FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

APPLICATION CHECKLIST
Health Care Licensing Application
CLINICAL LABORATORIES – NON-WAIVED
Including Provider-Performed Microscopy (PPM)

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 ***The application will be withdrawn from review if all the required documents and fees are not included with this application or received within 21 days of an omission notice.***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.

A. Initial, Renewal and Change of Ownership applications for Non-Waived Laboratories (including Provider-performed microscopy procedures) must include:

Note to all applicants: The Agency will verify that all applications, licenses, and controlling interests subject to Chapters 607, 608 or 617, F.S. related to business organizations have complied with applicable Department of State registration and filing requirements. The principal and mailing addresses submitted with any application must be the same as the addresses that appear as registered with the Department of State, Division of Corporations.

☐ The biennial licensure fee in accordance with the fee schedule in s. 483.172, Florida Statutes is provided in Section 2 of this application. Please make check or money order payable to the Agency for Health Care Administration. All fees are nonrefundable. Applications received without payment cannot be accepted and will be returned. ***NOTE: Starter checks and temporary checks are not accepted.***

☐ Health Care Licensing Application, Clinical Laboratory (Non-Waived), AHCA Form 3170-2004

☐ Health Care Licensing Application Addendum, AHCA Form 3110-1024 – refer to Sections 3 & 4 of the application for further details. Complete all applicable information. Write "N/A" on any field or section that is not applicable with explanation as to why it is not applicable. Return this completed, signed and dated with application AHCA Form 3170-2004.

☐ 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.*

☐ Copy of Medical/professional license for the laboratory director.

☐ Copy of Florida Department of State and Certificate of Status and fictitious name registration (if applicable) for Management Company of applicant and applicant . **NOTE**: Not needed for renewal application if no change and documentation previously submitted. Out of state laboratories reference http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/out_state.shtml.

☐ Evidence that the director is qualified (see s. 483.824, F.S.). Documentation must show laboratory experience/training. **NOTE**: If this is a renewal application and there has been no change in director, this documentation is not needed.

☐ Level 2 background screening of the Lab Director and Financial Officer is required every 5 years. Please select all that apply):

☐ The ☐ Lab Director and co-director, if applicable and/or ☐ Financial Officer submitted a Level 2 screening through a **LiveScan service provider** 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.

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.

☐ The ☐ Lab Director and co-director, if applicable and/or ☐ 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). The completed fingerprint card must then be submitted to:

☐ The Agency's contracted vendor, Cogent Systems (www.cogentid.com), along with a fee of $55.50 ($40.50 for the screening + 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 ATTN: FL Cardscan
5025 Bradenton Ave., Ste A
Dublin, OH 43017

☐ 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 and co-director, if applicable and/or ☐ 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 and co-director, if applicable and/or ☐ 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.

B. *Additional* Information needed for INITIAL Applications:

☐ Proof of the licensee's right to occupy the building such as a copy of a lease, sublease agreement, or deed.

☐ Self Evaluation Survey found in Section 16 **NOTE:** Only needed for applicants who have been licensed previously and have had a survey within the past two years.

☐ Proof of fictitious name registration, if applicable.

☐ Evidence that the director is qualified (see s. 483.824, F.S.). **NOTE:** Documentation must show laboratory experience/training.

☐ If you are applying to become an accredited laboratory, proof of enrollment with the accrediting agency.

☐ Copy of current Certificate of Status filed with the Florida Department of State for licensee and Management Company, if applicable.

***NOTE to Initial Applicants**:*

Laboratories must also obtain a CLIA certificate prior to operation. CMS FORM 116 is available on the Agency's website for download at: http://www.cms.gov/cmsforms/downloads/cms116.pdf. This form may be submitted with the licensing application. CLIA fees are assessed in addition to state licensure fees. CLIA fees are submitted directly to the federal CLIA program. The CLIA program directly bills labs for the federal CLIA fee. The remittance address is provided on the bill. Checks should never be mailed to the Agency for CLIA fee payment.

C. *Additional* Information needed for CHANGE OF OWNERSHIP Applications:

☐ Proof of the licensee's right to occupy the building such as a copy of a lease, sublease agreement, or deed.

