



**APPLICATION CHECKLIST**  
**Health Care Licensing Application**  
**CLINICAL LABORATORIES – NON-WAIVED**  
(Addition of Specialty, Subspecialty or Change in Specialty at Time Other than Licensure Renewal)

Applicants **must** include the following attachments as stated in Chapter 483, Part I, Florida Statutes (F.S.) regarding Clinical Laboratories, Chapter 408, Part II, F.S., and Chapters 59A-35 and 59A-7, Florida Administrative Code (F.A.C.). 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 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. **The application will be withdrawn from review if all the required documents and fees are not included with this application or received within 21 days of an omission notice.**

All forms listed below may be obtained from the Agency's website: <http://ahca.myflorida.com/Publications/Forms/HQA.shtml>. Send completed applications to: Agency for Health Care Administration, Lab Unit, 2727 Mahan Drive, Mail Stop 32, Tallahassee, FL 32308.

**Addition of Specialty, Subspecialty or Change in Specialty at Time Other than Licensure Renewal, application for Non-Waived Laboratory** (including Provider-performed microscopy procedures)

- The licensure fee in accordance with the fee schedule in section 483.172, F.S. is provided in Section 2 of this application and in accordance with the requirements of subsection 59A-7.036 (5) & (6), F.A.C. Please make check or money order payable to the Agency for Health Care Administration. All fees are nonrefundable. *NOTE: Starter checks and temporary checks are not accepted.*
- Health Care Licensing Application, Clinical Laboratory (Non-Waived), AHCA Form 3170-2004D
- Provider Performed Microscopy Evaluation Survey – *only applicable to labs that limit procedures to provider performed microscopy (waived tests are also allowed) – see list at: <http://www.cms.hhs.gov/CLIA/downloads/ppmp.list.pdf>.*
- A completed federal CMS 116 form.
- Copy of Medical/professional license.
- Provide evidence that the director is qualified (see section 483.824, F.S.) for the additions. **NOTE:** Documentation must show laboratory experience/training.
- Level 2 background screening of the Lab Director and Financial Officer is required every 5 years. Please select all that apply:
  - The  Lab Director  Financial Officer submitted a Level 2 screening through a **LiveScan vendor** approved to submit fingerprint requests through the Florida Department of Law Enforcement (FDLE). For more information regarding LiveScan vendors please see the Agency's background screening website 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).

All screening results **must be sent** to the **Agency for Health Care Administration** (Agency) for review and eligibility determinations. If you choose to use a LiveScan source other than the Agency's contracted vendor you **must provide** the following **ORI FL922020Z** and identify the Agency for Health Care Administration as the recipient of the screening results to ensure the results are reviewed by the Agency. If the Agency does not receive the result, additional screening and fees may be required.

The Agency has created a form that you may use to take to the vendor. You may access this form, Background Screening Validation, on the Agency's website 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).

- The  Lab Director  Financial Officer are out of state and do not have access to a Florida LiveScan vendor and will submit a fingerprint card (**you must obtain a fingerprint card from the Agency**. To request a fingerprint card please contact the Agency's Background Screening Section at (850)412-4503 or email [bgscreen@ahca.myflorida.com](mailto:bgscreen@ahca.myflorida.com)). The completed fingerprint card must then be submitted to:
- The Agency's contracted vendor, Cogent Systems, along **with a fee of \$58.25** (\$43.25 for the screening + \$15.00 processing fee). The fingerprint card must be filled out completely and the fingerprints taken by law enforcement personnel or individual trained in processing fingerprints. Return the completed card to:

Cogent Systems  
5450 Frantz Rd.  
Dublin, OH 43016

- Another LiveScan vendor authorized to provide services in Florida that is equipped to transmit the images of the fingerprints from the fingerprint card electronically. This requires special equipment and not all LiveScan vendors have this ability. You may find

LiveScan vendor contact information on the FDLE website: <http://www.fdle.state.fl.us/Content/getdoc/04833e12-3fc6-4c03-9993-379244e0da50/livescan.aspx>.

- Proof of Level 2 screening within the previous 5 years for the  Lab Director  Financial Officer from the Agency's Medicaid Division, the Department of Children and Families, Department of Health, Agency for Persons with Disabilities or Department of Financial Services (if the applicant has a certificate of authority to operate a continuing care retirement community) is included with this application. An Affidavit of Compliance with Background Screening Requirements, AHCA Form 3100-0008, is also enclosed.
- Level 2 screening has been conducted within the previous 5 years for the  Lab Director  Chief Financial Officer through the Agency's Background Screening Unit or a LiveScan vendor. An Affidavit of Compliance with Background Screening Requirements, AHCA Form 3100-0008, is also enclosed.

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**Definitions of terms used in this application and the addendum, AHCA Form 3110-1024:**

**"Administrator"** means individual who is responsible for the day-to-day operation of the provider. For clinical laboratories, this individual is the Laboratory Director. [see s. 408.809 (1), F.S]

**"Clinical Consultant"** as described in section 493.1411 -1419 of the Code of Federal Regulation and required for clinical laboratory operations under Florida Rule 59A-7.035, Florida Administrative Code.

