

# Clinical Laboratories: Regulatory Overview and the Application Process



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# Target Audience

- Office Managers, Practice Administrators and Physicians within Dermatologic Surgery practices who are responsible for, or involved in, the completion of clinical laboratory applications for Florida licensure or federal certification.

# Regulation

- Clinical laboratory testing provides critical information to health care practitioners.
- No matter where the testing is performed, it is essential that the results are accurate and reliable.
- Therefore, both the federal government and State of Florida have laws and regulations that govern clinical laboratories.

# Federal Government

# CLIA

- CLIA stands for Clinical Laboratory Improvement Amendments of 1988
- The CLIA program is part of the Centers for Medicare and Medicaid Services (CMS) within the U.S. Department of Health and Human Services
- CLIA Regulations are found in [Title 42, Part 493 of the Code of Federal Regulations](#) (CFR).
- The objective of the CLIA program is to ensure quality laboratory testing.
- The regulations cover all aspects of laboratory operations.

# Food & Drug Administration

- The Office of In Vitro Device Evaluation and Safety is a program of the Center for Devices & Radiological Health within the Food and Drug Administration (FDA) of the US Department of Health and Human Services.
- This program *and* the CLIA program are responsible for evaluating and approving the instruments and test systems used in clinical laboratories.

# State Government



# Agency for Health Care Administration

- The Agency for Health Care Administration (Agency) is responsible, in part, for the regulation and licensure of health care facilities that provide services to Floridians. This includes *some* clinical laboratories.
- The Agency and all health care facilities licensed by AHCA are required to act in accordance with the Health Care Licensing Procedures Act found in [Chapter 408, Part II, Florida Statutes \(F.S.\)](#) and [Chapter 59A-35, Florida Administrative Code \(F.A.C.\)](#).

# Agency for Health Care Administration

- In addition, clinical laboratories are governed by Chapter 483, Part I, F.S. and Chapter 59A-7, F.A.C. .

# Department of Health

- The Board of Medicine within the Department of Health (DOH) is responsible for the licensure and regulation of physicians practicing in the State of Florida.
  - This includes those physicians who act as the director of a clinical laboratory.
- The Board of Clinical Laboratory Personnel within DOH is responsible for the licensure and regulation of the individuals, other than physicians, who work in clinical laboratories.
- Board of Clinical Laboratory Personnel laws and regulations are found in [Chapter 483, Part III, F. S.](#) and [Chapter 64B3, F.A.C.](#) .

# Applicability

# Which laboratories need a CLIA certificate?

- All clinical laboratories in the United States are required to be certified by the CLIA program.
- Certification is required regardless of billing and/or payer source.

## Example of a CLIA Certificate



The image shows a sample CLIA Certificate of Registration. It features a decorative border and a central text area. The text is as follows:

**CENTERS FOR MEDICARE & MEDICAID SERVICES**  
**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS**  
*CERTIFICATE OF REGISTRATION*

<b>LABORATORY NAME AND ADDRESS</b> [Redacted]	<b>CLIA ID NUMBER</b> [Redacted]
<b>LABORATORY DIRECTOR</b> [Redacted]	<b>EFFECTIVE DATE</b> 12/04/2006
	<b>EXPIRATION DATE</b> 12/03/2008

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

*Judith A. Yost*  
Judith A. Yost, Director  
Division of Laboratory Services  
Survey and Certification Group  
Center for Medicaid and State Operations

- All CLIA Certificates for Florida laboratories begin with 10D.
- They also show the certification type, laboratory name, physical address, director name, effective/expiration dates.
- On certain certificate types, a lower portion (not shown) lists the non-waived specialties/subspecialties the certification covers.

# Which laboratories are licensed by AHCA?

- Any health care facility that performs non-waived laboratory testing is required to maintain a State of Florida Clinical Laboratory License.

## Example of a State of Florida Clinical Laboratory License



- All Florida clinical laboratory licenses start with 8000.
- The license also shows the licensee, provider, location of the laboratory, effective/expiration dates and the non-waived specialties and subspecialties the laboratory is authorized to perform.

# Which clinical laboratory personnel need to be licensed by DOH Board of Clinical Laboratory Personnel?

- Clinical laboratory personnel who are employed in laboratories **other than** **Exclusive Use Laboratories** are required to be licensed by DOH Board of Clinical Laboratory Personnel.

