AHCA USE ONLY:
File #: _____
Application #: _____
Check #: _____
Check Amt: _____
Batch #: _____

Health Care Licensing Application
Forensic Toxicology Laboratory

The Agency for Health Care Administration (AHCA) has implemented the **ONLINE LICENSING SYSTEM,** which allows the electronic submission of renewal and change during licensure period applications and fees, along with the ability to upload supporting documentation. To submit online please go to: https://ahca.myflorida.com/health-care-policy-and-oversight/online-licensure-information/online-licensing-system

Applications must be received **at least 60 days prior to** the expiration of the current license or effective date of a change of ownership to avoid a late fee. If the renewal application is received by the Agency less than 60 days prior to the expiration date, it is subject to a late fee as set forth in statute. The applicant will receive notice of the amount of the late fee as part of the application process or by separate notice. The application will be withdrawn from review if all the required documents and fees are not included with the application or received within 21 days of an omission notice. **Applications will not be considered for review until payment has been received. Renewal and Change During Licensure Period applications: Supporting documentation, responses to omissions and payments may be submitted using the online system even if the application was originally mailed to the Agency.** Please fill in all blanks or mark N/A if not applicable.

Under the authority of Chapter 408, Part II, and Sections 112.0455 and 440.102, Florida Statutes (F.S.), and Chapters 59A-35 and 59A-24, Florida Administrative Code (F.A.C.), an application is hereby made to operate a forensic toxicology laboratory as indicated below:

1. Provider / Licensee Information

A. PROVIDER INFORMATION – Please complete the following for the forensic toxicology laboratory name and location. Provider name, address and telephone number will be listed on https://quality.healthfinder.fl.gov/index.html			
Permanent License Number:			
Name of Forensic Toxicology Laboratory (if operated under a fictitious name, enter as it filed with the Florida Division of Corporations)			
Street Address			
City	County	State	Zip
Telephone Number	Fax Number		
Email Address	**Note**: By providing your e-mail address, you agree to accept e-mail correspondence from the Agency.		
Provider Website			
Mailing Address or ☐ Same as above			
City	County	State	Zip
Telephone Number	E-mail Address		

B. CONTACT PERSON - For this application	
Contact Person for this application	Contact Telephone Number
Contact e-mail address or ☐ Do not have e-mail	**Note**: By providing your e-mail address, you agree to accept e-mail correspondence from the Agency.

C. **LICENSEE INFORMATION** - Please complete the following for the entity seeking to operate the forensic toxicology laboratory.			
Licensee Name (This is the owner of the forensic toxicology laboratory **)**			Federal Employer Identification Number (EIN)
Mailing Address			
City		State	Zip
Telephone Number	Fax Number	E-mail Address	

Description of Licensee (check one):

For Profit:	Not for Profit	Public
☐ Corporation	☐ Corporation	☐ State
☐ Limited Liability Company	☐ Religious Affiliation	☐ City/County
☐ Partnership	☐ Other:	☐ Special Tax District
☐ Individual		
☐ Sole Proprietorship		
☐ Other:		

2. Application Type and Fees

Indicate the type of fees submitted with an "X." **Applications will not be processed if all applicable fees are not included.** Please make check or money order payable to the Agency for Health Care Administration (AHCA). **Pursuant to section 408.805(4), F.S., fees are nonrefundable.** Renewal and Change of Ownership applications must be received 60 days prior to the expiration of the license or the proposed effective date of the change to avoid a late fine. If the renewal application is received by the Agency less than 60 days prior to the expiration date, it is subject to a late fee as set forth in statute. The applicant will receive notice of the amount of the late fee as part of the application process or by separate notice.