☐ Proof of fictitious name registration, if applicable.

☐ Copy of closing document (bill of sale) showing the date of the change. The license will not be issued until a document showing the effective date of the change is received.

☐ Effective date of change of ownership must be provided in Section 2: The effective date of the change of ownership cannot be extended more than 60 days from the date provided in this application and written notification must be provided for any extension of the date given in this application. All change of ownership applications must be submitted at least 60 days prior to the effective date of the change or be subject to a late fee. [*see* s. 59A-7.070(3), F.A.C.]

☐ Copy of current Certificate of Status filed with the FL Department of State for licensee and Management Company, if applicable.

NOTE for those filing Change of Ownership applications *[see 59A-35.070, Florida Administrative Code]:*

A change of ownership application **must include the effective date of the change of ownership.** [see Section 2 of this application form]

The change of ownership **effective date cannot be prior to the date the application is received by the Agency.** Failure to submit an application for licensure prior to the effective date of a change of ownership to a different legal entity constitutes unlicensed activity.

The effective date of the change of ownership shall not be extended more than 60 days from the effective date reported on the application; written notification of a change in the effective date must be received by the Agency prior to the originally reported effective date. The Agency will deem the application withdrawn if the change of ownership does not occur within 60 days of the reported effective date.

All required application documents and information must be received with the application or within 21 days of the request by the Agency with the exception of the transferee's proof of right to occupy if required, which must be received by the Agency within 10 days after the effective date.

When a change of ownership application is submitted during the review of a renewal licensure application, the pending renewal will be administratively withdrawn from review if the change of ownership application is approved with an effective date prior to the expiration of the license. A change of ownership application and "renewal" application cannot be submitted on the same form. [*see* Section 2 of this application form]

Expiration of a license prior to the approval of the change of ownership application, when no renewal application has been submitted, will result in the denial of a change of ownership application.

If the applicant has not been issued the license on the effective date of the change of ownership, documentation must be submitted that provides for continuation of operation of the licensee for those days between the date of the change of ownership and the date the applicant is licensed by the Agency.

D. Reporting Changes:

All changes must be reported timely or be subject to a late fine. Review Chapter 59A-35, Florida Administrative Code for reporting times requirements.

It is recommended that this form **not** be used for reporting any of the changes listed below except laboratories seeking to change from accredited to compliance (non-accredited). When writing the AHCA to report a change, please include the license or file number and the CLIA ID number as well as the laboratory name (both old and new if the name is changing) and address (both old and new if the address is changing):

- Change from a compliance laboratory to an accredited laboratory or from an accredited laboratory to a compliance laboratory (must also complete a CLIA CMS-116: http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf) **NOTE**: This application, AHCA Form 3170-2004, must be completed and submitted to report this change.
- Change in laboratory director(s) - must complete a CLIA CMS-116: http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf.
- Closures – Letter on owner letterhead signed by the owner. Original license and CLIA Certificate must be returned to the AHCA: Laboratory Unit, 2727 Mahan Dr. MS 32, Tallahassee, FL 3208.
- Change in test volumes or other testing changes that would require staffing changes – Letter on owner letterhead signed by the laboratory director detailing changes.
- Change in provider name – Letter on owner letterhead signed by the owner or laboratory director with proof of fictitious name registration if applicable and a check made payable to the AHCA for $25.
- Change of address – Letter on owner letterhead signed by the owner or laboratory director with proof of right to occupy and a check made payable to the AHCA for $25.
- Removal of specialty/subspecialty - Letter on owner letterhead signed by the laboratory director describing changes with a check made payable to the AHCA for $25. The $25 is needed only if the removal results in a change to the information listed on the face of the license.

- Addition of specialty/subspecialty or change in specialty/subspecialty. ***NOTE:*** **Use AHCA Form 3170-2004D, effective September 2009, to request an addition of specialty or subspecialty.** (must also complete a CLIA CMS-116: http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf)
- Change in location of collection stations or addition of collection stations – Letter on owner letterhead signed by the owner or laboratory director providing street locations.
- Change in laboratory supervisor(s) or consultant - Letter on owner letterhead signed by the laboratory director detailing changes.

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.

FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

AHCA USE ONLY:

File #: _____
Application #: _____
Check #: _____
Check Amt: _____
Batch #: _____

Health Care Licensing Application
CLINICAL LABORATORIES (NON-WAIVED)

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

A. ***Provider Information –*** please complete the following for the clinical laboratory name and location. *Provider name, address and telephone number will be listed on http://www.floridahealthfinder.gov/*			
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 – see definition of "provider" on the instruction checklist.):			
Street Address			
City	County	State	Zip
Telephone Number / Fax Number	E-mail Address	Provider Website	
Mailing Address or ☐ 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 ☐ Do not have e-mail	***NOTE:*** By providing your e-mail address you agree to accept e-mail correspondence from the Agency		
B. ***Licensee Information*** - please complete the following for the entity seeking to operate the laboratory.			
Licensee Name (This is the owner of the laboratory - see definition of "licensee" on the instruction checklist	Federal Employer Identification Number (EIN)		
Mailing Address			
City	State	Zip	
Telephone Number / Fax Number	E-mail Address		

Description of Licensee (check one):

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

2. Application Type and Fees

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. Renewal and Change of Ownership applications must be received 60 days prior to the expiration of the license or the proposed effective date of the change to avoid a late fine. If the renewal application is received by the Agency less than 60 days prior to the expiration date, it is subject to a late fee as set forth in statute. The applicant will receive notice of the amount of the late fee as part of the application process or by separate notice.

***DO NOT "X" MORE THAN ONE BOX BELOW.**

☐ 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. ***NOTE:*** If you are changing status **and** renewing, only "X" the "renewal license" box; DO NOT "X" this box.

**If more than one action is needed, then a separate application and fee must be submitted. Providers may not "X" both "change of ownership" and "renewal" boxes, for example. Two separate applications and two fees are required and the information contained with these applications will, by definition [see 408.803(5), F.S.], be different. Applications with an "X" in more than one box will not be accepted and will be returned.*

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)

- 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: **DO NOT "X" MORE THAN ONE BOX BELOW.

☐ Total Annual Non-waived test volume _____ / Fee $ _____	$ _____
OR ☐ Accredited lab fee	$100.00
☐ Change During Licensure Period/Replacement License	$ 25.00

***The fee for accredited laboratories is $100. Laboratories that are not accredited or initial applicants who do not intend to become accredited must use the fee schedule above and pay the fee that is based on testing volume.*

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

NOTE: Starter checks and temporary checks are not accepted.

3. Controlling Interests of Licensee

AUTHORITY:

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

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.

Management Company, as defined in s. 59A-35.030 (4), F.A.C., means an entity retained by a licensee to administer or direct the operation of a provider. This does not include an entity that serves solely as a lender or lien holder.

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 *(5% or more ownership interest)*

☐ Check here if no individual or entity has 5% or more ownership interest in the licensee (see definition of "licensee" on Application Checklist) and put N/A in "A." below.

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

Note: If total does not equal 100%, please attach documentation explaining remaining ownership interest. Information provided above should not be the same information contained in 1B of this application.

B. Board Members and Officers of Licensee

TITLE	FULL NAME	PERSONAL OR BUSINESS ADDRESS	TELEPHONE NUMBER	% OWNERSHIP INTEREST
Director/CEO				
President				
Vice President				
Secretary				
Treasurer				
Other				

C. Voluntary Board Members and Officers of Licensee

If the licensee is a not-for-profit corporation/organization, provide the requested information for **each individual that serves as a voluntary board member**. Attach additional sheets if necessary.

FULL NAME	PERSONAL OR BUSINESS ADDRESS	TELEPHONE NUMBER

4. Management Company Controlling Interests

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

If ☐ NO, skip to section 5 – *Required Disclosure.*

If ☐ YES, provide the following information:

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

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 management company. Attach additional sheets if necessary.

A. Individual and/or Entity Ownership of Management Company *(5% or more ownership interest)*

☐ Check here if no individual or entity has 5% or more ownership interest in the licensee (see definition of "licensee" on Application Checklist) and put N/A in "A." below.

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

Note: If total does not equal 100%, please attach documentation explaining remaining ownership interest.

