from the laboratory's established specifications for performance: (a) Any necessary remedial action is taken and documented;			
NAC652.282(8)(b) L0025 - Lab Director Duties: Procedures & Results	A director shall ensure that: 8. Whenever there is a significant deviation from the laboratory's established specifications for performance: (b) The results of patients' tests are not reported until the deviation is corrected.			
NAC/TAG	PROFICIENCY TESTING	Yes	No	Remarks
NAC652.284(1) L0030 - Lab Director Duties: Proficiency Testing	A director shall ensure that: 1. The laboratory is enrolled in a program for proficiency testing regarding all the testing performed by the laboratory.			
NAC652.284(2)(a) L0031 - Lab Director Duties: Proficiency Testing	A director shall ensure that: 2. All procedures of the proficiency testing program are followed, including: (a) The testing of samples as required;			
NAC652.284(2)(b) L0032 - Lab Director Duties: Proficiency Testing	A director shall ensure that: 2. All procedures of the proficiency testing program are followed, including: (b) The return of results within the required time.			

NAC 652.284(3) L0034 - Duties of director: Program Proficiency Test	A director shall ensure that: 3. Corrective action, which is approved by the Division, is performed if any results are found to be unacceptable or unsatisfactory.			
NAC 652.284(4) L0035 - Duties of director: Program Proficiency Test	A Director shall ensure that: 4. The maintenance of documentation to verify that all reports received regarding the program are reviewed by appropriate members of the staff for evaluation of the performance of the laboratory and identification of any problems requiring corrective action.			
NAC 652.284(5) L0036 - Duties of director: Program Proficiency Test	A director shall ensure that: 5. If the laboratory fails to perform satisfactorily in two out of any three testing events for a procedure, the laboratory ceases to perform that procedure until it demonstrates to the satisfaction of the Division that the deficiencies of the laboratory have been corrected in such a manner as to ensure that they will not recur.			
NAC/TAG	LAB DIRECTOR DUTIES: Personnel	Yes	No	Remarks
NAC652.286(1) L0040 - Lab Director Duties: Personnel	A director shall ensure that: 1. The laboratory employs a sufficient number of personnel, with the appropriate education and appropriate experience or training, to perform tests and report the results accurately.			
NAC652.286(2)(a) L0041 - Lab Director Duties: Personnel	2. Before the laboratory tests the specimen of any patient, all the personnel of the laboratory: (a) Have the appropriate education and experience, and receive the appropriate training, for the type and complexity of services offered by the laboratory			

<p>NAC652.286(2)(b) L0042 - Lab Director Duties: Personnel</p>	<p>A director shall ensure that: 2. Before the laboratory tests the specimen of any patient, all the personnel of the laboratory: (b) Demonstrate their abilities reliably to perform all testing procedures in such a manner as to obtain and report accurate results.</p>			
<p>NAC652.286(3)(a)(b) L0043 - Lab Director Duties: Personnel</p>	<p>A director shall ensure that: 3. Policies and procedures are established for monitoring personnel who perform the analytic phase of each test, and any activities conducted before and after that phase, to: (a) Ensure that they are competent, and maintain their competency, to process specimens, perform testing procedures, and report the results promptly and proficiently; and (b) Identify any need for remedial training or continuing education to improve their skills.</p>			
<p>NAC 652.286(4) L0045 - Lab Director Duties: Personnel</p>	<p>A director shall ensure that: 4. A manual of the appropriate and current methods and procedures used in the laboratory, which is approved in writing by the director, is available to all personnel responsible for any aspect of the testing process.</p>			
<p>NAC 652.286(5)(b)(6) L0046 - Lab Director Duties: Personnel</p>	<p>A director shall ensure that: 5. The duties and responsibilities of: (b) Every person engaged in the performance of the analytic phase of each test and any activities conducted before and after that phase, are specified in writing. 6. Protocols specify the examinations and procedures each person is authorized to perform, and the supervision of the person required before the results of a patient's test may be reported.</p>			
<p>NAC 652.286(6) L0047 - Lab Director Duties: Personnel</p>	<p>A director shall ensure that: 6. Protocols specify the examinations and procedures each person is authorized to perform, and the supervision of the person required before the results of a patient's test may be reported.</p>			

