*NOTICE *
THIS APPLICATION WAS REVISED IN OCTOBER 2020 – PLEASE READ CAREFULLY -

Initial License Application
To Operate an Independent Clinical Laboratory

Regulations affecting the application for licensure of Independent Clinical Laboratories can be found by clicking the Rules tab or link on the applications page.

Effective October 1, 2020

Any clinical laboratory that meets the definition of an Independent Clinical Laboratory (ICL), including those that perform waived testing only, will be required to obtain the state license for laboratories and follow the rules set forth by the Alabama State Board of Health. The application and fee requirements can be found on this website.

All clinical laboratories that perform testing on human specimens for diagnosis, treatment, or preventive medicine are required to obtain and maintain a Clinical Laboratory Improvement Amendments (CLIA) certificate as required by CMS.

In addition to the information requested within the application, the following must also be submitted:

1. A completed license application and $240 application fee. Application fees are not refundable.

2. Organizational documents such as: Articles of Incorporation, LLC Agreement, Partnership Agreement, or Statement of Sole Proprietorship under which the facility will operate. A copy of the registration to conduct business in Alabama must accompany this application if the entity was established in a state other than Alabama.

3. Qualifications and licensure information regarding the medical director.

Following review of the application, a copy of the application will be forwarded to the Division of Health Care Facilities, Laboratory Unit. A staff member from the Division of Health Care Facilities Laboratory Unit may contact you regarding an on-site licensure visit to determine if the facility meets minimum requirements for a state license.

NOTE Due to workload volume, application review takes a minimum of thirty days. An on-site survey (if required) could add considerable time to completion of the licensure process.

Applications must be submitted well in advance of anticipated start of operations. Applications must be submitted with all required documents and certificates as noted in the instructions before the review can begin.

License Certificates
The earliest date a license can be granted is the first day the complete application and any surveys have been approved by the Department.

Printing of License Certificates
License certificates are now available on-line. When a license is granted or renewed the license certificate can be printed on-line at https://dph1.adph.state.al.us/FacilityCertificatePrint. A facility ID and pin number will be provided and must be used to print license certificates.

Please note: it is a violation of state law to provide independent clinical laboratory services before you are granted a license from this agency. If you have questions regarding your application, please call (334) 206-5175.

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ADDITIONAL INFORMATION
INDEPENDENT CLINICAL LABORATORY

Item 1, Applicant. The applicant is an individual, partnership, corporation or other entity which will be the governing authority of the facility and to whom the license will be granted **(not the facility name or the individual completing the application, unless the applicant is an individual)**. The name entered in this section must be exactly as printed on the legal document establishing the entity. A copy of the legal document must accompany this application. Entities established in a state other than Alabama must register to conduct business in Alabama with the Secretary of State's Office. A copy of the registration must also accompany this application. If the facility is leased, the lessee should be indicated as the applicant. The lessee may be an individual, partnership, corporation, or other entity. **NOTE - The applicant must be the operator of the facility, the entity that hires or fires the administrator, determines patient care issues, makes payment for facility obligations, etc.**

Item 5, Laboratory Director: Credentials or resume for qualified director must be attached to this application.

Item 6, Facility Name. The information provided on this line will be entered in the Provider Services Directory and the facility will be referred to by this name exactly as entered on this application. This name should be the same as on advertisements, facility letterhead, signs in front of the facility and certification information. This name must be unique; that is, it may not be the same as the name of any other licensed facility in Alabama, nor may it be so similar to the name of any other licensed facility that, in the judgment of ADPH staff, there could be any confusion to the public. Governing authorities operating more than one facility may give the facilities they operate similar, but not identical names. The name may be abbreviated if the abbreviation is also used on advertisements, facility letterhead, signs in front of the facility and certification information.

Item 8, Facility Mailing Address. The facility mailing address, street address or post office box must be within the same postal service area as the facility's physical location.

Item 12, Collection Station. A collection station is a facility that collects specimens and packages the specimen for transportation.

Item 17, Attestation of Responsible Person. A company officer, board member, administrator or other responsible person must sign the application and make the attestation.

Application Fee. The application fee for an independent clinical laboratory is $240. Application fees are not refundable. Make a check or money order payable to the Alabama Department of Public Health.

Attachments. Each attachment must be referenced as a specific applicable item. For example, attachment to item 14 d should be referenced in the document and labeled.

