



LABORATORY REGISTRATION OR LICENSURE APPLICATION

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NEVADA DIVISION OF PUBLIC AND
BEHAVIORAL HEALTH
727 Fairview Drive, Suite E
Carson City, Nevada 89701
Phone: (775) 684-1030 Fax: (775) 684-1075
<http://dpbh.nv.gov/Reg/RegulatoryPgms/>

THIS BOX FOR OFFICIAL USE ONLY

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)

INCOMPLETE APPLICATIONS WILL DELAY PROCESSING OF YOUR LICENSE

INDICATE CATEGORY OF LABORATORY:

- Registered Laboratory
- Licensed Laboratory

INDICATE TYPE OF APPLICATION:

- Initial Licensure
- Reactivation of a License
- Change of Ownership

State 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 (INCLUDE DAYS & TIMES)
CLIA Type (or attach application HCFA 116)

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

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.

CLIA CERTIFICATION – MUST CHECK ONE BOX

My laboratory performs laboratory tests for the purposes of diagnosis or treating patients (medical).

1. 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

2. A completed Disclosure of Ownership and Control Interest Statement (**Form 1513**) Form **must be submitted**:

<http://dpbh.nv.gov/uploadedFiles/dpbhnavgov/content/Reg/MedicalLabs/Docs/Forms/disclosureofownership001.pdf>

Note: Instructions to complete the disclosure form can be found at:

<http://dpbh.nv.gov/uploadedFiles/dpbhnavgov/content/Reg/MedicalLabs/Docs/Forms/InstructionsCompletingDisclosureOwnershipControlInterestStatementForm1513.pdf>

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 **ONLY** performs toxicology testing for non-medical purposes. *(Do not submit a CLIA application)*

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.

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/DIRECTOR(S) (if a corporation)	ADDRESS OF OWNER(S)/OFFICERS/DIRECTORS (Street, City, State, Zip Code)

CHECK ALL TESTS PERFORMED IN THE LABORATORY-MUST BE COMPLETED

- | | | |
|--|--|--|
| <input type="checkbox"/> Histocompatibility | <input type="checkbox"/> Chemistry | <input type="checkbox"/> Pathology |
| <input type="checkbox"/> Transplant | <input type="checkbox"/> Routine | <input type="checkbox"/> Histopathology |
| <input type="checkbox"/> Nontransplant | <input type="checkbox"/> Urinalysis | <input type="checkbox"/> Oral Pathology |
| <input type="checkbox"/> Microbiology | <input type="checkbox"/> Endocrinology | <input type="checkbox"/> Cytology |
| <input type="checkbox"/> Bacteriology | <input type="checkbox"/> Toxicology | <input type="checkbox"/> Radiobioassay |
| <input type="checkbox"/> Mycobacteriology | <input type="checkbox"/> Other | <input type="checkbox"/> Clinical Cytogenetics |
| <input type="checkbox"/> Mycology | <input type="checkbox"/> Hematology | |
| <input type="checkbox"/> Parasitology | <input type="checkbox"/> Immunohematology | |
| <input type="checkbox"/> Virology | <input type="checkbox"/> ABO Group & Rh Type | |
| <input type="checkbox"/> Other | <input type="checkbox"/> Antibody Detection (transfusion) | |
| <input type="checkbox"/> Diagnostic Immunology | <input type="checkbox"/> Antibody Detection (nontransfusion) | |
| <input type="checkbox"/> Syphilis Serology | <input type="checkbox"/> Antibody Identification | |
| <input type="checkbox"/> General Immunology | <input type="checkbox"/> Compatibility Testing | |
| | <input type="checkbox"/> Other | |

LIST ALL MODULES OF PROFICIENCY TESTING PROGRAM ENROLLMENT:

LABORATORY DIRECTOR REQUIREMENTS –MUST BE COMPLETED

- o Name of Registered or Licensed Laboratory Director: _____
 - o Laboratory Director License Number: _____
- OR**
- o Enter date Laboratory Director Application was submitted: _____

❖ Application to become a Laboratory Director can be found at:
<http://dpbh.nv.gov/uploadedFiles/dpbhnavgov/content/Reg/MedicalLabs/Docs/Applications/labdirectorlicense.pdf>

