



STATE OF TENNESSEE
DEPARTMENT OF HEALTH
MEDICAL LABORATORY BOARD
DIVISION OF HEALTH RELATED BOARDS
METRO CENTER COMPLEX
665 MAINSTREAM DRIVE 2nd FL
NASHVILLE, TN 37243
(615) 532-3202
1-800-778-4123 Ext. 532-5128
tennessee.gov/health

APPLICATION

FOR

A LICENSE TO OPERATE

A MEDICAL LABORATORY

Initial Fee \$1000.00

Routine

Esoteric

Regulatory Fee \$5.00

Application should be typed or legibly printed in ink.

Enclose the appropriate fee, \$1005.00, with this application. DO NOT MAIL CASH. Make check or postal money order payable to the State of Tennessee. Journal Vouchers must come to this office.

MAIL THE ORIGINAL DOCUMENT

KEEP A COPY FOR YOUR RECORDS

Please Submit To:

DEPARTMENT OF HEALTH

Division of Health Related Boards
Medical Laboratory Board Administrative Office
Metro Center Complex
665 Mainstream Drive 2nd FL
Nashville, TN 37243

5029)001	Initial Fee	\$1,000
5029)002	Renewal Fee	\$1,000
5029)002	Penalty Fee	\$ 500
5029)006	Regulatory Fee	\$ 5

Laboratory Name: _____

Laboratory Address (Street, City, County, Zip): _____

Mailing Address: _____

CLIA # _____ Telephone No. () _____

Type of ownership: Individual Partnership Corporation Government

Owner's Name (Individual(s) or partner(s) or officer if corporation): _____

Owner's Address: _____

Telephone No. () _____ - _____

Laboratory Director's Name: _____

Address: _____

Telephone No. () _____ - _____

Highest Educational Degree: _____ Current State License Held: _____

Date Became Director of this Laboratory: _____

If certified by American Specialty Board(s), Name of Board(s): _____

Copies of Boarding Certificates must be submitted with this application.

Other names and addresses of additional laboratories directed by this individual

(Cannot exceed three (3) licensed laboratories without Board approval: _____

If laboratory is located in a Tennessee Licensed Health Care Facility, indicate name and address of Chief Executive Officer:

Please indicate the days and hours of routine operation (Initial applications only): _____

SPECIALTIES (Indicate only those specialties performed on the premises.)

<input type="checkbox"/> 010	Histocompatibility	<input type="checkbox"/> 400	Hematology	<input type="checkbox"/>	Waived Testing:
<input type="checkbox"/> 100	Microbiology	<input type="checkbox"/> 500	Immunoematology	<input type="checkbox"/>	UA Dipstick
<input type="checkbox"/> 110	Bacteriology	<input type="checkbox"/> 510	ABO Group & RH Type	<input type="checkbox"/>	Whole Blood Glucose
<input type="checkbox"/> 115	Mycobacteriology	<input type="checkbox"/> 520	Antibody Detection Transfusion	<input type="checkbox"/>	Fecal Occult Blood
<input type="checkbox"/> 120	Mycology	<input type="checkbox"/> 530	Antibody Detection Non Transfusion	<input type="checkbox"/>	Gastric Occult Blood
<input type="checkbox"/> 130	Parasitology	<input type="checkbox"/> 540	Antibody Identification	<input type="checkbox"/>	Vaginal pH
<input type="checkbox"/> 140	Virology			<input type="checkbox"/>	Body fluid pH
<input type="checkbox"/> 150	Other			<input type="checkbox"/>	UCG
				<input type="checkbox"/>	Amines
<input type="checkbox"/> 200	Diag. Immunology	<input type="checkbox"/> 600	Pathology	<input type="checkbox"/>	Total Cholesterol
<input type="checkbox"/> 210	Syphilis Serology	<input type="checkbox"/> 610	Histopathology	<input type="checkbox"/>	HDL Cholesterol
<input type="checkbox"/> 220	Gen. Immunology	<input type="checkbox"/> 620	Oral Pathology	<input type="checkbox"/>	Triglycerides
		<input type="checkbox"/> 630	Cytopathology (Gyn) (Non-Gyn)	<input type="checkbox"/>	LDL Calculated
<input type="checkbox"/> 300	Chemistry			<input type="checkbox"/>	Prothrombin Time
<input type="checkbox"/> 310	Routine, Clinical Chemistry	<input type="checkbox"/> 900	Cytogenetics	<input type="checkbox"/>	<i>H. pylori</i>
<input type="checkbox"/> 320	Urinalysis			<input type="checkbox"/>	BUN
<input type="checkbox"/> 330	Endocrinology		Independent Laboratory	<input type="checkbox"/>	Creatinine
<input type="checkbox"/> 340	Toxicology		Blood Donor Center	<input type="checkbox"/>	Hemoglobin
<input type="checkbox"/> 350	Other		Plasma Donor Center	<input type="checkbox"/>	Hemoglobin A1C
	pH & Blood Gas		Collection Station	<input type="checkbox"/>	Strep Group A kit
				<input type="checkbox"/>	Influenza A & B Kit
			<u>Esoteric (please specify)</u>		
			Toxicology		
			Molecular Diagnostics		
			Other		