A. TYPE OF APPLICATION

☐ Initial Licensure **Proposed Effective Date**: _____

Was this entity previously licensed as a forensic toxicology laboratory in Florida? YES ☐ NO ☐

If YES, please provide the name of the agency (if different), the EIN # and the date the prior license expired or closed:

NAME:	EIN #	Date Expired/Closed:

☐ Renewal Licensure

☐ Change of Ownership **Proposed Effective Date**: _____

- ☐ Licensee sale or transfer of ownership to a different individual/entity
- ☐ Transfer or assignment of 51% or more ownership, shares, membership, or controlling interest of the licensee

☐ Change During Licensure Period – select all that apply: **Proposed Effective Date**: _____

Fee Required	No Fee Required
☐ Provider Name	☐ Personnel
☐ Provider Address	☐ Collection Station ☐ Add ☐ Remove
Services/Qualifications:	☐ Management Company
☐ Type of Specimen Collected	☐ Management Company Controlling Interest
	☐ Equipment
	☐ Transfer or assignment of less than 51% ownership, shares, membership, or controlling interest of the licensee

B. LICENSURE FEES

ACTION	FEE	TOTAL FEES
License Fee (Initial, Renewal and Change of Ownership)	$16,435.00	$
Change During Licensure Period	$25.00	$
TOTAL FEES INCLUDED WITH APPLICATION		**$**
Please make check or money order payable to the Agency for Health Care Administration (AHCA)		

3. Controlling Interests of Licensee

AUTHORITY:

Pursuant to sections 408.806(1)(a) and (b), F.S., an application for licensure must include: the name, address and social security number of the applicant and each controlling interest, if the applicant or controlling interest is an individual; and the name, address, and federal employer identification number (EIN) of the applicant and each controlling interest, if the applicant or controlling interest is not an individual. Disclosure of social security number(s) is mandatory. The Agency for Health Care Administration shall use such information for purposes of securing the proper identification of persons listed on this application for licensure. However, in an effort to protect all personal information, **do not include social security numbers on this form. All social security numbers must be entered on the Health Care Licensing Application Addendum, AHCA Form 3110-1024.**

DEFINITIONS:

Controlling interests, as defined in section 408.803(7), F.S., are the applicant or licensee; a person or entity that serves as an officer of, is on the board of directors of, or has a 5-percent or greater ownership interest in the applicant or licensee; or a person or entity that serves as an officer of, is on the board of directors of, or has a 5-percent or greater ownership interest in the management company or other entity, related or unrelated, with which the applicant or licensee contracts to manage the provider. The term does not include a voluntary board member.

Note: Pursuant to section 408.809, F.S., any controlling interest are required to have an Agency screening through the Care Provider Background Screening Clearinghouse. If background screening has been conducted by the Department of Financial Services for an applicant for a certificate of authority to operate a continuing care retirement community under Chapter 651, F.S., the Attestation of Compliance with Background Screening Requirements, AHCA Form 3100-0008 may be submitted in lieu of Agency screening. To verify who is to be screened, visit Background Screening (myflorida.com).

INSTRUCTIONS:

For new individual – complete all fields except the End Date.
For existing individuals – complete all fields except the Effective and End Date.
To remove an individual – complete all fields including the End Date.

A. Individual and/or Entity Ownership of Licensee (as listed in Section 1C above – Provide the information for each individual or entity (corporation, partnership, association) with 5% or greater ownership interest in the licensee. Attach additional sheets if necessary. This excludes Not-for-Profit and publicly held licensees. **Note**: A written explanation will be required if the percentage of ownership interest indicated below does not equal 100%.

FULL NAME of INDIVIDUAL or ENTITY	PERSONAL/PRIMARY ADDRESS	TELEPHONE NUMBER	EIN (No SSN)	% OWNERSHIP	EFFECTIVE DATE	END DATE

B. Board Members and Officers of Licensee as listed in Section 1C above – Provide the information for each individual that serves as an officer or is on the board of directors. Do not include voluntary board members.

TITLE	FULL NAME	PERSONAL/PRIMARY ADDRESS	TELEPHONE NUMBER	EFFECTIVE DATE	END DATE
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					

4. Management Company

Does a company other than the licensee manage the licensed provider?

If ☐ NO, **skip to Section 6 - Personnel**

If ☐ YES, provide the following information:

Name of Management Company	EIN (No SSN)	Telephone Number / Fax	
Street Address	E-mail Address		
City	County	State	Zip
Mailing Address or ☐Same as above			
City		State	Zip
Contact Person	Contact E-mail	Contact Telephone Number	

5. Management Company Controlling Interests

DEFINITION:

Controlling interests, as defined in section 408.803(7), F.S., are the applicant or licensee; a person or entity that serves as an officer of, is on the board of directors of, or has a 5% or greater ownership interest in the applicant or licensee; or a person or entity that serves as an officer of, is on the board of directors of, or has a 5% or greater ownership interest in the management company or other entity, related or unrelated, with which the applicant or licensee contracts to manage the provider. The term does not include a voluntary board member.