B. Board Members and Officers of Management Company

TITLE	FULL NAME	PERSONAL OR BUSINESS ADDRESS	TELEPHONE NUMBER	% OWNERSHIP INTEREST
Director/CEO				
President				
Vice President				
Secretary				
Treasurer				
Other				

C. Voluntary Board Members and Officers of Management Company

If the management company is a not-for-profit corporation/organization, provide the requested information for **each individual that serves as a voluntary board member**. Attach additional sheets if necessary.

FULL NAME	PERSONAL OR BUSINESS ADDRESS	TELEPHONE NUMBER

5. Required Disclosure

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.

6. 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.

7. Federal Certification

Participation in the federal CLIA program is mandatory for all clinical laboratories.

Does the provider participate in or intend to participate in the Florida Medicaid program? YES ☐ NO ☐

Medicaid:

Visit the Agency's website at: http://ahca.myflorida.com/Medicaid/index.shtml in order to obtain information and an application for enrollment in Medicaid.

8. Type of Laboratory

Check the type that best describes the facility:

- ☐ Ambulance
- ☐ Ambulatory Surgical Center
- ☐ Nursing Facility
- ☐ Ancillary Testing Site in a Health Care Facility
- ☐ Blood Bank
- ☐ Community Clinic
- ☐ Comp. Outpatient Rehab Facility
- ☐ End Stage Renal Dialysis Facility
- ☐ Federally Qualified Health Center
- ☐ Health Maintenance Organization
- ☐ Hospital
- ☐ Independent/Reference
- ☐ Industrial
- ☐ Intermediate Care Facility for the Developmentally Disabled
- ☐ Mobile Laboratory
- ☐ Pharmacy
- ☐ Physician Office

  Is this a shared lab?

  If questions call (850) 412-4500

  ☐ YES ☐ NO
- ☐ Practitioner Other (specify) _____
- ☐ Prison
- ☐ Public Health Laboratory
- ☐ Rural Health Clinic
- ☐ School/Student Health Service
- ☐ Tissue Bank/Repositories
- ☐ Other (specify) _____

9. Hours of Operation

List the regular operating hours (**NOTE:** Site inspections by surveyors will occur during the business hours submitted. Failure to be open during the listed hours may result in a fine. For physician offices, AHCA surveyors need to be able to review testing, so please provide testing hours):

Day of the Week	Opening Time	Closing Time
☐ Sunday		
☐ Monday		
☐ Tuesday		
☐ Wednesday		
☐ Thursday		
☐ Friday		
☐ Saturday		

10. Collection Stations / Alternate Testing Sites

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

11. 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: _____

12. Personnel

Provide the following information:

DIRECTOR (full name)	Professional Degree	Board Certified By	Florida Professional License #	Hours Spent in Lab (Per Week)	Lab Experience (Years)

CO-DIRECTOR (full name)	Professional Degree	Board Certified By	Florida Professional License #	Hours Spent in Lab (Per Week)	Lab Experience (Years)

FINANCIAL OFFICER (Full Name)	Financial Officer Florida Professional License # (optional)

☐ 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 (other than PPM) and high complexity testing. Director may serve as clinical consultant. [*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 #

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. ***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.

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
☐ **MICROBIOLOGY**				☐ **HEMATOLOGY**			
☐ Bacteriology				☐ **IMMUNO-HEMATOLOGY**			
☐ Mycobacteriology				☐ ABO Group & Rh Group			
☐ Mycology				☐ Antibody Detection (Transfusion)			
☐ Parasitology				☐ Antibody Detection (Non-Transfusion)			
☐ Virology				☐ Antibody Identification			
☐ **DIAGNOSTIC IMMUNOLOGY**				☐ Compatibility Testing			
☐ Syphilis Serology				☐ **PATHOLOGY**			
☐ General Immunology				☐ Histopathology			
☐ **CHEMISTRY**				☐ Oral Pathology			
☐ Routine Chemistry				☐ Cytology			
☐ Urinalysis				☐ **CLINICAL CYTOGENETICS**			
☐ Endocrinology				☐ **HISTO-COMPATIBILITY**			

☐ Toxicology				☐ **RADIOBIOASSAY**			
☐				☐ PPM Only			
☐				☐			
☐				☐			
☐				☐			