# Exclusive Use Laboratories

# Definition

- Defined by ss. 59A-7.020(11), F.A.C. as:  
“A clinical laboratory operated by one or more of the following exclusively in connection with the diagnosis and treatment of their own patients:
  - (a) Physician licensed under Chapter 458 or 459, F.S.;
  - (b) Chiropractor licensed under Chapter 460, F.S.;
  - (c) Podiatrist licensed under Chapter 461, F.S.;
  - (d) Naturopath licensed under Chapter 462, F.S.; or
  - (e) Dentist licensed under Chapter 466, F.S.”

# Explanation

- If a health care facility that performs non-waived testing in Florida meets the definition of an Exclusive Use Laboratory, the personnel working in that laboratory *do not* have to be licensed by the Board of Clinical Laboratory Personnel.
- They *do* have to meet the personnel requirements of the CLIA program found in [42 CFR, Part 493, Subpart M](#) – Personnel for Non-waived Testing.

# Types of Laboratory Testing

- The application of state and federal laboratory regulations often depend on the type of testing that a laboratory is performing.
- It is important to have a general understanding of the types of laboratory testing.

# Complexity

- Laboratory testing is categorized by their complexity into:
  - Waived
  - Non-waived, Moderate Complexity
    - Provider Performed Microscopy Procedures
  - Non-waived, High Complexity

# Waived

According to Section 493.15(b), CFR waived tests must meet the following criteria:

- Test systems are simple laboratory examinations and procedures which—
  - (1) Are cleared by FDA for home use;
  - (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
  - (3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.
- As of April 19, 2011 these are the tests that meet the criteria to be waived. This listing is updated by CMS.  
<https://www.cms.gov/CLIA/downloads/waivetbl.pdf>

# Non-Waived

- Non-waived testing is first categorized as either moderate or high complexity and then further classified into a specialty or subspecialty.
  - The complexity describes how difficult the test is to perform.
  - The specialty or subspecialty describes the focus of the test.

# Provider Performed Microscopy(PPM) Procedures

- A subcategory of the Moderate Complexity level.
- Added after the original CLIA publication.
- First described as Physician Performed Microscopy
- Now called Provider Performed Microscopy (PPM).

# PPM Criteria

- Must be performed by a physician or a mid-level practitioner (i.e., nurse practitioners, nurse midwives and physician assistants) during the patient visit on a specimen obtained from the provider's patient or a patient of the group practice.
- Must be moderately complex.
- Primary instrument for the test must be a microscope.
- Specimen must be labile or a delay in testing could compromise the accuracy of the test
- Control materials are not available to monitor the entire testing process.
- Limited specimen handling is required.

# PPM Tests

- **Wet mounts, including preparations of vaginal, cervical or skin specimens**
- **All potassium hydroxide (KOH) preparations**
- **Pinworm examinations**
- **Fern test**
- **Post-coital direct, qualitative examinations of vaginal or cervical mucous**
- **Urinalysis; microscopic only**
- **Urinalysis**
  - by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; **non-automated, with microscopy**
- **Urinalysis,**
  - by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; **automated, with microscopy (NOTE: May only be used when the lab is using an automated dipstick urinalysis instrument approved as waived.)**
- **Urinalysis; two or three glass test**
- **Fecal leukocyte examination (Effective: January 1, 2004)**
- **Semen analysis; presence and/or motility of sperm excluding Huhner**
- **Nasal smears for eosinophils**

# Non-Waived Specialties & Subspecialties

- **Histocompatibility**
- **Microbiology**
  - Bacteriology
  - Mycobacteriology
  - Mycology
  - Parasitology
  - Virology
- **Diagnostic Immunology**
  - Syphilis Serology
  - General Immunology
- **Chemistry**
  - Routine Chemistry
  - Urinalysis
  - Endocrinology
  - Toxicology
- **Hematology**
- **Immunohematology**
  - ABO/RH
  - Antibody Detection
  - Antibody Identification
  - Compatibility Testing
  - Immunohematology (Other)
- **Pathology**
  - Histopathology
  - Oral Pathology
  - Cytology
- **Clinical Cytogenetics**
- **Radiobioassay**

# Classification of Tests

- Clinical laboratories are required to be licensed by the State of Florida and certified by CLIA in the non-waived specialties or subspecialties in which they perform testing.
- Therefore, it is important to know which tests belong to which specialty or subspecialty.

# Classification Resources

- The [FDA-CLIA Database](#)
  - The FDA and CLIA have developed a database that provides information about the complexity and specialty/subspecialty of all currently approved laboratory test systems.
  - Several ways to search including: test system or manufacturer and analyte.