Note: For each controlling interest an AHCA screening through the Care Provider Background Screening Clearinghouse is needed or the Attestation of Compliance with Background Screening Requirements, AHCA Form 3100-0008 if background screening was conducted by the Department of Financial Services for an applicant for a certificate of authority to operate a continuing care retirement community under Chapter 651, F.S. To verify who is to be screened, visit Background Screening (myflorida.com).

INSTRUCTIONS:
For new individual – complete all fields except the End Date.
For existing individuals – complete all fields except the Effective and End Date.
To remove an individual – complete all fields including the End Date.

A. Individual and/or Entity Ownership of Management Company: Provide the information for each individual or entity (corporation, partnership, association) with 5% or greater ownership interest in the management company. Attach additional sheets if necessary.

FULL NAME OF INDIVIDUAL OR ENTITY	PERSONAL/PRIMARY ADDRESS	TELEPHONE NUMBER	EIN (NO SSN)	% OWNERSHIP	EFECTIVE DATE	END DATE

B. Board Members and Officers of Management Company: Provide the information for each individual that serves as an officer or is on the board of directors. Do not include voluntary board members.

TITLE	FULL NAME	PERSONAL/PRIMARY ADDRESS	TELEPHONE NUMBER	EFFECTIVE DATE	END DATE
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					

6. Personnel

Please provide information for the individual(s) who perform the following roles. Note: For the administrator, financial officer, director and co-director, if applicable, an AHCA screening through the Care Provider Background Screening Clearinghouse is needed or the Attestation of Compliance with Background Screening Requirements, AHCA Form 3100-0008, if background screening was conducted by the Department of Financial Services for an applicant for a certificate of authority to operate a continuing care retirement community under Chapter 651, F.S. To verify who is to be screened, visit Background Screening (myflorida.com).

INSTRUCTIONS:
For new individual – complete all fields except the End Date.
For existing individuals – complete all fields except the Effective and End Date.
To remove an individual – complete all fields including the End Date.

A. Administrator and Financial Officer – Pursuant to section 408.806(1), F.S., an application for licensure must include the name, address, phone number, and social security number of the administrator and financial officer.

INFORMATION	ADMINISTRATOR / MANAGING EMPLOYEE	FINANCIAL OFFICER / PERSON RESPONSIBLE FOR FINANCIAL OPERATIONS
Full Name		
Effective Date		
End Date		
Telephone Number		
Email Address		
Personal/Primary Address		

B. Director and Co-Director – The director and co-director, if applicable, must meet the qualifications in section 59A-24.006(1)(a), F.A.C.

INFORMATION	DIRECTOR	Co DIRECTOR
Full Name		
Effective Date		
End Date		
Telephone Number		
Email Address		
Personal/Primary Address		

Florida Dept. of Health License Number	FL DOH License #:	FL DOH License #:
Business Degree		
Board Certified By		
Lab Experience (Years)		
Hours Spent in Lab (Per week)		
Serves as Director at other laboratories? ☐ Yes ☐ No If yes, provide the following information		**Co-Director at other laboratories? ☐ Yes ☐ No If yes, provide the following information**
Laboratory Name:		
Street Address:		
Laboratory Name:		
Street Address:		
Laboratory Name:		
Street Address:		
Laboratory Name:		
Street Address:		
Laboratory Name:		
Street Address:		

C. Certifying Scientists – certifying scientists must meet the requirements of section 59A-24.006(1)(c), F.A.C.

NAME	FLORIDA DEPT OF HEALTH CLINICAL LABORATORY PERSONNEL LICENSE NUMBER (REQUIRED IF LABORATORY IS LOCATED IN FLORIDA)	FLORIDA LICENSE LEVEL (IF REQUIRED)	FLORIDA LICENSURE SPECIALTY(IES) (IF REQUIRED)	# OF YEARS TOXICOLOGY EXPERIENCE
	FL DOH License #:			
	FL DOH License #:			
	FL DOH License #:			
	FL DOH License #:			

D. Certifying Scientists for Negative Tests – Certifying scientists for negative tests must meet the requirements of Section 59A-24.006(1)(c), F.A.C.