14. 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, CO2, Chloride, BUN, Creatinine * Please note, do not list tests with calculated results.
CMP	Glucose, Calcium, Albumin, Total Protein, Sodium, Potassium, CO2, Chloride, BUN, Creatinine, ALP, ALT, AST, Bilirubin * Please note, do not list tests with calculated results.
ABG	pH, H^+, PO_2, PCO_2, HCO_3^-, SBC_e, HPO_4^{2-}, total CO_2, total O_2 * Please note, do not list tests with calculated results.
Lipids	LDL, HDL, trigycerides

- **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, Immunofluroescence
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 #13 on page 9 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)** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm	**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
Print Name of Laboratory Director
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: _____ Date: _____
Laboratory Director's Signature

15. Microscopy Evaluation Survey

Only to be completed by applicants seeking to establish a provider performed microscopy (PPM) laboratory or those currently operating a PPM laboratory. If you are not seeking to establish a PPM laboratory or renewing a PPM license, please put "N/A" in this section.

REGULATORY REQUIREMENTS		
Yes	No	*Note: Completion of this self-evaluation survey does not exempt your laboratory from survey should the Agency determine a survey is needed.*
		1. Has the office been issued a biomedical waste permit issued by the Department of Health, as required by s. 381.0098, F.S., or documentation of exemption from such permitting? [*see* 59A-7.023(1) F.A.C.]
		2. Do you have written policies and procedures designed to maintain the environment so that the safety and well being of patients and personnel are assured (such as the prohibition of food, drink, or patient care and treatment items in areas where laboratory testing is being performed?) [*see* 59A-7.023(5) F.A.C.]
		3. Do you and other personnel performing testing have available and follow written laboratory policies and procedures for patient preparation, specimen collection, labeling and processing? This includes all specimens collected for transport to outside laboratories for testing [*see* 59A-7.028(2) F.A.C.]
		4. Are laboratory tests performed only at the written or electronic request of an authorized person? [*see* 59A-7.028(3) F.A.C.]
		5. Is a reliable record system that ensure identification of patient specimens maintained in the office? [*see* 59A-7.028(2) F.A.C.]
		6. Are laboratory patient results documented and maintained for a period of at least two years? [*see* 59A-7.028(4) F.A.C.]
		7. Is there a written laboratory procedure manual describing each step of the testing process, the performance of quality control, the reporting of patient results, and the maintenance of equipment that is reviewed and signed biennially by the director maintained by the office? [*see* 59A-7.029(3) F.A.C.]
		8. Is the microscope used for testing in good working order and has routine maintenance been documented and retained? [*see* 59A-7.029 F.A.C.]
		9. Are reagents, solutions, control materials, and other supplies used for laboratory testing labeled to indicate identity, expiration date and other pertinent information required for proper use? [*see* 59A-7.029(2) F.A.C.]
		10. Is written criteria available and followed for the proper storage of reagents and specimens? [*see* 59A-7.029(3) F.A.C.]
		11. Do you and other testing personnel have a quality assurance program to address problems experienced during laboratory testing, including specimen handling, test results and reporting of test results? [*see* 59A-7.031 F.A.C.] **ATTACH A COPY OF THE LABORATORY'S QUALITY ASSURANCE POLICY & PROCEDURE.**
		12. Do you and other testing personnel determine and document action taken when inconsistencies occur between patient information and patient test results? [*see* 59A-7.031 F.A.C.]
		13. Does any owner, director, administrator, physician, surgeon, consultant, employee, organization, agency, representative or person either directly or indirectly, pay or receive any commission, bonus, kickback, rebate or gratuity or engage in any split fee arrangement in any from whatsoever for the referral of a patient [*see* 483.245, FS and 59A-7.028(2) F.A.C.]