# Classification Resources

- The [Healthcare Common Procedure Coding System \(HCPCS\) Code Subject to CLIA Edits](#)
  - Every year the CLIA program publishes a list of tests that are subject to CLIA regulations.
  - The above link is the listing as of June 20, 2011.
  - The list is organized by Current Procedural Terminology (CPT©) Code and HCPCS Code and provides a description of each in addition to the Laboratory Certification (LC) Code.
  - The [LC Code](#) listing will indicate the specialty/subspecialty the test belongs to.

# Caution!

- Not all tests are listed in the FDA-CLIA database.
  - i.e. Pathology testing is not listed since it doesn't use a “test system”.
- The HCPCS List does not tell you the complexity of the test.
  - All Pathology testing is High Complexity.
- Sometimes there is more than one LC Code in the HCPCS for a listed test.
  - In these instances you will need to determine the intent of the testing.
    - i.e. A given test may show LC Codes for Routine Chemistry and General Immunology. If you are looking for an antigen it would be Routine Chemistry but, if you are looking for an antibody it would be General Immunology.

# Obtaining and Maintaining Certification & Licensure



# Keys to Success

- Be familiar the laws and regulations.
- Plan and prepare.
- Use the correct forms.
- Read the instructions.
- Include the payment.
- Keep a copy.
- Submit to the correct address.
- Know key timeframes.
- Monitor your mail.

# Laws and Regulations

- CLIA

[Title 42, Part 493 of the Code of Federal Regulations](#)

- AHCA

[Chapter 483, Part I, F.S.](#)

[Chapter 408, Part II, F.S.](#)

[Chapter 59A-7, F.A.C.](#)

[Chapter 59A-35, F.A.C.](#)

- DOH

[Chapter 483, Part III, F.S.](#)

[Chapter 64B3, F.A.C.](#)

# Plan and Prepare

- Be familiar with the ownership structure of your facility.
- Know the specific tests your laboratory performs or intends to perform and their complexity and classifications.
- Identify key personnel i.e. Laboratory Director, Clinical Consultants, Financial Officers, etc.
- Review information on the Lab Unit's [website](#).

# Use the Correct Forms

- There are currently two versions of recommended clinical laboratory licensure applications.
- Both are available in pdf format at this website:

[http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Laboratory\\_Licensure/applications.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/applications.shtml)

- One for initial, renewal, change of ownership, change of status and other changes.
  - Includes:
    - AHCA Form 3170-2004, Revised August 2010
    - AHCA Recommended Form 3110-1024, August 2010
    - AHCA Form 3100-0008, August 2010
    - Form CMS-116 (10/10)
- One for addition of specialty/subspecialty outside of the renewal period.
  - Includes:
    - AHCA Form 3170-2004D, Revised August 2010
    - AHCA Form 3100-0008, August 2010
    - Form CMS-116 (10/10)

# Uses

AHCA Form 3170-2004, Revised August 2010

- Initial
  - Establishes licensure of a new location
  - Re-establishes licensure of an existing location who failed to renew the license or timely report a change of ownership
  - **CLIA application Required**
- Renewal
  - May also add specialties/subspecialties at time of renewal.
  - **CLIA application only required if adding specialties/subspecialties or changing laboratory director at time of renewal.**
- Change of Ownership
  - Submitted by the **transferee** to report one of the following transactions, as defined by s. 408.803(5), F.S.:
    - An event in which the licensee sells or otherwise transfers its ownership to a different individual or entity as evidenced by a change in federal employer identification number or taxpayer identification number
    - An event in which 51 percent or more of the ownership, shares, membership, or controlling interest of a licensee is in any manner transferred or otherwise assigned. This paragraph does not apply to a licensee that is publicly traded on a recognized stock exchange.
  - **Does NOT “renew” or maintain existing license.**
  - **CLIA application required.**

# Uses

- AHCA Form 3170-2004, Revised August 2010
  - Change of Status
    - Changing survey entities i.e. accredited to compliance
    - **CLIA application required.**
  - Other changes
    - Change of provider name (not change of ownership)
    - Change of physical address
    - Change of licensee name (not change of ownership)
    - May also be reported via correspondence.
    - Change of Laboratory Director (**CLIA application required.**)
- AHCA Form 3170-2004D, Revised August 2010
  - Addition of Specialty/Subspecialty
    - To expand services at an existing laboratory at times other than initial, renewal or change of ownership.
    - **CLIA application required.**

# The Instructions are Key

- In addition to the provided forms the instruction checklist identifies additional information that must be included with the application(s).

