



EXEMPT LABORATORY APPLICATION & CHECKLIST

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, Nevada 89701
Phone: (775) 684-1030 Fax: (775) 684-1075
Website: <http://dpbh.nv.gov/Reg/RegulatoryPgms/>

Exempt Laboratories are a physician's private practice in which tests are collected or performed by the physician, the partners, associates or qualified personnel of the private practice. An Exempt Laboratory can also be an Outpatient Center of a Laboratory.

THIS BOX FOR OFFICAL USE ONLY

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COMPLETE THIS FORM. PLEASE FILL IN THIS FORM ELECTRONICALLY, PRINT, SIGN, DATE AND SUBMIT. *(If unable to complete electronically type or print in black or blue ink and submit)*

INDICATE CATEGORY:

- Exempt Laboratory**
- Exempt Laboratory: Outpatient Center of a Laboratory**

- MUST be operated by a licensed laboratory
- **ENTER** name of licensed laboratory under which this laboratory will operate: _____
- **ENTER** licensed laboratory license number under which this laboratory will operate: _____

INDICATE APPLICATION TYPE. *(Check only one):*

- Initial License (New Laboratory)**
- Reactivation of License (License expired 30 days or more)**
- Change of Ownership**

LICENSE NUMBER: _____

Laboratory/Business Name
Phone Number (starting with the area code)
Laboratory Email Address
Street Address
City
State
Zip Code
Laboratory Director, Title
Hours of Operation (DAYS & TIMES MUST BE NOTED)

Doing Business As (DBA)
Fax Number (starting with the area code)
Mailing Address or PO BOX (if different from street address)
City
County
State
Zip Code
Contact Person and Phone Number
CLIA Number

COMPLETE ALL SECTIONS

(Regulations governing medical laboratories and laboratory personnel may be found at: <http://leg.state.nv.us/NAC/NAC-652.html>)

Application Attestation *(Check if applicable)*

If you do not provide a method of electronic communication, such as an e-mail address of the laboratory or any other method by which to communicate with you other than by telephone or U.S. mail, you must check this box attesting that this is not feasible and acknowledge that the U.S. mail is the only means of communication.

Safe Injection Attestation **(MUST check this box)**

I attest that the laboratory is in continued compliance with the Centers for Disease Control and Prevention's safe injection practices.

CLIA Certification **(MUST check one box)**

My laboratory performs laboratory tests for the purposes of diagnosis or treating patients (medical). An **APPLICATION** for CLIA Certification (Form CMS-116) **must be submitted** with your licensure application by completing the form at: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf> AND A **Completed Disclosure of Ownership and Control Interest Statement (Form 1513)** Form must be completed by following the instructions found at:

My laboratory **ONLY** collects specimens. No testing is performed at this location. *(Do not submit a CLIA application)*

My laboratory performs laboratory tests that are **NOT** used to medically diagnose or treat patients. For example, my laboratory is a staffing agency that performs laboratory testing for employment purposes only. *(Do not submit a CLIA application)*

Laboratory Director Requirement **(MUST check one box)**

The Laboratory Director is:

- A physician licensed as a doctor of medicine in Nevada (MD)
- A physician licensed as a doctor of osteopathic medicine in Nevada (DO)
- A chiropractic physician licensed in Nevada (DC)
- A podiatric physician licensed in Nevada (DPM)

Type of specimens collected and/or testing to be performed in the laboratory **(MUST BE COMPLETED)**

Waived Tests pursuant to 42 C.F.R. Part 493, Subpart A *(Check all that apply – if does not apply leave blank)*

- Urinalysis/Dipstick Urine Urine pregnancy tests Fecal occult blood tests Blood glucose tests
 PT/INR Rapid Strep Other:

❖ For a full list of tests granted waived status under CLIA go to: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/waivetbl.pdf>

NOTE: *To collect specimens or perform waived tests a person must be a Nevada licensed/certified MD, DO, optometrist, chiropractor, podiatrist, licensed practical nurse, registered nurse, perfusionist, certified advanced emergency medical technician, physician assistant, paramedic, practitioner of respiratory care, dentist or office laboratory assistant. To become a certified office laboratory assistant complete and submit an application by going to: <http://health.nv.gov/HCQC/Forms/2014/OfficeLabAssistantApplication.pdf>*

- Verify that all of the above listed staff members are competent to perform the listed tests;
- Ensure that the tests are performed in accordance with the manufacturer's instructions;
AND
- Validate and verify the manner in which the test is performed by using controls which insure that the results of the test will be accurate and reliable.