**"Exclusive Use Laboratory"** means a clinical laboratory operated by one or more of the following exclusively in connection with the diagnosis and treatment of their own patients: physician licensed under Chapter 458 or 459, F.S.; chiropractor licensed under Chapter 460, F.S.; podiatrist licensed under Chapter 461, F.S.; naturopathist licensed under Chapter 462, F.S.; or dentist licensed under Chapter 466, F.S. [see 59A-7.020(11), F.A.C.]

**"Financial Officer"** means individual who is responsible for the financial operation of the licensee or provider. [see s. 408.809 (1), F.S]

**"Licensee"** means 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.** [see s. 408.803 (9), F.S]

**"Provider"** means any activity, service, agency, or facility regulated by the agency such as a clinical laboratory. *Providers* are often the fictitious name used by the *licensee*. [see s. 408.803 (11), F.S]

The Agency for Health Care Administration scans all documents for electronic storage. In an effort to facilitate this process, we ask that you **please place checks, money orders and fingerprint cards on top of the application and paperclip** everything together. Please **do not staple or bind documents** submitted to the Agency.



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

## Health Care Licensing Application CLINICAL LABORATORIES (NON-WAIVED)

(Addition of Specialty, Subspecialty or Change in Specialty at Time Other than Licensure Renewal)

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.

### 1. Provider / Licensee Information

<b>A. Provider Information</b> – please complete the following for the clinical laboratory name and location. <i>Provider name, address and telephone number will be listed on <a href="http://www.floridahealthfinder.gov/">http://www.floridahealthfinder.gov/</a></i>			
AHCA Laboratory License #:		CLIA # ___ D _____	
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	
<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: _____			

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## 2. Application Fees

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Applications will be returned and not processed if not accompanied by appropriate fee. All fees are nonrefundable.

**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:

- Total Annual Non-waived test volume \_\_\_\_\_ / Fee \$ \_\_\_\_\_ \$ \_\_\_\_\_  
OR  
 Accredited lab fee \$100.00

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

*NOTE: Starter checks and temporary checks are not accepted.*

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## 3. Required Disclosure

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The following disclosures are required:

- A. Pursuant to s. 408.809(1)(d), F.S., the applicant shall submit to the Agency a description and explanation of any convictions of offenses prohibited by ss. 435.04 and 408.809(5), F.S., for each controlling interest.

Has any individual listed in sections 3 and 4 of this application been convicted of any level 2 offense pursuant to s. 408.809(1)(d), F.S.? (These offenses are listed on the [Affidavit of Compliance with Background Screening Requirements](#), AHCA Form #3100-0008.)

YES  NO

If yes, enclose the following information:

- The full legal name of the individual and the position held
- A description/explanation of the conviction(s) - If the individual has received an exemption from disqualification for the offense, include a copy.

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

Has any individual 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
- A description/explanation of the exclusion, suspension, termination or involuntary withdrawal.

C. Pursuant to s. 408.815(4), F.S., does the applicant or any controlling interest in an applicant have any of the following:

YES  NO  Convicted of, or enters 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, within the previous 15 prior to the date of the application;

YES  NO  Terminated for cause from the Florida Medicaid Program pursuant to s. 409.913, and have not been in good standing with the Florida Medicaid Program for the most recent 5 years;

YES  NO  Terminated for cause, pursuant to the appeals procedures established by the state or federal government, from the federal Medicare program or from any other state Medicaid program, have not been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination was less than 20 years prior to the date of the application.

## 4. Provider Fines and Financial Information

Pursuant to s. 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):

Amount: \$ \_\_\_\_\_ assessed by:  Agency for Health Care Administration Case # \_\_\_\_\_  CMS

Date of related inspection, application or overpayment period if applicable: \_\_\_\_\_

Due date of payment: \_\_\_\_\_

Is there an appeal pending from a Final Order? YES  NO

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

## 5. Accreditation

Is this Laboratory a member of an approved accreditation organization?  YES  NO

If yes, please select the appropriate accreditation organization: (**NOTE:** Participation in a Proficiency Testing Program is not equivalent to accreditation.)

CAP  COLA  TJC  AABB  ASHI  AOA Date of last Accreditation Survey: \_\_\_\_\_

## 6. Personnel

Provide the following information:

<b>DIRECTOR (full name)</b>	<b>Professional Degree</b>	<b>Board Certified By</b>	<b>Florida Professional License #</b>	<b>Hours Spent in Lab (Per Week)</b>	<b>Lab Experience (Years)</b>
<b>CO-DIRECTOR (full name)</b>	<b>Professional Degree</b>	<b>Board Certified By</b>	<b>Florida Professional License #</b>	<b>Hours Spent in Lab (Per Week)</b>	<b>Lab Experience (Years)</b>
<b>FINANCIAL OFFICER (Full Name)</b>			<b>Financial Officer Florida Professional License # (optional)</b>		

Check this box if the Laboratory Director also serves as the Financial Officer.