# Include the Payment

- The licensure fee must be included with any State of Florida Clinical Laboratory application.
- Applications will be returned to the applicant unprocessed if the fee does not accompany the application.
- Make checks or money orders payable to the Agency for Health Care Administration.
- Do NOT submit payment for CLIA certification to the Agency.
  - If submitted they will be returned.
  - Your laboratory will be invoiced by the CLIA Program for any required fee.

# Keep a Copy

- It is highly recommended that you maintain a copy of all documents submitted to the Agency for your records.

# Submit to the Correct Address

- All Florida Clinical Laboratory Licensure and CLIA applications should be submitted to:

Agency for Health Care Administration  
Laboratory Licensure Unit  
2727 Mahan Drive, MS#32  
Tallahassee, Florida 32308

# Know Key Timeframes

- Renewal applications must be received between 120 and 60 days before expiration of the current license.
  - Failure to timely file renewal will result in fines.
- Change of Ownership applications must be received at least 60 days before the effective date of the transaction.
  - Failure to submit an application for licensure prior to the effective date of the change of ownership to a different legal entity constitutes unlicensed activity.
  - Applications submitted after the effective date will result in administrative action to deny the application.
  - The effective date of the change of ownership shall not be extended more than 60 days from the effective date reported on the application.
    - The Agency will deem the application withdrawn if the change of ownership does not occur within 60 days of the reported effective date.
  - Written notification of a change in the effective date must be received by the Agency prior to the originally reported effective date.

# Key Timeframes

- Requests to change the name and/or address of record must be received at least 21 days before the change.
  - Failure to timely file will result in a \$500.00 fine.
  - The provider is not authorized to operate in the new location until a license is obtained that specifies the new location.
  - Failure to amend a license prior to a change of address of record constitutes unlicensed activity.
    - The fine for unlicensed activity is \$1000.00/day.
- Requests to change the laboratory director of record must be received at least 21 days before the change.

# Monitor Your Mail

- The Agency will send a renewal reminder notice to the mailing address of record from 120 to approximately 90 days before the expiration of the current license.
- Once received all applications will be reviewed within 30 days of receipt.
- If a letter of omission is needed to request incorrect or incomplete documentation, it will be sent by certified mail within 30 days of the application's receipt.
- All information needed to complete the application must be received by the Agency within 21 calendar days of receipt of the omission letter.
  - Failure to return all information within this timeframe will result in administrative action to deem the application incomplete and withdrawn from further consideration.
  - **EXCEPTION:** In a Change of Ownership application, the transferee's right to occupy (i.e. Bill of Sale/Closing Documents) must be received within 10 days of the effective date.
- Once complete (including proof of successful on-site inspection if required) the license will be issued within 60 days.

# Important Points!

- The license is valid only for the provider, licensee, services and locations for which the license is issued as it appears on the license.
- Clinical laboratories are not authorized to perform any non-waived testing (including PPM procedures) until they have been issued a license.
- The State of Florida does not issue a laboratory license until after their application is complete and they have passed on-site inspection (if required).

# Common Mistakes in Completing Applications

## Section 1A – Provider Information

Under the authority of Chapter 408 Part II and Chapter 483, Part I, Florida Statutes (F.S.), and Chapter 59A-7, Florida Administrative Code (F.A.C.), an application is hereby made to operate a non-waived clinical laboratory as indicated below.			
<b>1. Provider / Licensee Information</b>			
<b>A. Provider Information</b> – please complete the following for the clinical laboratory name and location. Provider name, address and telephone number will be listed on <a href="http://www.floridahealthfinder.gov/">http://www.floridahealthfinder.gov/</a>			
AHCA Laboratory License #:		CLIA # <u>  </u> D <u>  </u>	
National Provider Identifier (NPI) (if applicable)		Medicare # (CMS CCN)	Medicaid #
Name of Laboratory (This is not the owner of the laboratory; it is the lab name, which is often fictitious.):			
Street Address			
City		County	State    Zip
Telephone Number	Fax Number	E-mail Address	Provider Website
Mailing Address or <input type="checkbox"/> Same as above (All certified correspondence will be sent to the mailing address.)			
City		State	Zip
Contact Person for this application:			Contact Telephone Number:
Contact e-mail address or <input type="checkbox"/> Do not have e-mail		<b>NOTE:</b> By providing your e-mail address you agree to accept e-mail correspondence from the Agency	

“Provider” is defined by s. 408.803(11), F.S. as “any activity, service, agency or *facility* regulated by the agency and listed in s. 408.802”.