REFERRED SPECIMENS

A. Are specimens referred to other laboratories for examination?

No Yes If yes, please provide the following information regarding the referring facilities to include name and address.

B. Are specimens referred to your laboratory from other laboratories, facilities or offices for examination?

No Yes If yes, please provide the following information regarding the referring facilities to include name and address.

TECHNICAL PERSONNEL WORKING IN LABORATORY

Please list the name(s) and SSN of licensed personnel currently working in the laboratory according to the chart provided: the application will not be considered complete and a temporary or permanent license will not be issued without this information. Category – MT, MLT, Director, Special Analyst, Respiratory Therapists (ABG endorsed), MD, etc.

*** Esoteric Laboratory Personnel:** laboratories with non- licensed personnel may put N/A for State License Category, State License Number and Expiration Date however each individual must be listed with a copy of their respective transcript for surveyor/administrative office review.

NAME OF ALL TECHNICAL PERSONNEL	SOCIAL SECURITY NO.	STATE LICENSE CATEGORY *	STATE LICENSE NO. *	EXPIRATION DATE *

68-29-126. Suspension, Revocation and Denial of Medical Laboratory License - Grounds.

The board has the power to suspend or revoke a medical laboratory license or to deny the issuance or renewal of a license or deny approval whenever a medical laboratory owner or director or owner of a medical laboratory training facility commits any of the following offenses:

- (1) Making false statements on an application for a medical laboratory license or any other documents required by the board;
- (2) Permitting unauthorized persons to perform technical procedures or to issue or sign reports;
- (3) Demonstrating incompetence or making consistent errors in the performance of medical laboratory examinations and procedures;
- (4) Reporting which is erroneous;
- (5) Performing a test and rendering a report thereon to a person not authorized by law to receive such services;
- (6) Referring a specimen for examination to a medical laboratory which has not been licensed under this chapter, with exceptions noted in §68-29-104;
- (7) Rendering a report on medical laboratory work actually performed in another medical laboratory without designating the name of the director and the name and address of the medical laboratory in which the test was performed;
- (8) Having professional connection with or lending the use of the name of the licensed medical laboratory or its director to an unlicensed medical laboratory;
- (9) Making statements, in writing or orally, of a character tending to deceive or mislead physicians, dentists or hospitals;
- (10) The performing of cytological and anatomical pathological examinations in a medical laboratory not under the direction of a pathologist certified or eligible for certification by the American Board of Pathology, licensed to practice medicine in the State of Tennessee;
- (11) Violating or aiding and abetting in the violation of any provision of this chapter or the rules and regulations promulgated hereunder;
- (12) Failing to file any request or report required by the provisions of this chapter or the rules and regulations promulgated hereunder; or
- (13) Fraudulent advertising for patronage of the general public by means of bills, posters, circulars, letters, newspapers, magazines, directories, radio, television, or any other medium.