Has either the Director or Financial Officer ever been excluded, suspended, terminated or involuntarily withdrawn from participation in the Medicare, Medicaid, or any other governmental or private health care/insurance programs pursuant to Chapter 483, F.S.?

YES  NO  If yes, enclose the following information:

- The full legal name of the individual and the position held
- A description and explanation of any exclusions, permanent suspensions, terminations or involuntary withdrawals from any of the above listed programs. (Proof of compliance with the requirements for disclosure of ownership and control interest under the Medicare or Medicaid programs may be accepted in lieu of this submission).

Has either the Director or Financial Officer ever been found by any professional licensing, certifying or standards board/agency to have violated the standards or conditions relating to licensure or certification or the quality of services provided pursuant to s. 483.825, F.S.?

YES  NO  If yes, enclose the following information:

- The full legal name of the individual and the position held
- A description and explanation of any violations found and the name of the professional board/agency. (Proof of compliance with the requirements for disclosure of ownership and control interest under the Medicare or Medicaid programs may be accepted in lieu of this submission).

**Please list other laboratories directed by Director or Co-Director listed above. Note - no individual may be the director of more than five laboratories.**

LABORATORY NAME	AHCA Laboratory License #	Location
	8000	
	8000	
	8000	
	8000	
	8000	

All non-waived laboratories are required to have a qualified clinical consultant for moderately complex and high complexity testing.  
 [see CLIA regulations section 493.1450 & 493.1453]

CLINICAL CONSULTANT (Full Name)	Degree	Board Certified By	Florida Professional License #

LABORATORY SUPERVISOR(S) (Full Name)	Degree	Board Certified By	Florida Professional License #

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## 7. Collection Stations / Alternate Testing Sites

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Does the Laboratory operate any of the following?     Collection Stations     Alternate Site Testing (Hospitals Only)

Please complete the following as applicable:

**COLLECTION STATIONS: Reference 59A-7.024 F.A.C.** (attach additional sheets as needed):

Collection Station Name	Location

**ALTERNATE SITE TESTING (Hospitals Only): Reference 59A-7.034, F.A.C.** (attach additional sheets as needed).

If each bedside is a location, please note that as a single location by indicating "each bedside".

Location

## 8. Non-Waived Tests

- **Quality Assurance** – Attach copy of protocol if you do not use a PT company. This applies to PPM labs.
- **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). NOTE for renewal applicants: If the tests listed below do not match your CLIA certificate and state license, please explain the change and date of change in an attachment.
- **Annual Test Volume** – Enter the test volume for the previous calendar year for each specialty/subspecialty unless you expect a change. If initial applicant, please estimate. 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.
- **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.

### Check Boxes for Additions

Do not include tests for which the lab is currently license and certified.

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			
<input type="checkbox"/> Toxicology				<input type="checkbox"/> RADIOBIOASSAY			
<input type="checkbox"/> Provider- Performed Microscopy				<input type="checkbox"/>			



## 9. List of Tests Performed

Individually list all tests you intend to perform or if renewing the license, performed by name.

- Please be aware that injections do not qualify as laboratory tests
- **Do NOT** list panels such as CBC, BMP, CMP, ABG, Lipids, etc. You must separately list each component test of these panels.

Example Incorrect Listing	Example Correct Listing
CBC	WBC, RBC, Hgb, MCV, Differential (3 part, 5 part, manual or auto), Platelet * Please note, do not list tests with calculated results.
BMP	Glucose, Calcium, Sodium, Potassium, CO <sub>2</sub> , Chloride, BUN, Creatinine * Please note, do not list tests with calculated results.
CMP	Glucose, Calcium, Albumin, Total Protein, Sodium, Potassium, CO <sub>2</sub> , Chloride, BUN, Creatinine, ALP, ALT, AST, Bilirubin * Please note, do not list tests with calculated results.
ABG	pH, H <sup>+</sup> , PO <sub>2</sub> , PCO <sub>2</sub> , HCO <sub>3</sub> <sup>-</sup> , SBC <sub>e</sub> , HPO <sub>4</sub> <sup>2-</sup> , total CO <sub>2</sub> , total O <sub>2</sub> * Please note, do not list tests with calculated results.
Lipids	LDL, HDL, triglycerides

- **Do NOT** list specialties/subspecialties such as Mycology, Parasitology, Histopathology, PPMP, etc. You must separately list each test with the specialty/subspecialty.

Example Incorrect Listing	Example Correct Listing
Mycology	Skin fungi culture, Chlamydia culture, Yeast identification, Mold identification, Wet Mount, KOH preparations
Parasitology	Ova & Parasites, Pinworm, Trichomonas, Wet Mounts, KOH preparations
Histopathology	H&E stains, Mohs, frozen sections, bone marrow biopsies, Immunohistochemistry, Immunofluorescence
Clinical Cytogenetics	Urovysion FISH
PPM	Wet Mount, KOH preparations, Fern Tests, Post Coital exams

- Quality Assurance methodology for Provider Performed Microscopy Procedures should be listed in the column for Proficiency Testing Company and Program Set.
- Total non-waived information provided in #7 on page 5 should match the information provided here. Fees for non-accredited laboratories are calculated based on test volumes. Please make sure that you have submitted the proper fee.