This section should list information about where the clinical laboratory services are provided.

If the laboratory name listed in this section is different than the licensee name reported in Section 1A there must be proof of fictitious name registration on file with the Department of State Division of Corporations.

## Section 1B – Licensee Information

<b>B. Licensee Information</b> - please complete the following for the entity seeking to operate the laboratory.			
Licensee Name (This is the owner of the laboratory and the individual or entity to which the license will be issued)		Federal Employer Identification Number (EIN)	
Mailing Address			
City		State	Zip
Telephone Number	Fax Number	E-mail Address	

Description of Licensee (check one):		
<u>For Profit:</u>	<u>Not for Profit</u>	<u>Public</u>
<input type="checkbox"/> Corporation	<input type="checkbox"/> Corporation	<input type="checkbox"/> State
<input type="checkbox"/> Limited Liability Company	<input type="checkbox"/> Religious Affiliation	<input type="checkbox"/> City/County
<input type="checkbox"/> Partnership	<input type="checkbox"/> Limited Liability Company	<input type="checkbox"/> Special Tax District
<input type="checkbox"/> Individual	<input type="checkbox"/> Other: _____	
<input type="checkbox"/> Other: _____		

“Licensee” is defined by s. 408.803(9), F.S. as “an individual, corporation, partnership, firm, association, governmental entity, or other entity that is issued a permit, registration, certificate, or license by the agency. *The licensee is legally responsible for all aspects of the provider operation*”.

If an applicant, licensee, or controlling interest is required to file with the Florida Secretary of State, Division of Corporations, the principle, fictitious name and mailing address submitted with the licensure application for the applicant, licensee, and controlling interests must be the same as the information registered with the Division of Corporations. (Reference 59A-35.060, F.A.C.)

# Section 2 – Application Type

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## 2. Application Type and Fees

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AHCA Form 3170-2004, Revised August 2010  
Page 1 of 15

Subsection 59A-35.060(1), Florida Administrative Code  
Form available at: <http://ahca.myflorida.com/Publications/Foms/HQA.shtml>

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**Indicate the type of application with an “X”. Applications will be returned and not processed if not accompanied by appropriate fee. All fees are nonrefundable.**

- Initial license *(CMS-116 form must accompany the application)*  
Was this a previously licensed clinical laboratory in Florida?  Yes  No  
If yes, what was the license number: 8000 \_\_\_\_\_ and CLIA number  D \_\_\_\_\_
- Renewal license
- Change of Ownership *(include CMS-116 form)* Proposed Effective Date: \_\_\_\_\_
- Change in Status **-required** for change from accredited to compliance laboratory; may be used when changing from compliance to accredited laboratory. *(CMS 116 form must accompany the application)* Full fee must be included if changing from accredited to compliance.
- Other Change Include cover letter describing the change and CMS-116 form if required

- Cannot change ownership and renew with the same application.
- Cannot renew after the expiration of the current license.
- Must indicate the proposed effective date of the change of ownership.
- Cannot change ownership after the effective date.

# Section 2 – Application Fees

**FEE SCHEDULE** (for assistance in determining how to count tests, please review information at:

[http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Laboratory\\_Licensure/count.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/count.shtml))

- If a laboratory performs no more than 2,000 tests annually, the fee is \$400.
- If a laboratory performs no more than 3 categories of procedures with a total annual volume of more than 2,000 but no more than 10,000 tests, the license fee is \$965.
- If a laboratory performs at least 4 categories of procedures with a total annual volume of not more than 10,000 tests, the license fee is \$1,294.
- If a laboratory performs not more than 3 categories of procedures with a total annual volume of more than 10,000 but not more than 25,000 tests, the license fee is \$1,592.
- If a laboratory performs at least 4 categories of procedures with a total annual volume of more than 10,000 but not more than 25,000 tests, the license fee is \$2,103.
- If a laboratory performs a total of more than 25,000 but no more than 50,000 tests annually, the license fee is \$2,364.
- If a laboratory performs a total of more than 50,000 but no more than 75,000 tests annually, the license fee is \$2,625.
- If a laboratory performs a total of more than 75,000 but no more than 100,000 tests annually, the license fee is \$2,886.
- If a laboratory performs a total of more than 100,000 but no more than 500,000 tests annually, the license fee is \$3,397.
- If a laboratory performs a total of more than 500,000 but no more than 1 million tests annually, the license fee is \$3,658.
- If a laboratory performs a total of more than 1 million tests annually, the license fee is \$3,919.