COMPLETE THE FOLLOWING REGARDING EACH PROVIDER PERFORMED MICROSCOPY PROCEDURE TEST PERFORMED IN YOUR OFFICE [*see* 483.111, F.S.]			
Laboratory Test Performed	Annual Volume	Name of Person(s) Performing Tests	Florida Medical License Number (include prefix)

OTHER PERTINENT INFORMATION

16. Self Evaluation Survey (non-Provider Performed Microscopy laboratories)

Only to be completed by non- PPM applicants who once held a non-waived State of Florida clinical laboratory license, but are not currently licensed **and** who have had a clinical laboratory on-site survey for that non-waived license within the past two years. If you have never held a Florida non-waived clinical laboratory license, you have not had a survey on a once held license within two years, you are seeking to renew an existing clinical laboratory license **or** filing a change of ownership application, please put "N/A" in this section.

REGULATORY REQUIREMENTS

Yes	No	*Note: Completion of this self-evaluation survey does not exempt your laboratory from survey should the Agency determine a survey is needed.*
		1. Has the office been issued a biomedical waste permit issued by the Department of Health, as required by s. 381.0098, F.S., or documentation of exemption from such permitting? [*see* 59A-7.023(1) F.A.C.]
		2. Do you have written policies and procedures designed to maintain the environment so that the safety and well being of patients and personnel are assured (such as the prohibition of food, drink, or patient care and treatment items in areas where laboratory testing is being performed?) [*see* 59A-7.023(5) F.A.C.]
		3. Do you and other personnel performing testing have available and follow written laboratory policies and procedures for patient preparation, specimen collection, labeling and processing? This includes all specimens collected for transport to outside laboratories for testing [*see* 59A-7.028(2) F.A.C.]
		4. Are laboratory tests performed only at the written or electronic request of an authorized person? [*see* 59A-7.028(3) F.A.C.]
		5. Is a reliable record system that ensure identification of patient specimens maintained in the office? [*see* 59A-7.028(2) F.A.C.]
		6. Are laboratory patient results documented and maintained for a period of at least two years? [*see* 59A-7.028(4) F.A.C.]
		7. Is there a written laboratory procedure manual describing each step of the testing process, the performance of quality control, the reporting of patient results, and the maintenance of equipment that is reviewed and signed biennially by the director maintained by the office? [*see* 59A-7.029(3) F.A.C.]
		8. Does the laboratory include positive and negative control materials each day of testing for qualitative tests and at least two samples of different concentrations of control materials for quantitative tests? [*see* 59A-7.029(7) F.A.C.]
		9. Are control samples tested in the same manner as patient specimens and processed through each step of patient testing? [*see* 59A-7.029(7) F.A.C.]
		10. Does the laboratory document remedial action taken when results of control and calibration materials fail to meet the laboratory's established criteria for acceptability? [*see* 59A-7.029(8) F.A.C.]
		11. Are the quality control records retained for a period of at least two years? [*see* 59A-7.029(9) F.A.C.]
		12. Are reagents, solutions, control materials, and other supplies used for laboratory testing labeled to indicate identity, expiration date and other pertinent information required for proper use? [*see* 59A-7.029(2) F.A.C.]
		13. Is written criteria available and followed for the proper storage of reagents and specimens? [*see* 59A-7.029(3) F.A.C.]
		14. Is there a quality assurance program to address problems experienced during laboratory testing, including specimen handling, test results and reporting of test results? [*see* 59A-7.031 F.A.C.]
		15. Do testing personnel determine and document action taken when inconsistencies occur between patient information and patient test results? [*see* 59A-7.031 F.A.C.]
		16. Is the laboratory enrolled in an approved proficiency testing program or programs for each of the CLIA regulated analytes or tests, for which it seeks licensure: [*see* 59A-7.025) F.A.C.] YOU MUST ATTACH PROOF OF ENROLLMENT.
		17. Does the laboratory examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens? [*see* 59A-7.025 F.A.C.]
		18. Are proficiency testing samples tested in your own laboratory and not sent to another laboratory for analysis? [see 59A-7.025 F.A.C.]
		19. Is there a qualified laboratory director? [see 59A-7.035 F.A.C.] YOU MUST ATTACH A COPY OF PROOF OF THE DIRECTOR'S QUALIFICATIONS.
		20. Does the director ensure that the laboratory employs laboratory personnel with education, experience or training, to provide consultation , supervise and accurately perform tests and report test results? [*see* 59A-7.035 F.A.C.]
		21. Does any owner, director, administrator, physician, surgeon, consultant, employee, organization, agency, representative or person either directly or indirectly, pay or receive any commission, bonus, kickback, rebate or gratuity or engage in any split fee arrangement in any from whatsoever for the referral of a patient [*see* 483.245, FS and 59A-7.028(2) F.A.C.]