Tests Performed On-Site (Waived and Non-waived Tests Required)	Exact Instrument, Test Kit, Dipstick, Etc. (reference FDA & CLIA Databases) <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm</a>	Annual Test Volume per test	Proficiency Testing Company and Program Set (not required for waived tests)

ATTESTATION: I \_\_\_\_\_, affirm under penalty of law that the above information and any attached information is a true representation of the testing to be performed at the above named clinical laboratory. I understand that omissions and errors in this declaration may affect the laboratory's licensure status and may affect payment for laboratory services under the Medicare and/or Medicaid programs.

Signed: \_\_\_\_\_  
Laboratory Director's Signature

Date: \_\_\_\_\_

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## 10. Affidavit

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I, \_\_\_\_\_, hereby swear or affirm that the statements in this application are true and correct. As administrator or authorized representative of the above named provider/facility, I hereby attest that all employees required by law to undergo Level 2 background screening have met the minimum standards of ss. 435.04, and 408.809(5), Florida Statutes (F.S.) or are awaiting screening results.

I further attest, under penalty of perjury, that no offenses listed under Chapter 435, F.S. for the level 2 screening have been committed by the Laboratory Director or Chief Financial Officer of this laboratory since the successful level 2 screening conducted through the Agency's background screening unit or LiveScan vendor for this provider, and therefore the provider is in compliance with the requirements under ss. 408.809(2), F.S.

In addition, I attest that all employees subject to Level 2 screening standards have attested to meeting the requirements for qualifying for employment and agree to inform me immediately if convicted of any of the disqualifying offenses while employed here as specified in s. 435.04(5), F.S.

\_\_\_\_\_  
Signature of Laboratory Director

\_\_\_\_\_  
Date

**RETURN THIS COMPLETED FORM WITH FEES TO:**

AGENCY FOR HEALTH CARE ADMINISTRATION  
CLINICAL LAB UNIT  
2727 MAHAN DR MS 32  
TALLAHASSEE FL 32308-5407

**Questions?**

Review the information available at:

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

If the director or administrator has questions after review, call 850.412.4500

## CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

### I. GENERAL INFORMATION

<input type="checkbox"/> Initial Application <input type="checkbox"/> Survey <input type="checkbox"/> Change in Certification Type <input type="checkbox"/> Other Changes <i>(Specify)</i> _____			CLIA IDENTIFICATION NUMBER  _____ D _____  <i>(If an initial application leave blank, a number will be assigned)</i>		
FACILITY NAME			FEDERAL TAX IDENTIFICATION NUMBER		
EMAIL ADDRESS			TELEPHONE NO. <i>(Include area code)</i>		FAX NO. <i>(Include area code)</i>
FACILITY ADDRESS — <i>Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing address is specified</i>			MAILING/BILLING ADDRESS <i>(If different from street address)</i>		
NUMBER, STREET <i>(No P.O. Boxes)</i>			NUMBER, STREET		
CITY	STATE	ZIP CODE	CITY	STATE	ZIP CODE
NAME OF DIRECTOR <i>(Last, First, Middle Initial)</i>			<b>FOR OFFICE USE ONLY</b>  Date Received _____		

### II. TYPE OF CERTIFICATE REQUESTED *(Check only one)*

- Certificate of Waiver *(Complete Sections I – VI and IX – X)*
- Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I – X)*
- Certificate of Compliance *(Complete Sections I – X)*
- Certificate of Accreditation *(Complete Sections I – X)* and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes
 

<input type="checkbox"/> The Joint Commission	<input type="checkbox"/> AOA	<input type="checkbox"/> AABB
<input type="checkbox"/> CAP	<input type="checkbox"/> COLA	<input type="checkbox"/> ASHI

**If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.**

**NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application.**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. The time required to complete this information collection is estimated to average 30 minutes to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

**III. TYPE OF LABORATORY** (Check the one most descriptive of facility type)

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> 01 Ambulance                                      | <input type="checkbox"/> 11 Health Main. Organization                        | <input type="checkbox"/> 22 Practitioner Other (Specify)               |
| <input type="checkbox"/> 02 Ambulatory Surgery Center                      | <input type="checkbox"/> 12 Home Health Agency                               |  |
| <input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility | <input type="checkbox"/> 13 Hospice  | <input type="checkbox"/> 23 Prison                                     |
| <input type="checkbox"/> 04 Assisted Living Facility                       | <input type="checkbox"/> 14 Hospital   | <input type="checkbox"/> 24 Public Health Laboratories                 |
| <input type="checkbox"/> 05 Blood Bank                                     | <input type="checkbox"/> 15 Independent                                      | <input type="checkbox"/> 25 Rural Health Clinic                        |
| <input type="checkbox"/> 06 Community Clinic                               | <input type="checkbox"/> 16 Industrial                                       | <input type="checkbox"/> 26 School/Student Health Service              |
| <input type="checkbox"/> 07 Comp. Outpatient Rehab Facility                | <input type="checkbox"/> 17 Insurance  | <input type="checkbox"/> 27 Skilled Nursing Facility/ Nursing Facility |
| <input type="checkbox"/> 08 End Stage Renal Disease Dialysis Facility      | <input type="checkbox"/> 18 Intermediate Care Facility for Mentally Retarded | <input type="checkbox"/> 28 Tissue Bank/Repositories                   |
| <input type="checkbox"/> 09 Federally Qualified Health Center              | <input type="checkbox"/> 19 Mobile Laboratory                                | <input type="checkbox"/> 29 Other (Specify)                            |
| <input type="checkbox"/> 10 Health Fair                                    | <input type="checkbox"/> 20 Pharmacy   |  |
|  | <input type="checkbox"/> 21 Physician Office                                 |  |
- Is this a shared lab?  Yes  No