NAC652.286(7) L0048 - Lab Director Duties: Personnel	A director shall ensure that: 7. A qualified pathologist reviews all abnormal cytologic slides within 3 days after their initial screening.			
NAC 652.470.1(a)(d) L0049 - Certification of personnel	1. Before working in a laboratory at any technical level: (a) An application for certification must be made on a form provided by the Division giving information on the applicant 's educational background; (d) The fee prescribed in NAC 652.488 must accompany the application. Laboratory personnel are certified in accordance with NAC 652.470 as evidenced by active personnel certificates issued by the Division.			
NAC/TAG	STERILIZATION & DISPOSAL	Yes	No	Remarks
NAC 652.290(1) L0051 - Sterilization & Disposal	<ul style="list-style-type: none"> Never re-use single-use devices such as syringes, needles and lancets. 			
NAC 652.290(2) L0052 - Sterilization & Disposal	2. All microbial materials and blood and its products must be properly decontaminated or placed in two bags and marked "biohazard" before they are discarded in a public disposal service.			
NAC 652.290(3) L0053 - Sterilization & Disposal	3. All disposable needles and syringes must be properly decontaminated and discarded in a container which cannot be punctured.			
NAC/TAG	TEST REQUESTS & REPORTS	Yes	No	Remarks

NAC 652.300(1) L0055 - Test Requests & Reports	1. Except as otherwise provided in subsection 3, if a specimen is received by the laboratory, it must be accompanied by an authorized written request or a computerized authorization.			
NAC 652.300(2) L0056 - Test Requests & Reports	2. If the laboratory receives specimens referred from another laboratory, it shall report the results to the laboratory submitting the specimens.			
NAC 652.300(3) L0057 - Test Requests & Reports	3. Verbal requests from authorized persons may be accepted by the laboratory with proper verification. The laboratory shall obtain an authorized written request or a computerized authorization to supplement a verbal request within 30 days after the laboratory accepted the verbal request.			
NAC 652.300(4)(a) L0058 - Test Requests & Reports	Each request must contain the following information: (a) The full name of or a number which identifies the person from whom the specimen was taken.			
NAC 652.300(4)(b) L0059 - Test Requests & Reports	4. Each request must contain the following information: (b) The name of the licensed physician, other authorized person or clinical laboratory that submitted the specimen.			
NAC 652.300(4)(c) L0060 - Test Requests & Reports	4. Each request must contain the following information: (c) The date and time the specimen was collected for testing.			
NAC 652.300(4)(d) L0061 - Test Requests & Reports	4. Each request must contain the following information: (d) The type of test or specific test required.			
NAC/TAG	SPECIMEN ACCESSION RECORDS	Yes	No	Remarks

NAC 652.310(1) L0065 - Specimen Accession Records	1. A laboratory must maintain a daily record of accessions of specimens, each of which must be numbered or otherwise appropriately identified.			
NAC652.310(2)(b) L0066 - Specimen Accession Records	2. Daily records of accessions of specimens must: (b) Include the following information: (1) A number that uniquely identifies each specimen, including, without limitation, an accession number or a number which identifies the person from whom the specimen was taken. (2) The date and time each specimen was received by the laboratory. (3) The condition and disposition of each specimen that does not meet the laboratory's criteria for the acceptability of specimens. (4) The date on which each specimen is tested. (5) The identity of the person who performs each test.			
NAC/TAG	REPORTS: Contents, Terminology & Retention	Yes	No	Remarks
NAC 652.340(1)(a) L0067 - Reports: Contents	1. A report by the laboratory to the source requesting the report must include, without limitation, the following: (a) The full name of or a number which identifies the person from whom the specimen was taken.			
NAC 52.340(1)(b) L0068 - Reports: Contents	1. A report by the laboratory to the source requesting the report must include, without limitation, the following: (b) The name and address of the reporting laboratory.			
NAC 652.340(1)(c) L0069 - Reports: Contents	1. A report by the laboratory to the source requesting the report must include, without limitation, the following: (c) The date and time the specimen was received in the laboratory.			