NAME	FLORIDA DEPT OF HEALTH CLINICAL LABORATORY PERSONNEL LICENSE NUMBER (REQUIRED IF LABORATORY IS LOCATED IN FLORIDA)	FLORIDA LICENSE LEVEL (IF REQUIRED)	FLORIDA LICENSURE SPECIALTY(IES) (IF REQUIRED)	# OF YEARS TOXICOLOGY EXPERIENCE
	FL DOH License #:			
	FL DOH License #:			
	FL DOH License #:			
	FL DOH License #:			

E. Person(s) Responsible for the day-to-day Supervision of Analysts – The person(s) responsible for supervision of analysts must meet the requirements of Section 59A-24.006(1)(d), F.A.C.

NAME	FLORIDA DEPT OF HEALTH CLINICAL LABORATORY PERSONNEL LICENSE NUMBER (REQUIRED IF LABORATORY IS LOCATED IN FLORIDA)	FLORIDA LICENSE LEVEL (IF REQUIRED)	FLORIDA LICENSURE SPECIALTY(IES) (IF REQUIRED)	# OF YEARS TOXICOLOGY EXPERIENCE
	FL DOH License #:			
	FL DOH License #:			
	FL DOH License #:			
	FL DOH License #:			

F. Technical Personnel Performing Toxicology Testing – Technical personnel must meet the requirements of Section 59A-24.006(1)(e), F.A.C.

NAME	FLORIDA DEPT OF HEALTH CLINICAL LABORATORY PERSONNEL LICENSE NUMBER (REQUIRED IF LABORATORY IS LOCATED IN FLORIDA)	FLORIDA LICENSE LEVEL (IF REQUIRED)	FLORIDA LICENSURE SPECIALTY(IES) (IF REQUIRED)	# OF YEARS TOXICOLOGY EXPERIENCE
	FL DOH License #:			
	FL DOH License #:			
	FL DOH License #:			
	FL DOH License #:			

7. Required Disclosure

The following disclosures are required:

A. Pursuant to section 408.809, F.S., the applicant shall submit to the Agency a description and explanation of any convictions of offenses prohibited by sections 435.04 and 408.809(4), F.S., for each controlling interest.

Has the applicant or any individual listed in Sections 3 and 4 of this application been convicted of any level 2 offense pursuant to section 408.809, F.S.? YES ☐ NO ☐

If YES, provide the following information:

☐ The full legal name of the individual and the position held

☐ A description/explanation of any convictions

B. Pursuant to section 408.810(2), F.S., the applicant must provide a description and explanation of any exclusions, suspensions, or terminations from the Medicare, Medicaid, or federal Clinical Laboratory Improvement Amendment (CLIA) programs.

Has the applicant or any individual/entity listed in Sections 3 and 4 of this application been excluded, suspended, terminated or involuntarily withdrawn from participation in Medicare or Medicaid in any state? YES ☐ NO ☐

If YES, enclose the following information:

☐ The full legal name of the individual (and the position held) or the entity

☐ A description/explanation of the exclusion, suspension, termination or involuntary withdrawal.

C. Pursuant to section 408.815(4), F.S., has the applicant or a controlling interest in the applicant, or any entity in which a controlling interest of the applicant was an owner or officer when the following actions occurred ever been:

Convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, chapter 893, 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, Medicaid fraud, Medicare fraud, or insurance fraud, within the previous 15 years prior to the date of this application? YES ☐ NO ☐

Terminated for cause from the Medicare program or a state Medicaid program? YES ☐ NO ☐

If YES, has applicant been in good standing with the Medicare program or a state Medicaid program for the most recent five (5) years and the termination occurred at least twenty (20) years before the date of the application. YES ☐ NO ☐

8. Provider Fines and Financial Information

Pursuant to section 408.831(1)(a), F.S., the Agency may take action against the applicant, licensee, or a licensee which shares a common controlling interest with the applicant if they have failed to pay all outstanding fines, liens, or overpayments assessed by final order of the agency or final order of the Centers for Medicare and Medicaid Services (CMS), not subject to further appeal, unless a repayment plan is approved by the agency.