*The agency shall assess a biennial fee of \$100 license fee for facilities surveyed by an approved accrediting organization.*

**LICENSE FEE:**

<input type="checkbox"/> Total Annual Non-waived test volume	<input type="text"/>	/ Fee \$	<input type="text"/>	\$	<input type="text"/>	
OR <input type="checkbox"/> Accredited lab fee				\$	100.00	
<input type="checkbox"/> Change During Licensure Period/Replacement License				\$	25.00	
<b>TOTAL FEES INCLUDED WITH APPLICATION:</b>					\$	<input type="text"/>

*Please make check or money order payable to the Agency for Health Care Administration (AHCA)*

**Application Fees:**

- If your facility is NOT accredited, the initial or renewal fee is based on the non-waived annual test volume.
- If your facility IS accredited, the initial or renewal fee is \$100.00.
- The fee for a CHOW is the same as initial or renewal.
- Contact the Laboratory Unit if you are changing from accredited to compliance during the licensure period to determine what, if any, fee is required.
- If you are changing your name/address the fee is \$25.00.
- If adding specialties/subspecialties minimum fee of \$25.00. If there is a change in overall volume the difference is required.



# Calculating Test Volumes

- Established by Section 59A-7.036, F.A.C.
- Do Not Count:
  - Tests defined as waived pursuant to Section 483.041(10), F.S.
  - Tests referred to another laboratory.
  - Calculated test results
    - Example: On a Complete Blood Count (CBC) the Hematocrit (Hct), Mean Platelet Volume (MPV), Mean Corpuscular Hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration (MCHC) and Red Cell Distribution (RDW) are calculated values.
  - Quality Control Samples
  - Proficiency Testing Samples
  - Calibration/Calibration Verification Testing Samples

# Counting Test Volumes

- Each test performed shall be counted individually.
- If test profiles composed of multiple tests are performed on the same patient sample, each individual measured analyte shall be counted as one test.
  - Example:
    - A CBC is a panel/profile composed of 5 measured analytes:
      - White Blood Cells (WBC),
      - Red Blood Cells (RBC),
      - Hemoglobin (Hgb),
      - Platelet Count, and
      - Mean Corpuscular Volume (MCV))
    - and calculated values:
      - Hematocrit (Hct),
      - Mean Platelet Volume (MPV),
      - Mean Corpuscular Hemoglobin (MCH)
      - Mean Corpuscular Hemoglobin Concentration (MCHC) and
      - Red Cell Distribution (RDW)
  - Differentials (3-part, 5-part, automated or manual) count as one (1) measured analyte.
  - If your laboratory performs 100 CBC's all with a 5-part automated Differential per year you are actually performing 600 non-waived tests (one (1) for each of the measured analytes).

# Calculating Test Volumes

- For microbiology:
  - Each sample shall be counted as one test, regardless of the number of organisms isolated or identified.
  - Each organism for which an antibiotic sensitivity testing is performed shall be counted as one test.
- For histopathology:
  - Each block shall be counted as one test, regardless of the number of slides prepared.
  - Each special stain is counted as one test.
- For cytology, each cytology slide shall be counted as one test.
- For histocompatibility, each HLA typing, antibody screen, and crossmatch shall be counted as one test each.
- For allergen testing, each allergen shall be counted as one test.
- For urinalysis:
  - Each non-waived macroscopic examination shall be counted as one test.
  - Each urinalysis microscopic examination shall be counted as one test.
- For immunohematology, each ABO grouping, Rh typing, antibody detection, antibody identification, and cross match shall be counted as one test each.
- For cytogenetics, each separate specimen type tested is counted as one test.

## Section 3A – Individual and/or Entity Ownership of Licensee.

**DEFINITIONS:**

**Controlling interests**, as defined in s. 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.

**Voluntary Board Member**, as defined in s. 408.803(13), F.S., means a board member or officer of a not-for-profit corporation or organization who serves solely in a voluntary capacity, does not receive any remuneration for his or her services on the board of directors, and has no financial interest in the corporation or organization.

In Sections A and B below, 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.

**A. Individual and/or Entity Ownership of Licensee**

FULL NAME of INDIVIDUAL or ENTITY	PERSONAL OR BUSINESS ADDRESS	TELEPHONE NUMBER	EIN (No SSNs)	% OWNERSHIP INTEREST

- Name(s) of any individual or other legal entity that has 5% or greater ownership interest in the licensee reported in Section 1B.
- Cannot list the licensee itself.
- If non-profit indicate “N/A – No individual/entity with 5% or greater ownership interest in licensee.”