**IV. HOURS OF LABORATORY TESTING** (List times during which laboratory testing is performed in HH:MM format)

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

**V. MULTIPLE SITES** (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?

- No. If no, go to section VI.  Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

- Is this a laboratory that has temporary testing sites?  
 Yes  No
- Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?  
 Yes  No  
If yes, provide the number of sites under the certificate \_\_\_\_\_ and list name, address and test performed for each site below.
- Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?  
 Yes  No  
If yes, provide the number of sites under this certificate \_\_\_\_\_ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here  and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION (Number, Street, Location if applicable)		
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION (Number, Street, Location if applicable)		
CITY, STATE, ZIP CODE	TELEPHONE NO. (Include area code)	

In the next three sections, indicate testing performed and annual test volume.

### VI. WAIVED TESTING

Identify the waived testing performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed \_\_\_\_\_

Check if no waived tests are performed

### VII. PPM TESTING

Identify the PPM testing performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all PPM tests performed \_\_\_\_\_

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the "total estimated test volume" in section VIII.

Check if no PPM tests are performed

If additional space is needed, check here  and attach additional information using the same format.

### VIII. NON-WAIVED TESTING (Including PPM testing)

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	
<b>HISTOCOMPATIBILITY</b>			<b>HEMATOLOGY</b>			
<input type="checkbox"/> Transplant			<input type="checkbox"/> Hematology			
<input type="checkbox"/> Nontransplant			<b>IMMUNOHEMATOLOGY</b>			
<b>MICROBIOLOGY</b>			<input type="checkbox"/> ABO Group & Rh Group			
<input type="checkbox"/> Bacteriology		<input type="checkbox"/> Antibody Detection (transfusion)				
<input type="checkbox"/> Mycobacteriology		<input type="checkbox"/> Antibody Detection (nontransfusion)				
<input type="checkbox"/> Mycology		<input type="checkbox"/> Antibody Identification				
<input type="checkbox"/> Parasitology		<input type="checkbox"/> Compatibility Testing				
<input type="checkbox"/> Virology			<b>PATHOLOGY</b>			
<b>DIAGNOSTIC IMMUNOLOGY</b>			<input type="checkbox"/> Histopathology			
<input type="checkbox"/> Syphilis Serology		<input type="checkbox"/> Oral Pathology				
<input type="checkbox"/> General Immunology		<input type="checkbox"/> Cytology				
<b>CHEMISTRY</b>			<b>RADIOBIOASSAY</b>			
<input type="checkbox"/> Routine			<input type="checkbox"/> Radiobioassay			
<input type="checkbox"/> Urinalysis			<b>CLINICAL CYTOGENETICS</b>			
<input type="checkbox"/> Endocrinology			<input type="checkbox"/> Clinical Cytogenetics			
<input type="checkbox"/> Toxicology		<b>TOTAL ESTIMATED ANNUAL TEST VOLUME:</b>				

**IX. TYPE OF CONTROL**

**VOLUNTARY NONPROFIT**

- 01 Religious Affiliation
- 02 Private Nonprofit
- 03 Other Nonprofit

\_\_\_\_\_  
*(Specify)*

**FOR PROFIT**

- 04 Proprietary

**GOVERNMENT**

- 05 City
- 06 County
- 07 State
- 08 Federal
- 09 Other Government

\_\_\_\_\_  
*(Specify)*

**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

**ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION**

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)*

DATE

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# THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

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## INSTRUCTIONS FOR COMPLETION

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CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

**NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.**

**NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application. Information to be submitted with the application include:**

- Verification of State Licensure, as applicable
- Documentation of qualifications:
  - Education (copy of Diploma, transcript from accredited institution, CMEs),
  - Credentials, and
  - Laboratory experience.

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

**ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.**

### **I. GENERAL INFORMATION**

For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check "Change in certificate type". For all other changes, including change in location, director, etc., check "other changes".

For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. Be specific when indicating the name of your facility, particularly when it is a component of a larger entity; e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. **NOTE: The information provided is what will appear on your certificate.**

Facility street address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable. **DO NOT USE A POST OFFICE BOX NUMBER OR A MAIL DROP ADDRESS FOR THE NUMBER AND STREET OF THE ADDRESS.** If the laboratory has a separate mailing address, please complete that section of the application.