Are there any incidences of outstanding fines, liens or overpayments as described above? YES ☐ NO ☐
If YES, please complete the following for each incidence (attach additional sheets if necessary):

AHCA CASE NUMBER	CMS	ASSESSED AMOUNT	DATE OF RELATED INSPECTION, APPLICATION, OR OVERPAYMENT	PAYMENT DUE DATE	PENDING APPEAL OF FINAL ORDER	
					YES	NO
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐

Please attach a copy of the approved repayment plan if applicable.

9. Days and Hours of Operation

List the regular operating hours. **Note:** Site inspections by surveyors will occur during the business hours submitted. Failure to be open during the listed hours may result in a fine.

☐ 24 hours / 7 days a week **OR**

DAY OF THE WEEK	OPENING TIME	CLOSING TIME	BY APPOINTMENT
☐ Monday			☐
☐ Tuesday			☐
☐ Wednesday			☐
☐ Thursday			☐
☐ Friday			☐
☐ Saturday			☐
☐ Sunday			☐

10. Accreditation / Certification

The applicant participates in the accreditation and/or certification organization below or ☐ Not accredited/certified.

ACCREDITING/CERTIFYING ORGANIZATION	ACCREDITATION/ CERTIFICATION ID	ACCREDITATION/CERTIFICATION STATUS		SURVEY END DATE
		EFFECTIVE DATE	END DATE	
☐ College of American Pathologists (CAP)				
☐ Substance Abuse and Mental Health Services Administration (SAMHSA)				

Note: If accredited or certified, provide a copy of the full accreditation and/or certification survey report, award letter and any follow-up letters to or from the accreditation and/or certification organization.

☐ I understand that the complete accreditation and/or certification survey report must be submitted to the Agency for review if the survey report is to be accepted in lieu of a complete licensure inspection and such reports used to meet licensure requirements are considered public documents subject to disclosure per Chapter 119, F.S. A complete accreditation and/or certification report includes correspondence from the accrediting and/or certifying organization containing the dates of the survey, any citations to which the accrediting and/or certifying organization requires a response, the facility's response to each citation, the effective date of accreditation and/or certification, and verification of Medicare (CMS) deemed status, if applicable.

11. Proficiency Testing Provider Information

Select the option(s) that apply to this provider:

☐ SAMHSA (HHS) ☐ CAP (UDC)

Note: Participation in a Proficiency Testing Program is not equivalent to accreditation and/or certification.

12. Specimen Type

Select the option(s) that apply to this provider:

☐ Hair ☐ Urine ☐ Blood

13. Equipment

List the major equipment/test systems used by the laboratory. Ancillary equipment such as centrifuges, shakers, rotators, computer equipment, etc., does not need to be included. Abbreviations are acceptable. Attach additional sheets as needed.

INITIAL SCREENING/TESTING EQUIPMENT		

CONFIRMATION TESTING EQUIPMENT		

14. Collection Stations

List all locations in Florida for which the laboratory accepts drug free workplace specimens. Attach additional sheets as needed.

COLLECTION SITE NAME	ADDRESS	CITY	ZIP

15. Supporting Documents

Applicants must include the following attachments as stated in Chapters 408, Part II and Sections 112.0455 and 440.102, F.S., and Chapters 59A-35 and 59A-24, F.A.C. **Note: Required documents listed below are dependent on the type of application submitted. (Initial, Renewal, Change of Ownership, Change During Licensure Period)**