# Section 12- Personnel

- The financial officer/ Chief Financial Officer (CFO) or similarly titled individual responsible for the financial operation of the provider.
- Laboratories performing non-waived testing, other than PPM testing are required by state and federal regulations to have a clinical consultant.
  - Clinical consultant can be the laboratory director.
  - Must be qualified to direct the laboratory OR be currently licensed as a physician (MD or DO) in the state where the laboratory is physically located.

# Section 13 – Non-Waived Tests

## 13. Non-Waived Tests

- **Quality Assurance** – Attach copy of protocol if you do not use a PT company. This applies to PPM labs and Histopathology.
- **Specialty/Subspecialty** – Check the box preceding each specialty/subspecialty for which the laboratory seeks licensure. If you do not know which specialty to mark a listing of all tests and their related specialties can be found on the FDA website at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm>, or on the Federal CLIA website at [http://www.cms.hhs.gov/CLIA/10\\_Categorization\\_of\\_Tests.asp#TopOfPage](http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage).
- **Annual Test Volume** – Enter the test volume for the previous calendar year for each specialty/subspecialty.
- **Accreditation Program Name** – If your program is accredited by an approved accreditation organization, enter the name (initials) of the organization for each specialty/subspecialty in which the laboratory is accredited.
- **Proficiency Program Name** – Enter the name (initials) of the proficiency testing program in which the laboratory participates for each specialty/subspecialty.

Specialty/Subspecialty	Annual Test Volume	Accreditation Program Name	Quality Assurance or Proficiency Program Name	Specialty/Subspecialty	Annual Test Volume	Accreditation Program Name	Quality Assurance or Proficiency Program Name
<input type="checkbox"/> MICROBIOLOGY				<input type="checkbox"/> HEMATOLOGY			
<input type="checkbox"/> Bacteriology				<input type="checkbox"/> IMMUNO- HEMATOLOGY			
<input type="checkbox"/> Mycobacteriology				<input type="checkbox"/> ABO Group & Rh Group			
<input type="checkbox"/> Mycology				<input type="checkbox"/> Antibody Detection (Transfusion)			
<input type="checkbox"/> Parasitology				<input type="checkbox"/> Antibody Detection (Non-Transfusion)			
<input type="checkbox"/> Virology				<input type="checkbox"/> Antibody Identification			
<input type="checkbox"/> DIAGNOSTIC IMMUNOLOGY				<input type="checkbox"/> Compatibility Testing			
<input type="checkbox"/> Syphilis Serology				<input type="checkbox"/> PATHOLOGY			
<input type="checkbox"/> General Immunology				<input type="checkbox"/> Histopathology			
<input type="checkbox"/> CHEMISTRY				<input type="checkbox"/> Oral Pathology			
<input type="checkbox"/> Routine Chemistry				<input type="checkbox"/> Cytology			
<input type="checkbox"/> Urinalysis				<input type="checkbox"/> CLINICAL CYTOGENETICS			
<input type="checkbox"/> Endocrinology				<input type="checkbox"/> HISTO-COMPATIBILITY			

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Subsection 59A-35.060(1), Florida Administrative Code  
Form available at: <http://ahca.myflorida.com/Publications/Forms/HQA.shtml>

- Report only non-waived test volumes.
- Only check specialty box if you perform testing in all subspecialties.
- Do not list individual tests.
- Do not list volume ranges.
- Do not list “0”.
- If you perform PPM or Histopathology, must include copy of Quality Assurance protocol or proof of Proficiency Testing participation.
- Volumes should correlate with what is reported in Section 14.

# Section 14 – List of Tests Performed

- Histopathology, Mycology, PPM etc. are NOT tests.
- Do not list CPT codes.
- Do not list panels i.e. CBC, BMP, Lipids, Urinalysis.
- Do not report volume ranges.
- Report a volume for each test.
- List all tests, waived and non-waived.
- List the specific instrument/test kit including manufacturer.

# Section 15 – Microscopy Evaluation Survey

- Not required if the laboratory performs testing other than waived and PPM.
- Must include Quality Assurance protocol if submitting.
- Must include proof of laboratory director qualifications if submitting.

# Section 16 – Self Evaluation Survey

- Not required for PPM only laboratories.
- Only required if the laboratory is applying to re-establish licensure of a facility who failed to renew.