Establish Recognized Laboratory Safety and Infection Control Guidelines

- Suggested guideline for Exempt Laboratories: the Centers for Disease Control and Prevention's (CDC) *Ready? Set? Test! Booklet* found for free at:
<http://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx>
- Free online training and continuing education credits can be found at:
<https://cdc.train.org/DesktopModules/eLearning/CourseDetails/CourseDetailsForm.aspx?tabid=96&courseid=1033476>

❖ ALL personnel collecting specimens or performing tests MUST comply with the policies and procedures established by the Laboratory Director.

OWNERSHIP INFORMATION (MUST BE COMPLETED)

List all individuals or organizations having direct or indirect ownership or control of 10% or more in the laboratory

NAME OF OWNER(S) OR OFFICERS (if a corporation)	ADDRESS OF OWNER (Street, City, State, Zip Code)

I understand that knowingly making a false statement on this application will be cause for denial, suspension, or revocation of licensure. I have examined this application and it is complete. I declare under penalty of perjury that the foregoing is true and correct.

Lab Physician/Director's Signature	_____ Please PRINT and SIGN Name Must be an ORIGINAL: photocopies or signature stamps are not acceptable.
Name and Signature of Notary:	_____ Date: _____
State of:	_____ County of: _____
Subscribed and sworn before me this:	_____ Day of: _____

COMPLETE APPLICATION CHECKLIST
SUBMIT COMPLETED APPLICATION WITH ALL REQUIRED DOCUMENTS AND FEES

INCOMPLETE APPLICATIONS WILL DELAY PROCESSING OF YOUR LICENSE

All applicants MUST SUBMIT:

- Completed, signed, dated application **to the Division** at the address provided below.
- A **\$500 fee with your application** via personal check, cashier's check or money order **paid to the order of Nevada State Treasurer.**
- Completed, signed, dated **CLIA application (CMS 116 form)** with your licensure application (*CLIA will send you a bill – PAY TO the PO BOX on the back of the bill you will be receiving*) found at: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>
- Completed Disclosure of Ownership and Control Interest Statement (**Form 1513**) found at: <http://health.nv.gov/HCQC/Forms/disclosureofownership0001.pdf>
- ALL** office laboratory assistant applications have been submitted for applicable staff members
- Copy of Laboratory Director's license or copy of on-line verification showing an active license
- Copy of **ALL** licenses/certificates or on-line verification showing an active license of health care professionals that will be collecting specimens or performing testing (*if applicable*)
- If personnel are not yet certified office laboratory assistants and application has not been submitted, include an application for certification as an office laboratory assistant with fee for EACH individual performing Waived tests.

NOTES:

- ❖ License is valid for two years from issue date
- ❖ Allow 30 days for application processing
- ❖ If insufficient funds are submitted a \$25 fee will be assessed
- ❖ **NO** collection of specimens or performance of any testing is allowed until you receive your license issued by the Division of Public and Behavioral Health. A CLIA certificate alone is not sufficient to be able to collect or perform laboratory tests.
- ❖ It is your responsibility to renew your certification before it expires, regardless of whether you receive a renewal notification or not.
- ❖ You will receive an on-site inspection of your laboratory prior to receiving a license. **PRIOR** to your inspection ensure you have completed the Exempt Laboratory Self-Attestation form found at: <http://health.nv.gov/HCQC/ExemptLabSelfAttestation.pdf>

Submit completed application, including all requested documentation and fee to:

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

If you have any questions please contact 775-684-1030 and request Medical Laboratory Services.

Change of Information

You must notify the Division of any change to the information contained in your application, including but not limited to a change in the laboratory director, a change of name or location and the addition of any new tests within 30 days after the change by completing and submitting the Change of Information/Addition of Testing Form: Exempt, Licensed or Registered Laboratory found

at: http://health.nv.gov/HCQC/Forms/2014/ChangeInformationFormAdditionTests_ExemptRegisteredLicenseLab.pdf