17. Affidavit

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

CONFIDENTIAL DOCUMENT

FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

Health Care Licensing Application Addendum

AUTHORITY: Pursuant to section 408.806, Florida Statutes (F.S.), the Agency for Health Care Administration is required to obtain the name, address and Social Security number of the applicant and each controlling interest if the applicant or controlling interest is an individual; and the name, address, and federal employer identification number (EIN) of the applicant and each controlling interest if the applicant or controlling interest is not an individual. Disclosure of your Social Security number is mandatory. Your Social Security number will be used to secure the proper identification of persons listed on this application for licensure, criminal background checks and the indexing of controlling interests.

1. Provider / Licensee Information

A. *Please complete the following and indicate whether background screening was conducted as part of this application.* *(if you are seeking licensure as a Risk Manager please skip to 1B; Applicants for Health Care Clinics **must also** complete 1C)*:

Provider/Facility Type:		**National Provider ID#: (**if applicable)
Provider/Facility Name:		
Administrator/CEO/Managing Employee:	**Social Security #:**	**Background Screening Conducted** ☐ YES ☐ NO
Financial Officer:	**Social Security #:**	**Background Screening Conducted** ☐ YES ☐ NO

Laboratory Directors are considered administrators for clinical laboratories.

B. *RISK MANAGERS ONLY:*

Name	**Social Security #:**
HCRM License # (for renewal applications) **550-**	**Background Screening Conducted** ☐ YES ☐ NO

C. *Additional information needed for HEALTH CARE CLINIC applicants:*

In accordance with sections 408.806(1)(a) and 400.991 F.S., the medical or clinic director and each licensed health care practitioners as provided in section 3D of the Health Care Licensing Application, Health Care Clinics, AHCA Form 3110-0013, must provide their Social Security number. The Social Security number will be used to secure the proper identification of persons listed on this application for licensure and criminal background checks. *Please attach additional sheets if necessary.*

FULL NAME	SOCIAL SECURITY NUMBER	BACKGROUND SCREENING CONDUCTED
Medical or Clinical Director:		☐ YES ☐ NO
		☐ YES ☐ NO
		☐ YES ☐ NO
		☐ YES ☐ NO
		☐ YES ☐ NO
		☐ YES ☐ NO

2. Controlling Interests of Licensee

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

Provide the following information for **each person with 5% or greater ownership interest** in the licensee/provider. This information must match the information contained in Section 3A of the *Health Care Licensing Application*. Attach additional sheets if necessary.

FULL NAME	SOCIAL SECURITY NUMBER

B. *Board Members and Officers of Licensee*

Provide the following information for **each person that serves as an officer or is on the board of directors** (excludes voluntary board members) for the licensee/provider. This information must match the information contained in Section 3B of the *Health Care Licensing Application*. Attach additional sheets if necessary.

TITLE	FULLNAME	SOCIAL SECURITY NUMBER
Director/CEO		
President		
Vice President		
Secretary		
Treasurer		
Other:		

3. Management Company Controlling Interests

If a company other than the licensee manages the licensee/provider, complete the following information:

A. *Individual and/or Entity Ownership of Management Company*

Provide the following information for **each person or entity (corporation, partnership, association) with 5% or greater ownership interest** in the management company. This information must match the information contained in Section 4A of the *Health Care Licensing Application*. Attach additional sheets if necessary.

FULL NAME of INDIVIDUAL	SOCIAL SECURITY NUMBER

B. Board Members and Officers of Management Company

Provide the following information for **each person that serves as an officer or is on the board of directors** (excludes voluntary board members). This information must match the information contained in Section 4B of the *Health Care Licensing Application*. Attach additional sheets if necessary.

TITLE	FULL NAME	SOCIAL SECURITY NUMBER
Director/CEO		
President		
Vice President		
Secretary		
Treasurer		
Other:		

4. Affidavit

I, _____, hereby swear or affirm, under penalty of perjury that the statements in this addendum to the application for licensure as a health care provider are true and correct.