**NOTE: For Office Use Only—Date received is the date the form is received by the state agency or CMS regional office for processing.**



## **II. TYPE OF CERTIFICATE REQUESTED**

When completing this section, please remember that a facility holding a:

- **Certificate of Waiver** can only perform tests categorized as waived;\*
- **Certificate for Provider Performed Microscopy Procedures (PPM)** can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;\*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization.

\*A current list of waived and PPMP tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm>.

## **III. TYPE OF LABORATORY**

Select your certificate type based on the highest level of test complexity performed by your laboratory. Laboratories performing non-waived tests can choose COA or COC based on the agency you wish to survey your laboratory.

A shared laboratory is when two or more sole practicing physicians collectively pool resources to fund a laboratory's operations. The definition of a shared laboratory may also include two or more physician group practices that share the expenses for the laboratory's operation.

## **IV. HOURS OF ROUTINE OPERATION**

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format.

## **V. MULTIPLE SITES**

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493. Hospice and HHA could qualify for an exception i.e. 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3).

## **VI. WAIVED TESTING**

Indicate the estimated total annual test volume for all waived tests performed. List can be found at:

<http://www.cms.gov/CLIA/downloads/waivetbl.pdf>

## **VII. PPM TESTING**

Indicate the estimated annual test volume for all PPM tests performed. List can be found at:

<http://www.cms.gov/clia/downloads/ppmp.list.pdf>

## **VIII. NON-WAIVED TESTING (INCLUDING PPM)**

The total volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

## **IX. TYPE OF CONTROL**

Select the type of control which most appropriately describes your facility.

## **X. DIRECTOR OF ADDITIONAL LABORATORIES**

List all other facilities for which the director is responsible and that are under different certificate.

Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

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Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency.

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**VIII. NON-WAIVED TESTING**

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**TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING  
LABORATORY SPECIALTIES/SUBSPECIALITIES**

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**HISTOCOMPATIBILITY**

HLA Typing (disease associated antigens)

**MICROBIOLOGY****Bacteriology**

Gram Stain

Culture

Susceptibility

Strep screen

Antigen assays (H.pylori, Chlamydia, etc.)

**Mycobacteriology**

Acid Fast Smear

Mycobacterial culture

Mycobacterial susceptibility

**Mycology**

Fungal Culture

DTM

KOH Preps

**Parasitology**

Direct Preps

Ova and Parasite Preps

Wet Preps

**Virology**

RSV (Not including waived kits)

HPV assay

Cell culture

**DIAGNOSTIC IMMUNOLOGY****Syphilis Serology**

RPR

FTA, MHATP

**General Immunology**

Allergen testing

ANA

Antistreptolysin O

Antigen/Antibody (hepatitis, herpes, rubella, etc.)

Complement (C3, C4)

Immunoglobulin

HIV

Mononucleosis assay

Rheumatoid factor

Tumor marker (AFP, CA 19-9, CA 15-3, CA 125)\*

\*Tumor markers can alternatively be listed under  
Routine Chemistry instead of General Immunology.

**HEMATOLOGY**

Complete Blood Count (CBC)

WBC count

RBC count

Hemoglobin

Hematocrit (Not including spun micro)

Platelet count

Differential

Activated Clotting Time

Prothrombin time (Not including waived instruments)

Partial thromboplastin time

Fibrinogen

Reticulocyte count

Manual WBC by hemocytometer

Manual platelet by hemocytometer

Manual RBC by hemocytometer

Sperm count

**IMMUNOHEMATOLOGY**

ABO group

Rh(D) type

Antibody screening

Antibody identification

Compatibility testing

**PATHOLOGY**

Dermatopathology

Oral Pathology

PAP smear interpretations

Other Cytology tests

Histopathology

**RADIOBIOASSAY**

Red cell volume

Schilling test

**CLINICAL CYTOGENETICS**

Fragile X

Buccal smear

Prader-Willi syndrome

FISH studies for: neoplastic disorders, congenital disorders  
or solid tumors.

## **CHEMISTRY**

### **Routine Chemistry**

Albumin  
Ammonia  
Alk Phos  
ALT/SGPT  
AST/SGOT  
Amylase  
Bilirubin  
Blood gas (pH, pO<sub>2</sub>, pCO<sub>2</sub>)  
BUN  
Calcium  
Chloride  
Cholesterol  
Cholesterol, HDL  
CK/CK isoenzymes  
CO<sub>2</sub>  
Creatinine  
Ferritin  
Folate  
GGT  
Glucose (Not fingerstick)  
Iron  
LDH/LDH isoenzymes  
Magnesium  
Potassium  
Protein, electrophoresis  
Protein, total  
PSA  
Sodium  
Triglycerides  
Troponin  
Uric acid  
Vitamin B12

### **Endocrinology**

Cortisol  
HCG (serum pregnancy test)  
T3  
T3 Uptake  
T4  
T4, free  
TSH

### **Toxicology**

Acetaminophen  
Blood alcohol  
Blood lead (Not waived)  
Carbamazepine  
Digoxin  
Ethosuximide  
Gentamicin  
Lithium  
Phenobarbital  
Phenytoin  
Primidone  
Procainamide  
NAPA  
Quinidine  
Salicylates  
Theophylline  
Tobramycin  
Therapeutic Drug Monitoring