GENERAL SUPERVISOR OF A LICENSED LABORATORY – LICENSED LABORATORY APPLICANTS MUST COMPLETE THIS SECTION

A licensed laboratory shall have on staff a general supervisor to oversee the technical and administrative functions of the laboratory and who may supervise other personnel, as assigned by the director. THERE MUST BE a general supervisor **on the premises during all routine hours of testing.**

❖ Application to become a General Supervisor can be found at:
<http://dpbh.nv.gov/uploadedFiles/dpbhnavgov/content/Reg/MedicalLabs/Docs/Applications/GeneralSupervisorLicensedLab.pdf>

LIST ALL GENERAL SUPERVISORS WORKING IN LABORATORY (Must have at least one)

Enter Names of General Supervisors	Certificate Number	Specialties

❖ Attach additional list of general supervisors if needed

LIST PERSONNEL PERFORMING TESTS – MUST BE COMPLETED

MUST LIST ALL LABORATORY PERSONNEL THAT WILL BE COLLECTING SPECIMENS AND/OR PERFORMING TESTING (ATTACH AN ADDITIONAL LIST IF NEEDED)

Full Name	Title	License/certificate number & Expiration Date	List tests performed or specialty

List name, address and phone number of individual(s) responsible for records in the event the laboratory closes:

Name	Address	Phone Number
_____	_____	_____
_____	_____	_____
_____	_____	_____

DIRECTOR'S SIGNATURE MUST BE NOTARIZED

I have read understood and agree to comply with the rules and regulations pertaining to the specific type of laboratory for which licensure applications are herein made. 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 <u>and</u> 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:

ALL APPLICANTS MUST SUBMIT A COMPLETED APPLICATION WITH ALL REQUIRED DOCUMENTS AND FEES

ALL APPLICANTS MUST SUBMIT

The **APPROPRIATE FEE** (see fee schedule below) with your application via personal check, cashier's check or money order **paid to the order of Nevada State Treasurer.**

LICENSED LABORATORY FEE* IS BASED ON ANNUAL TEST VOLUME

Annual test volume	Fee
Less than 25,000	\$1,100
25,000 and less than 100,000	\$3,000
100,000 or more	\$4,000

REGISTERED LABORATORY FEE* IS ONE SET FEE OF: **\$1,500**

*The fee charged is the same for an initial license, reactivation of a license or a change of ownership.

The following must be submitted with your licensure application:

- Completed, signed, dated application **to the Division** at the address provided below.
- Completed, signed, dated **CLIA application (Form CMS-116)** with your licensure application (*CLIA will send you a bill – PAY TO 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://dpbh.nv.gov/uploadedFiles/dpbhnavgov/content/Reg/MedicalLabs/Docs/Forms/disclosureofownership0001.pdf>
- ALL** laboratory personnel applications have been submitted for applicable staff members if they are not already certified.
- Copy of Laboratory Director's license or copy of on-line verification showing an active license **and** a copy of his or her physician's license.

Nationally Recognized laboratory safety and infection control guidelines:

- My laboratory has adopted nationally recognized laboratory safety and infection control guidelines
EXAMPLES of acceptable nationally recognized guidelines that can be obtained by a laboratory for free:
 - **OSHA Laboratory Safety Guidance:**
<https://www.osha.gov/Publications/laboratory/OSHA3404laboratory-safety-guidance.pdf>
 - **CDC's Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories:**
<http://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
 - **CDC's Guideline for Hand Hygiene in Health-Care Settings:**
<http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>

NOTES:

- ❖ License is valid for two years from issue date (there is NO grace period for licensed laboratories)
- ❖ 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 Licensed or Registered Laboratory Self-Attestation form found at:
<http://dpbh.nv.gov/uploadedFiles/dpbhngov/content/Reg/MedicalLabs/Docs/Inspections/LicenseRegisteredLabSelfAttestation.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, Registered or Licensed Laboratory found at:

<http://dpbh.nv.gov/uploadedFiles/dpbhngov/content/Reg/MedicalLabs/Docs/Inspections/ExemptLabSelfAttestation.pdf>