<p>NAC 652.340(1)(d) L0070 - Records: Contents</p>	<p>1. A report by the laboratory to the source requesting the report must include, without limitation, the following: (d) The condition of a specimen if considered unsatisfactory on receipt, for example, broken, leaked, hemolyzed or turbid.</p>			
<p>NAC 652.340(1)(e) L0071 - Records: Contents</p>	<p>1. A report by the laboratory to the source requesting the report must include, without limitation, the following: (e) The type of test or specific test performed.</p>			
<p>NAC 652.340(1)(f) L0072 - Records: Contents</p>	<p>1. A report by the laboratory to the source requesting the report must include, without limitation, the following: (f) The result of the test.</p>			
<p>NAC 652.340(1)(g) L0073 - Records: Contents</p>	<p>1. A report by the laboratory to the source requesting the report must include, without limitation, the following: (g) The date of the test.</p>			
<p>NAC 652.340(1) L0074 - Records: Contents</p>	<p>1. A report by the laboratory to the source requesting the report must include, without limitation, the following: (a) The full name of or a number which identifies the person from whom the specimen was taken. (b)The name and address of the reporting laboratory. (c) The date and time the specimen was received in the laboratory. (d) The condition of a specimen if considered unsatisfactory on receipt, for example, broken, leaked, hemolyzed or turbid. (e) The type of test or specific test performed. (f) The result of the test. (g) The date of the test. (h) If the specimen is sent to a reference laboratory for testing, the identity of the reference laboratory.</p>			
<p>NAC652.340(2) L0076 - Reports:</p>	<p>2. A report on tissue must be written using acceptable and standardized terminology.</p>			

Terminology				
NAC652.340(3) L0077 - Reports: Retention	3. Duplicate copies or a suitable record of all reports by a laboratory must be maintained by the laboratory in accordance with 42 C.F.R. Part 493 and in a manner which allows ready identification and accessibility.			
NAC/TAG	PERSONNEL: General Requirements	Yes	No	Remarks
NAC652.350(1)(a) L0081 - Personnel General Requirements	1. A laboratory shall establish: (a) Written policies and practices for personnel that encourage sound practice in a laboratory.			
NAC652.350(1)(b) L0082 - Personnel: General requirements	1. A laboratory shall establish: (b) A written program for the orientation of employees.			
NAC652.350(2)(a) L0083 - Personnel: General requirements	2. A laboratory shall maintain: (a) Current records on each employee, which include documentation of each employee's training, experience, and continuing education.			
NAC652.350(2)(b) L0084 - Personnel: General requirements	2. A laboratory shall maintain: (b) A health record for each employee, including the results of any physical examinations and tests performed by a laboratory which are required by the employer.			
NAC652.350(3) L0086 - Personnel: General requirements	3. For each licensed laboratory other than a specialty laboratory, at least one member of the technical staff must have the qualifications set forth in NAC 652.420 for a clinical laboratory technologist. At least one such technologist must be certified, in accordance with NAC 652.410, as a general supervisor unless the director or a physician associated with the laboratory is so designated.			

