



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.

Name(s) and address(es) of other 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:

Days and hours of routine operation (Initial applications only): _____

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

Check the specialties for which you seek a license to operate a medical laboratory.

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

REFERRED SPECIMENS

A. Are specimens referred to other laboratories for examination?

No Yes If yes, furnish the name(s) and address(es) of the laboratories below:

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

No Yes If yes, furnish the name(s) and address(es) of the laboratories below:

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. 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.

FACILITY APPLICATION

FACILITY NAME: _____

FACILITY ADDRESS: _____

DESCRIBE THE PREMISES AND ATTACHE A SCALE DRAWING, MAY BE HAND DRAWN.