STATE OF ALABAMA
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF PROVIDER SERVICES
P.O. BOX 303017 (MAILING ADDRESS)
MONTGOMERY, ALABAMA 36130-3017
THE RSA TOWER, SUITE 700, 201 MONROE STREET, MONTGOMERY, AL 36104
(PHYSICAL LOCATION)

INITIAL LICENSE APPLICATION TO OPERATE AN INDEPENDENT CLINICAL LABORATORY

APPLICATION FEE	FOR DEPARTMENTAL USE ONLY
APPLICATION FEES ARE NOT REFUNDABLE. The fee is $240. MAKE CHECK OR MONEY ORDER PAYABLE TO: ALABAMA DEPARTMENT OF PUBLIC HEALTH	Application Fee _____ Check # _____ Facility ID # _____

1._____
Applicant
(see instructions on page 3)

2._____
Applicant Address

3._____
City State Zip Code

4._____
Applicant Telephone Number

5._____
Laboratory Director
(Must be an M.D. or qualified Ph.D.
Attach credentials or resume to this application)

6._____
Name of the Facility
(see instructions on page 3)

7._____
Facility Physical Address

8._____
Facility Mailing Address
(see instructions on page 3)

9. _____
City Zip Code County

10. _____
Facility Telephone Number

11. Laboratory Classification

☐ Clinical (also complete 12b, if applicable)

☐ Blood Bank - check only if blood product is issued

☐ Pathology (anatomical and/or cytology)

☐ Plasmapheresis Bank

☐ Specimen Collection Station - check this box if the facility will operate only as specimen collection station and not perform other clinical procedures. Do not check this box if you have checked the clinical box above.
Give address and phone number of laboratory where the clinical procedures will be performed for specimens collected at this station?

_____

12a. Will this facility operate only as a mobile unit? YES ☐ NO ☐
Check yes, if test **will not** be performed at the physical location listed on the first page of this application.

12b. Will this facility operate as a waived test facility only? YES ☐ NO ☐
(If yes, please attach a list of the manufacturer of the tests and specimen type, when necessary to determined CLIA complexity)

13. Applicant Information

a. Applicant is a (check one):

Individual	☐	Nonprofit Corporation	☐	City	☐
Partnership	☐	Hospital Authority	☐	County	☐
Corporation	☐	State	☐	Joint City County	☐
Limited Liability Company	☐	Other: _____ Specify			☐

b. List all the applicant's board members and officers (attach additional paper if necessary).

_____ _____

_____ _____

c. List the name(s) of any person or business entity that has 5% or more ownership interest in the applicant (attach additional paper if necessary). Also, attach a diagram depicting the organizational structure.

_____ _____

_____ _____

d. Does this applicant or any of its owners listed in item “c” operate any other health care facility in Alabama or in any other state? YES ☐ NO ☐ If yes, attach a list including the type(s) of facility(s), name(s), address(s), and owner(s).

e. Have any of the facilities listed in item “d” had any adverse licensure action taken against them or been subject to exclusion from the Medicare or Medicaid Reimbursement Programs? YES ☐ NO ☐ If yes, attach an explanation.

f. Have the applicant, officers or principals ever had a license application denied by this or any other state? YES ☐ NO ☐ If yes, attach an explanation.

14. Has the laboratory director listed in item “5" of this application:

a. ever been convicted of a crime? YES ☐ NO ☐

b. ever been found guilty of abusing another individual? YES ☐ NO ☐

c. ever had adverse action taken against a professional license, for example, nursing home administrator license, attorney license, nurse license, physician license? YES ☐ NO ☐

d. ever been excluded from participation in Medicare or Medicaid Reimbursement Program? YES ☐ NO ☐

If a, b, c, or d are yes, attach an explanation for each affirmative answer.

15. Provide the name, phone number, and email address of a knowledgeable person who can supply details about this application. **PLEASE PRINT**

Name _____

Phone (____) _____

Email _____

16. Administrator or Director Signature:

I declare, under penalty of perjury, that I have not operated or allowed to be operated this facility, or any other facility, without a license. I agree to operate this facility according to the Rules of the Alabama State Board of Health.

_____ _____

Printed Name Signature

_____ _____

Date Title/Position

NOTARIZED:

Sworn to and subscribed before me this _____

day of _____ 20_____.

_____

(Notary Public)

17. Attestation of Responsible Person:

I declare, under penalty of perjury, that I have personal knowledge about the statements made in this application and certify that all statements are true and correct. To the best of my knowledge, neither the applicant nor any of the principals, including myself, the owners, and the administrator, have operated or allowed to be operated this facility, or any other facility, without a license. I certify that I am authorized to make this representation on behalf of the applicant.

Signature: _____ Printed Name:_____

Title/Position:_____ Date:_____

NOTARIZED:

Sworn to and subscribed before me this _____

day of _____ 20_____.

_____

(Notary Public)

MANDATORY ACKNOWLEDGMENT NOTICE

Pursuant to *Alabama Code* section 30-3-194, every applicant seeking from a state agency a license, certificate, permit, or authorization to engage in a profession, occupation, or commercial activity, must provide the social security number of the person signing the application, whether as an individual or on behalf of an entity or corporation. Failure to provide this social security number will result in the denial of the application.

Print or Type Name of Person Signing Application: _____

Full Social Security Number of Person Signing Application: _____

Print or Type the Facility Name: _____

THIS PAGE **IS NOT** PUBLIC RECORD