NAC652.350(4) L0087 - Personnel: General requirements	4. For each specialty laboratory, at least one member of the technical staff must be a technologist qualified in the appropriate specialty, except that a specialty laboratory in a rural area may, with the approval of the board, instead employ a clinical laboratory technologist. At least one such technologist must be certified, in accordance with NAC 652.410, as a general supervisor unless the director or a physician associated with the laboratory is so designated.			
NAC/TAG	DIRECTOR: Availability and Presence	Yes	No	Remarks
NAC652.370(1) L0090 - Director: Availability and presence	1. A director shall be available to the personnel of a laboratory, in person or by telephone or other electronic means, for any necessary consultation.			
NAC 652.370(2)(a) L0091 - Director: Availability and presence	2. If the laboratory provides: (a) Only routine services regarding hematology, urinalysis, chemistry, blood gas and microbiology, the director must be on the premises of the laboratory at least once every 30 consecutive days. If the director is absent from the laboratory for 30 consecutive days or more, he shall provide a licensed substitute to serve in his place, unless the laboratory is in a rural area and the Board determines that a substitute is not necessary.			
NAC 652.370(2)(b) L0092 - Director: Availability and presence	2. If the laboratory provides: (b) Services regarding vaginal cytology, nonvaginal cytology, flow cytometry or histopathology, or toxicologic analysis involving high-pressure liquid chromatography or gas chromatography with mass spectroscopy, the director must be on the premises of the laboratory at least once every 10 consecutive days of testing. If the director is absent from the laboratory for 10 consecutive days or more of testing, he shall provide for a licensed substitute to serve in his place.			

NAC 652.370(2)(c) L0093 - Director: Availability and presence	2. If the laboratory provides: (c) Any services other than those set forth in paragraphs (a) and (b), the Division may establish the minimum frequency with which the director must be on the premises of the laboratory, which must be based upon the complexity of the testing performed by the laboratory and must not be less than once every 30 consecutive days.			
NAC652.370(3) L0095 - Director: Availability and presence	3. Except as otherwise provided in this subsection, a natural person shall not simultaneously serve as director of more than five laboratories. A natural person may simultaneously serve as director of more than five laboratories if the laboratories are registered under one certificate pursuant to subsection 2 of NAC 652.180.			
NAC/TAG	QUALIFICATIONS OF DIRECTOR: Licensed Lab & Registered Lab	Yes	No	Remarks
NAC 652.380 L0097 - Director Qualifications: Licensed lab (<i>skip if Registered Lab</i>)	The Director of a licensed laboratory is qualified in accordance with NAC 652.380 as evidenced by an active Director of a Licensed Laboratory license issued by the Division of Public and Behavioral Health.			
NAC 652.395 L0099 - Director Qualifications: Registered lab (<i>skip if Licensed Lab</i>)	The Director of a registered laboratory is qualified in accordance with NAC 652.395 as evidenced by an active Director of a Registered Laboratory license issued by the Division of Public and Behavioral Health.			
NAC/TAG	GENERAL SUPERVISOR: Duties & Qualifications: Licensed Laboratory (<i>skip if registered lab</i>)	Yes	No	Remarks

NAC652.400(1) L0101 - General Supervisor Duties: Licensed lab	1. The general supervisor of a licensed laboratory shall oversee the technical and administrative functions of the laboratory and may supervise other personnel, as assigned by the director.			
NAC652.400(2) L0102 - General Supervisor Duties: Licensed lab	2. The general supervisor shall be on the premises during all hours in which routine tests are being performed. His presence is not required during the performance of emergency testing procedures after scheduled work hours, but he shall review these procedures during his next period of duty.			
NAC 652.410 L0105 - General Supervisor Qualifications: Licensed Lab	The General Supervisor of a Licensed Laboratory is qualified in accordance with NAC 652.410 as evidenced by an active General Supervisor license issued by the Division of Public and Behavioral Health.			
NAC/TAG	TECHNOLOGISTS: Specialties; activities	Yes	No	Remarks
NAC 652.478 L0111 - Technologists: Specialties; activities	A technologist may: 2. Perform a test in a specialty only if he is certified in that specialty.			

By checking this box, our laboratory is confirming that the Laboratory Director has reviewed and approved this self-attestation report.

Name of Individual submitting self-attestation:

Last Name: _____ First Name: _____ Title: _____

Phone number: _____ E-mail _____