

Dear Laboratory Director:

The Division of Public and Behavioral Health (DPBH) has developed this document to help you ensure that you are in compliance with the laws and regulations governing your laboratory.

New Laboratory Applicants: You are encouraged to complete this self-assessment prior to your scheduled initial inspection to ensure you are ready for your inspection to avoid delays in the issuance of your license.

Existing Laboratories: You are encouraged to complete this self-assessment on a yearly basis to ensure you maintain compliance with the laws and regulations governing your laboratory. This will assist you in being prepared the next time an inspector conducts an unannounced periodic inspection of your laboratory.

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.
 - For new laboratory applicants, please have this document available for your initial inspection.

Please call our Carson City office at 775-684-1030 or our Las Vegas office at 702-486-6515 and request to speak to a medical laboratory inspector if you have any questions regarding this document.

**MEDICAL LABORATORY SELF-ASSESSMENT
EXEMPT LABORATORIES**

Laboratory Name: _____ **Laboratory Address:** _____

Date Completed: _____

NAC/TAG	Regulatory Requirement	Yes	No	Remarks
652.155	There is a qualified director. <u>Guidance:</u> <i>The laboratory director is a physician (MD or DO), Chiropractor or Podiatrist as evidenced by having an active license issued by the appropriate professional licensing board.</i>			
652.155(2)(a) L0001	2. Except as otherwise provided in Tag L0005, a person who is employed by a laboratory that is licensed by or registered with the Division of Public and Behavioral Health pursuant to chapter 652 of NRS may perform a test without complying with the provisions of this chapter if: (a) The test has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; <u>Guidance:</u> <i>ONLY CLIA waived tests are being performed.</i>			
652.155(2)(b)(1) L0002	(b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed: (1) Verifies that the person is competent to perform the test; <u>Guidance:</u> <i>Written training and competency assessment of all testing personnel has been completed and is up-to-date.</i>			
652.155(2)(b)(2) L0003	(b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed: (2) Ensures that the test is performed in accordance with instructions of the manufacturer of the test; <u>Guidance:</u> <i>Follow the manufacturer's instructions for performing tests including monitoring/recording storage temperatures for reagents and having supplies that are consistent with manufacturer's instruction.</i>			

652.155(2)(b)(3) L0004	<p>(b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed:</p> <p>(3) Validates and verifies the manner in which the test is performed by using controls which ensure that the results of the test will be accurate and reliable.</p> <p><i>Performing and documenting internal and external controls as required by the manufacturer.</i></p>			
652.155(3)(a) L0005	<p>3. The provisions of subsection 2 do not relieve a person who performs a test of the requirement to:</p> <p>(a) Comply with the policies and procedures that the director of the laboratory at which the test is performed has established pursuant to NAC 652.280</p> <p>NAC 652.280: A director shall ensure that:</p> <ol style="list-style-type: none"> 1. Policies and procedures are established and enforced to ensure the health, welfare and safety of the personnel of the laboratory and visitors. 2. The physical premises and environmental conditions of the laboratory: <ol style="list-style-type: none"> (a) Are appropriate for the testing performed; and (b) Provide a safe environment in which employees are protected from biological, chemical and physical hazards. 3. The laboratory is adequately ventilated, with temperatures controlled within the requirements of the tests performed. 4. Showers and eyewashes are provided where necessary for safety. <p><u>Guidance:</u></p> <ul style="list-style-type: none"> • <i>No eating, drinking or smoking in the laboratory</i> • <i>Dispose of sharps in puncture proof containers</i> • <i>Do not bend, break or recap needles</i> • <i>Never re-use single-use devices such as syringes, needles and lancets</i> • <i>There is an eyewash in the testing area</i> 			

<p>NAC 652.155(4)(a)(b) L0122</p>	<p>4. An advanced practitioner of nursing as defined in NRS 632.012 or a physician assistant as defined in NRS 630.015 who is employed by a laboratory that is licensed by or registered with the Division of Public and Behavioral Health pursuant to chapter 652 of NRS and who has not received certification pursuant to NAC 652.470 may perform a test without complying with the provisions of this chapter if the test:</p> <p>(a) Has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; or</p> <p>(b) Is a provider-performed microscopy categorized pursuant to 42 C.F.R. § 493.19.</p>			
<p>NAC 652.155 (3) (b)</p>	<p>Testing personnel have an active certificate issued by the Division of Public and Behavioral Health as an Office Laboratory Assistant in accordance with NAC 652.470</p> <p>EXCEPTION: In accordance with NRS 652.210 the following active, licensed Nevada health care professionals do not need to obtain an office laboratory assistant certificate to perform laboratory tests classified as a waived test pursuant to Subpart A of Part 493 of Title 42 of the Code of Federal Regulations.</p> <ul style="list-style-type: none"> • Physicians • Optometrists • Licensed practical nurses • Registered nurses • Perfusionists • Physician assistants • Certified advanced emergency medical technicians • Certified paramedics • Practitioners of respiratory care • Dentists <p>NOTE: For an initial inspection, please have a list of all of your collection and testing personnel available for the inspector that conducts your initial inspection.</p>			