### **Urinalysis\*\***

Automated Urinalysis (Not including waived instruments)  
Microscopic Urinalysis  
Urine specific gravity by refractometer  
Urine specific gravity by urinometer  
Urine protein by sulfosalicylic acid

\*\* Dipstick urinalysis is counted in Section VI. WAIVED TESTING

**NOTE:** This is not a complete list of tests covered by CLIA. Other non-waived tests and their specialties/subspecialties can be found at <http://www.cms.gov/CLIA/downloads/subject.to.CLIA.pdf> and <http://www.cms.gov/CLIA/downloads/lcCodes.pdf>. You may also call your State agency for further information. State agency contact information can be found at: <http://www.cms.gov/CLIA/downloads/CLIA.SA.pdf>.

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## GUIDELINES FOR COUNTING TESTS FOR CLIA

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- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- For **general immunology**, testing for allergens should be counted as one test per individual allergen.
- For **hematology**, each **measured** individual analyte of a **complete blood count** or **flow cytometry** test that is ordered **and reported** is counted separately. The **WBC differential** is counted as one test.
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.
- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.
- For **chemistry**, each analyte in a profile counts as one test.
- For **urinalysis**, microscopic and macroscopia examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **all specialties/subspecialties**, do not count calculations (e.g., A/G ratiior, MCH, T7, etc.), quality control, quality assurance, or proficiency testing assays.

If you need additional information concerning counting tests for CLIA, please contact your State agency.



# AFFIDAVIT OF COMPLIANCE WITH Background Screening Requirements

**Authority:** This form may be used by **all employees** to comply with:

- the attestation requirements of **section 435.05(2), Florida Statutes**, which state that every employee required to undergo Level 2 background screening must attest, subject to penalty of perjury, to meeting the requirements for qualifying for employment pursuant to this chapter and agreeing to inform the employer immediately if arrested for any of the disqualifying offenses while employed by the employer; **AND**
- the proof of screening within the previous 5 years in **section 408.809(2), Florida Statutes** which requires proof of compliance with level 2 screening standards submitted within the previous 5 years to meet any provider or professional licensure requirements of the Agency, the Department of Health, the Agency for Persons with Disabilities, the Department of Children and Family Services, or the Department of Financial Services for an applicant for a certificate of authority or provisional certificate of authority to operate a continuing care retirement community under chapter 651 if the person has not been unemployed for more than 90 days.

**This form must be maintained in the employee's personnel file.** If this form is used as proof of screening for an administrator or chief financial officer to satisfy the requirements of an **application for a health care provider license**, please attach a copy of the screening results and submit with the licensure application.

**Employee/Contractor Name:**

**Health Care Provider/ Employer Name:**

**Address of Health Care Provider:**

I hereby attest to meeting the requirements for employment and that I have not been arrested for or been found guilty of, regardless of adjudication, or entered a plea of nolo contendere, or guilty to any offense, or have an arrest awaiting a final disposition prohibited under any of the following provisions of the Florida Statutes or under any similar statute of another jurisdiction:

**Criminal offenses found in section 435.04, F.S**

a) Section 393.135, relating to sexual misconduct with certain developmentally disabled clients and reporting of such sexual misconduct.

(b) Section 394.4593, relating to sexual misconduct with certain mental health patients and reporting of such sexual misconduct.

(c) Section 415.111, relating to adult abuse, neglect, or exploitation of aged persons or disabled adults.

(d) Section 782.04, relating to murder.

(e) Section 782.07, relating to manslaughter, aggravated manslaughter of an elderly person or disabled adult, or aggravated manslaughter of a child.

(f) Section 782.071, relating to vehicular homicide.

(g) Section 782.09, relating to killing of an unborn quick child by injury to the mother.

(h) Chapter 784, relating to assault, battery, and culpable negligence, if the offense was a felony.

(i) Section 784.011, relating to assault, if the victim of the offense was a minor.

(j) Section 784.03, relating to battery, if the victim of the offense was a minor.

(k) Section 787.01, relating to kidnapping.

(l) Section 787.02, relating to false imprisonment.

(m) Section 787.025, relating to luring or enticing a child.

(n) Section 787.04(2), relating to taking, enticing, or removing a child beyond the state limits with criminal intent pending custody proceedings.

(o) Section 787.04(3), relating to carrying a child beyond the state lines with criminal intent to avoid producing a child at a custody hearing or delivering the child to the designated person.

(p) Section 790.115(1), relating to exhibiting firearms or weapons within 1,000 feet of a school.

(q) Section 790.115(2)(b), relating to possessing an electric weapon or device, destructive device, or other weapon on school property.

(r) Section 794.011, relating to sexual battery.

(s) Former s. 794.041, relating to prohibited acts of persons in familial or custodial authority.

(t) Section 794.05, relating to unlawful sexual activity with certain minors.