_____ _____ _____

Signature of Licensee or Authorized Representative Title Date

FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

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

Affidavit

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

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☐ Survey

☐ Change in Certification Type

☐ Other Changes *(Specify)*

_____

CLIA IDENTIFICATION NUMBER

_____D_____

(If an initial application leave blank, a number will be assigned)

FACILITY NAME	FEDERAL TAX IDENTIFICATION NUMBER
EMAIL ADDRESS	TELEPHONE NO. *(Include area code)* / FAX NO. *(Include area code)*

FACILITY ADDRESS — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing address is specified*

NUMBER, STREET *(No P.O. Boxes)*

CITY | STATE | ZIP CODE

MAILING/BILLING ADDRESS *(If different from street address)*

NUMBER, STREET

CITY | STATE | ZIP CODE

NAME OF DIRECTOR *(Last, First, Middle Initial)*

FOR OFFICE USE ONLY

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

☐ The Joint Commission ☐ AOA ☐ AABB

☐ CAP ☐ COLA ☐ 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.

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

- ☐ 01 Ambulance
- ☐ 02 Ambulatory Surgery Center
- ☐ 03 Ancillary Testing Site in Health Care Facility
- ☐ 04 Assisted Living Facility
- ☐ 05 Blood Bank
- ☐ 06 Community Clinic
- ☐ 07 Comp. Outpatient Rehab Facility
- ☐ 08 End Stage Renal Disease Dialysis Facility
- ☐ 09 Federally Qualified Health Center
- ☐ 10 Health Fair
- ☐ 11 Health Main. Organization
- ☐ 12 Home Health Agency
- ☐ 13 Hospice
- ☐ 14 Hospital
- ☐ 15 Independent
- ☐ 16 Industrial
- ☐ 17 Insurance
- ☐ 18 Intermediate Care Facility for Mentally Retarded
- ☐ 19 Mobile Laboratory
- ☐ 20 Pharmacy
- ☐ 21 Physician Office

  Is this a shared lab? ☐ Yes ☐ No
- ☐ 22 Practitioner Other *(Specify)* _____
- ☐ 23 Prison
- ☐ 24 Public Health Laboratories
- ☐ 25 Rural Health Clinic
- ☐ 26 School/Student Health Service
- ☐ 27 Skilled Nursing Facility/ Nursing Facility
- ☐ 28 Tissue Bank/Repositories
- ☐ 29 Other *(Specify)* _____

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.

1. Is this a laboratory that has temporary testing sites?

   ☐ Yes ☐ No

2. 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.

3. 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
HISTOCOMPATIBILITY			**HEMATOLOGY**		
☐ Transplant			☐ Hematology		
☐ Nontransplant			**IMMUNOHEMATOLOGY**		
MICROBIOLOGY			☐ ABO Group & Rh Group		
☐ Bacteriology			☐ Antibody Detection (transfusion)		
☐ Mycobacteriology			☐ Antibody Detection (nontransfusion)		
☐ Mycology			☐ Antibody Identification		
☐ Parasitology			☐ Compatibility Testing		
☐ Virology			**PATHOLOGY**		
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology		
☐ Syphilis Serology			☐ Oral Pathology		
☐ General Immunology			☐ Cytology		
CHEMISTRY			**RADIOBIOASSAY**		
☐ Routine			☐ Radiobioassay		
☐ Urinalysis			**CLINICAL CYTOGENETICS**		
☐ Endocrinology			☐ Clinical Cytogenetics		
☐ Toxicology			**TOTAL ESTIMATED ANNUAL TEST VOLUME:**		

IX. TYPE OF CONTROL

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☐ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
_____ *(Specify)*		☐ 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

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

INSTRUCTIONS FOR COMPLETION

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.

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.

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALITIES

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, pO2, pCO2)
BUN
Calcium
Chloride
Cholesterol
Cholesterol, HDL
CK/CK isoenzymes
CO2
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/IcCodes.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.**

GUIDELINES FOR COUNTING TESTS FOR CLIA

- 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/subspecialities**, do not count calculations (e.g., A/G ratior, 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.