Acts 1967, ch. 355, § 26; 1973, ch. 141, § 10; T.C.A., § 53-4126; Acts 1989, ch. 467, §§ 7, 12.

68-29-138. Exemption for laboratories certified by certain organizations.

(a) Notwithstanding any provisions of official compilation Rules and Regulations of the State of Tennessee, Rule 1200-6-1, or any other rule promulgated by the medical laboratory board to the contrary, a Tennessee medical laboratory shall be licensed in accordance with the rules promulgated under of this chapter and as provided in this section if the laboratory:

- (1) Is engaged in advanced esoteric applied toxicological, forensic, or biochemical laboratory analysis utilizing emerging technologies, such as chromatographic and non-chromatographic techniques coupled with mass spectrometer based detector systems and molecular diagnostic techniques; and

(2) Is licensed, certified, or accredited by the United States department of health and human resources substance abuse and mental health service administration (SAMHSA). The American Society of Crime Laboratory Directors Laboratory Accreditation Board (ASCLD/LAB), the American Board of Forensic Toxicology (ABFT), the College of American Pathologists Laboratory Accreditation Program (CAP LAP), or a state that has been determined to be exempt in accordance with Section 353(p) of the Public Health Services Act, 42 U.S.C. § 263a, as having enacted laboratory requirements that are equal to or more stringent than the statutory and regulatory requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

(b) A laboratory licensed under subsection (a) shall be exempt from the provisions of this chapter, including any rules promulgated under this chapter, that require persons who accept specimens for laboratory examination and perform analytical testing or report the results of a laboratory examination, be licensed as a technologist, technician, laboratory trainee, or special analyst.

(c) In such medical laboratories, laboratory personnel who analyze or report laboratory results shall possess a baccalaureate or advanced degree in the appropriate sciences with at least sixteen (16) semester hours of chemistry and/or biological science courses. Nothing in this section shall be construed to prohibit licensed personnel from performing the tasks for which they are appropriately licensed and trained in such medical laboratories.

(d) Except as provided in subsection (b), such laboratories shall be subject to all other provisions of this chapter, including any rules promulgated under this chapter.

HISTORY: Acts 2006, ch. 934, § 3, Acts 2013, ch. 213.

**AFFIDAVIT OF APPLICANT
APPLICANT'S CONSENT AND RELEASE**

In applying for licensure in the State of Tennessee, I HEREBY:

SIGNIFY my willingness to appear to answer such questions as the Board may find necessary and which may include a full Board interview.

RELEASE to the Board, its staff, and their representatives, any and all documentation necessary now and in the future to establish compliance with the rules and regulations pertaining to medical laboratory facilities in Tennessee.

AUTHORIZE the Board, its staff and their representatives to consult with individuals working in the this laboratory environment to review laboratory techniques, quality control, appropriate practices and any other issues concerning the laboratory medicine in this physical location.

RELEASE from liability the Board, its staff and all their representatives any and all organizations which provide information for their acts performed and statements made in good faith and without malice concerning issues of competence, ethics, character, other qualifications for this facility environment.

ACKNOWLEDGE this application for a laboratory license contains the adequate information for a proper evaluation of this laboratory operation concerning the scope of best practices in medical laboratory medicine.

AUTHORIZE release, use and disclosure of health information to the limited extent necessary for this laboratory application to receive full consideration up to and including discussion in a public forum should that become necessary.

THIS CERTIFIES THAT THE INFORMATION SUBMITTED IN THIS APPLICATION IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

SIGNATURE

DATE

LABORATORY WORK AREA

FACILITY NAME: _____

FACILITY ADDRESS: _____

DESCRIBE THE PREMISES AND ATTACH A SCALE DRAWING OF THE LABORATORY AREA
(MAY BE HAND-DRAWN) YOU CAN USE THIS PAGE