(u) Chapter 796, relating to prostitution.

(v) Section 798.02, relating to lewd and lascivious behavior.

(w) Chapter 800, relating to lewdness and indecent exposure.

(x) Section 806.01, relating to arson.

(y) Section 810.02, relating to burglary.

(z) Section 810.14, relating to voyeurism, if the offense is a felony.

(aa) Section 810.145, relating to video voyeurism, if the offense is a felony.

(bb) Chapter 812, relating to theft, robbery, and related crimes, if the offense is a felony.

(cc) Section 817.563, relating to fraudulent sale of controlled substances, only if the offense was a felony.

(dd) Section 825.102, relating to abuse, aggravated abuse, or neglect of an elderly person or disabled adult.

(ee) Section 825.1025, relating to lewd or lascivious offenses committed upon or in the presence of an elderly person or disabled adult.

(ff) Section 825.103, relating to exploitation of an elderly person or disabled adult, if the offense was a felony.

(gg) Section 826.04, relating to incest.

(hh) Section 827.03, relating to child abuse, aggravated child abuse, or neglect of a child.

(ii) Section 827.04, relating to contributing to the delinquency or dependency of a child.

(jj) Former s. 827.05, relating to negligent treatment of children.

(kk) Section 827.071, relating to sexual performance by a child.

(ll) Section 843.01, relating to resisting arrest with violence.

(mm) Section 843.025, relating to depriving a law enforcement, correctional, or correctional probation officer means of protection or communication.

(nn) Section 843.12, relating to aiding in an escape.

(oo) Section 843.13, relating to aiding in the escape of juvenile inmates in correctional institutions.

(pp) Chapter 847, relating to obscene literature.

(qq) Section 874.05(1), relating to encouraging or recruiting another to join a criminal gang.

(rr) Chapter 893, relating to drug abuse prevention and control, only if the offense was a felony or if any other person involved in the offense was a minor.

(ss) Section 916.1075, relating to sexual misconduct with certain forensic clients and reporting of such sexual misconduct.

(tt) Section 944.35(3), relating to inflicting cruel or inhuman treatment on an inmate resulting in great bodily harm.

(uu) Section 944.40, relating to escape.

(vv) Section 944.46, relating to harboring, concealing, or aiding an escaped prisoner.

(ww) Section 944.47, relating to introduction of contraband into a correctional facility.

(xx) Section 985.701, relating to sexual misconduct in juvenile justice programs.

(yy) Section 985.711, relating to contraband introduced into detention facilities.

(3) The security background investigations under this section must ensure that no person subject to this section has been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, any offense that constitutes domestic violence as defined in s. 741.28, whether such act was committed in this state or in another jurisdiction.

#### **Criminal offenses found in section 408.809(4), F.S**

(a) Any authorizing statutes, if the offense was a felony.

- (b) This chapter, if the offense was a felony.
- (c) Section 409.920, relating to Medicaid provider fraud.
- (d) Section 409.9201, relating to Medicaid fraud.
- (e) Section 741.28, relating to domestic violence.
- (f) Section 817.034, relating to fraudulent acts through mail, wire, radio, electromagnetic, photoelectronic, or photooptical systems.
- (g) Section 817.234, relating to false and fraudulent insurance claims.
- (h) Section 817.505, relating to patient brokering.
- (i) Section 817.568, relating to criminal use of personal identification information.
- (j) Section 817.60, relating to obtaining a credit card through fraudulent means.
- (k) Section 817.61, relating to fraudulent use of credit cards, if the offense was a felony.
- (l) Section 831.01, relating to forgery.
- (m) Section 831.02, relating to uttering forged instruments.
- (n) Section 831.07, relating to forging bank bills, checks, drafts, or promissory notes.
- (o) Section 831.09, relating to uttering forged bank bills, checks, drafts, or promissory notes.
- (p) Section 831.30, relating to fraud in obtaining medicinal drugs.
- (q) Section 831.31, relating to the sale, manufacture, delivery, or possession with the intent to sell, manufacture, or deliver any counterfeit controlled substance, if the offense was a felony.

If you are also using this form to provide evidence of prior Level 2 screening (fingerprinting) in the last 5 years and have not been unemployed for more than 90 days, please provide the following information. **A copy of the prior screening results must be attached.**

Purpose of Prior Screening: \_\_\_\_\_

Screened conducted by: \_\_\_\_\_ Date of Prior Screening: \_\_\_\_\_

- Agency for Health Care Administration
- Department of Health
- Agency for Persons with Disabilities
- Department of Children and Family Services
- Department of Financial Services

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## Affidavit

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Under penalty of perjury, I, \_\_\_\_\_, hereby swear or affirm that I meet the requirements for qualifying for employment in regards to the background screening standards set forth in Chapter 435 and section 408.809, F.S. In addition, I agree to immediately inform my employer if arrested or convicted of any of the disqualifying offenses while employed by any health care provider licensed pursuant to Chapter 408, Part II F.S.

\_\_\_\_\_  
Employee/Contractor Signature

\_\_\_\_\_  
Title

\_\_\_\_\_  
Date