DOCUMENTS TO BE PROVIDED:	REQUIRED FOR:
Accreditation Documentation, if applicable	Initial, Renewal and Change of Ownership application types
Health Care Licensing Application Addendum, AHCA Form 3110-1024	Initial, Renewal, Change of Ownership, Change of Personnel or Controlling Interest application types
Laboratory Personnel Qualifications – Documentation of required laboratory experience/training/licensure for Director/Co-Director, Certifying Scientist(s), Person(s) supervising analysts, Technical Personnel.	Initial, Renewal, Change of Ownership and Change of Laboratory Personnel application types.
Documentation of change of ownership transaction stating effective date and executed by all parties	Change of Ownership application type
A signed agreement to pay any outstanding payments owed to the Agency. The agreement must include who will pay and when payment will be made	Change of Ownership application type
Required disclosures related to actions taken by Medicare, Medicaid or CLIA, if applicable	All application types, if documentation is required due to responses provided in application
Approved repayment plan, if applicable	All application types

16. Attestation

I, _____, attest as follows:

(1) Pursuant to section 837.06, Florida Statutes, I have not knowingly made a false statement with the intent to mislead the Agency in the performance of its official duty.

(2) Pursuant to section 408.815, Florida Statutes, I acknowledge that false representation of a material fact in the license application or omission of any material fact from the license application by a controlling interest may be used by the Agency for denying and revoking a license or change of ownership application.

(3) Pursuant to section 408.806, Florida Statutes, under penalty of perjury, the applicant is in compliance with the provisions of section 408.806 and Chapter 435, Florida Statutes.

(4) Pursuant to sections 408.809 and 435.05, Florida Statutes, every employee of the applicant required to be screened has attested, subject to penalty of perjury, to meeting the requirements for qualifying for employment pursuant to Chapter 408, Part II, and Chapter 435, Florida Statutes, and has agreed to inform the employer immediately if arrested for any of the disqualifying offenses while employed by the employer.

(5) Pursuant to section 435.05, Florida Statutes, the applicant has conducted a level 2 background screening through the Agency on every employee required to be screened under Chapter 408, Part II, or Chapter 435, Florida Statutes, as a condition of employment and continued employment and that every such employee has satisfied the level 2 background screening standards or obtained an exemption from disqualification from employment.

(6) Pursuant to section 408.810(12), Florida Statutes, the licensee ensures that no person holds any ownership interests, either directly or indirectly, regardless of ownership structure; who has a disqualifying offense pursuant to section 408.809, Florida Statutes or in a provider that had a license revoked or application denied pursuant to section 408.815, Florida Statutes.

(7) Pursuant to sections 408.810(14) and 408.051(3), FS, the licensee ensures that all patient information stored in an offsite physical or virtual environment, including through a third-party or subcontracted computing facility or an entity providing cloud computing services, is physically maintained in the continental United States or its territories or Canada.

(8) Pursuant to section 408.810(15), FS, the licensee ensures that controlling interests of the licensee do not hold, either directly or indirectly, regardless of ownership structure, an interest in an entity that has a business relationship with a foreign country of concern or that is subject to section 287.135, FS.

Signature of Licensee or Authorized Representative	Title	Date

NOTICE: If you are a **Medicaid** provider, you may have a separate obligation to notify the Medicaid program of a name/address change, change of ownership or other change of information. Please refer to your Medicaid handbooks for additional information about Medicaid program policy regarding changes to provider enrollment information

Notice: If you are a **Medicaid** provider, you may have a separate obligation to notify the Medicaid program of a name/address change, change of ownership or other change of information. Please refer to your Medicaid handbooks for additional information about Medicaid program policy regarding changes to provider enrollment information.

RETURN THIS COMPLETED FORM WITH FEES AND ALL REQUIRED DOCUMENTS TO:

AGENCY FOR HEALTH CARE ADMINISTRATION
LABORATORY IN-HOME SERVICES UNIT
2727 MAHAN DR., MS 32
TALLAHASSEE FL 32308-5407

Questions? Visit the Agency's website at https://ahca.myflorida.com/ or contact the Laboratory and In-Home Services Unit at (850) 412-4500 or Emails: labstaff@ahca.myflorida.com

The Agency for Health Care Administration scans all documents for electronic storage. In an effort to facilitate this process, we ask that you please remember to:

- Please place checks or money orders on top of the application
- Include license number or case number on your check
- Do not submit carbon copies of documents
- No staples, paperclips, binder clips, folders, or notebooks
- Please ***do not bind any*** of the documents submitted to the Agency