# Health Care Licensing Application Addendum

- Must be completed.
- Section 1A:
  - The Laboratory Director is considered to be the “Administrator/CEO/Managing Employee”
  - The CFO is the financial officer reported in Section 12.
- Sections 2 and 3:
  - Information in these sections must match what is reported in Sections 3 and 4 of the Health Care Licensing Application.

# Background Screening

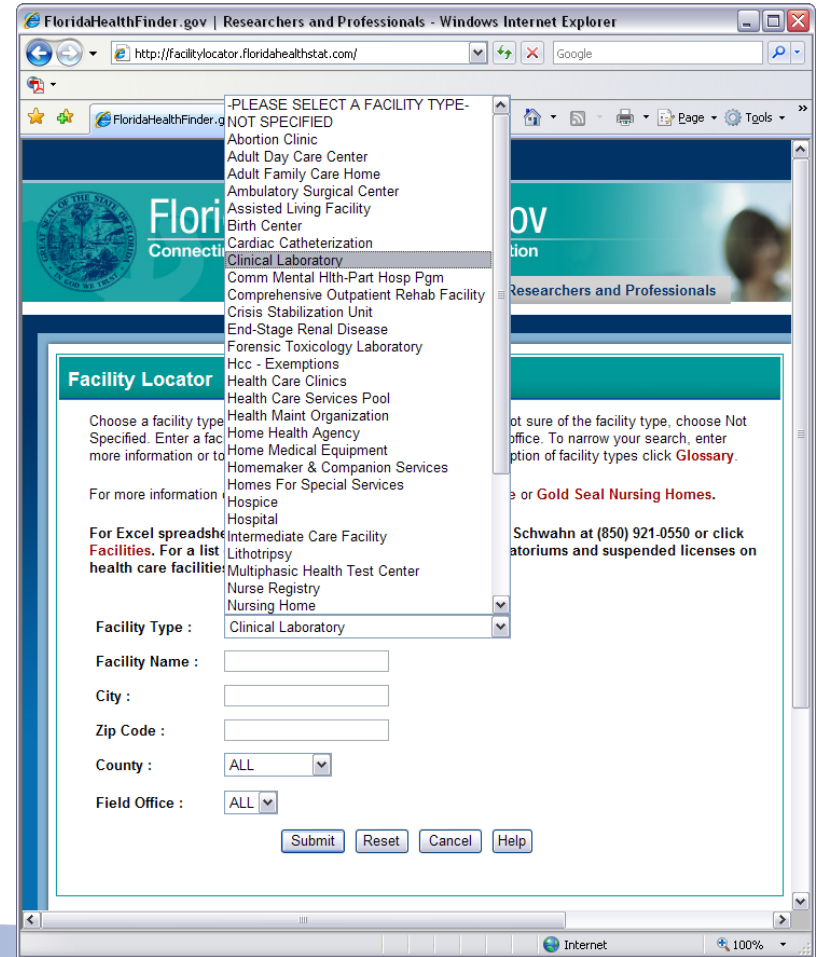
- Required for the Laboratory Director AND Financial Officer (if different).
- Must be performed through the Agency.
- Results of screenings performed within the past five (5) years should be submitted with the application along with the Affidavit of Compliance with Background Screening Requirement.
- More information available at:  
[http://ahca.myflorida.com/MCHQ/Long\\_Term\\_Care/Background\\_Screening/index.shtml](http://ahca.myflorida.com/MCHQ/Long_Term_Care/Background_Screening/index.shtml).

# Verify License Status



# Florida Health Finder

- An existing laboratory can check the status of its application on-line at: <http://www.floridahealthfinder.gov/>
- Choose “facility locator”
- Then choose “clinical laboratory”
- Enter search parameters.
- Results can be exported into an Excel spreadsheet.



# Laboratory Unit Contacts & Information



- Main Line: (850) 412-4500
- Unit E-mail:  
[LABSTAFF@ahca.myflorida.com](mailto:LABSTAFF@ahca.myflorida.com)
- Specific Consultant Contacts are available at:  
[http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Laboratory\\_Licensure/maps.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/maps.shtml)

- **Clinical Laboratory Unit Website:**  
[http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Laboratory\\_Licensure/clinical.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/clinical.shtml)
- **Laboratory Rule Development:**  
[http://ahca.myflorida.com/mchq/health\\_facility\\_regulation/laboratory\\_licensure/rule\\_dev.shtml](http://ahca.myflorida.com/mchq/health_facility_regulation/laboratory_licensure/rule_dev.shtml)

# Questions?



# Thank You!

