NOTICE
THIS APPLICATION WAS REVISED DECEMBER 2021
PLEASE READ CAREFULLY

Change of Ownership 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.

The following information should be submitted in support of an application for a change of ownership at least 30 days prior to the effective date of the change.

1. A completed Change of Ownership license application and $240 application fee. Application fees will not be refunded. Checks or money orders must be made payable to the Alabama Department of Public Health.

2. A copy of the Articles of Incorporation, Articles of Organization, LLC Agreement, Partnership Agreement or Statement of Sole Proprietorship under which the Independent Clinical Laboratory will operate post transaction. Corporations, Limited Partnerships and Limited Liability Companies filing an application for a change of ownership must provide a copy of their Certificate of Existence (for domestic entities) or Certificate of Registration (for foreign entities) from the Alabama Secretary of State as proof of authority to transact business in the state of Alabama.

3. A draft copy of the agreement effecting the change of ownership, such as an asset purchase, lease, or management agreement. An unsigned copy of the agreement or a final draft is acceptable for submittal with this application; however, a copy of the fully executed agreement **must** be submitted prior to the issuance of a license certificate.

4. A copy of the Laboratory Director's license and credentials or resume.

A copy of the application will be forwarded to the Division of Healthcare Facilities Clinical Laboratory Improvement Amendments (CLIA) Laboratory Unit following initial review by the Licensure Unit. A staff member from the CLIA Laboratory Unit will contact the applicant if an onsite licensure survey is required before the license can be granted.

NOTE Due to workload volume, application review takes a minimum of 30 days. An onsite survey (if required) could add considerable time to completion of the review process. Applications must therefore be submitted well in advance of the date of the anticipated change of ownership and with all required documentation, as noted in the instructions, before the review can begin.

The earliest date a license can be granted is the first day the complete application and any required surveys have been approved by the Department. [For certified health care facilities and agencies, application to the appropriate Medicare Administrative Contractor (MAC) is recommended 180 days in advance of the anticipated date of the change of ownership.]

FOR STATE LICENSURE PURPOSES, A CHANGE OF OWNERSHIP IN NOT EFFECTIVE UNTIL A NEW LICENSE CERTIFICATE REFECTING THE CHANGE HAS BEEN ISSUED.

Printing of License Certificates

License certificates are now available online. 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 operate as an Independent Clinical Laboratory before you are granted a license from the Alabama Department of Public Health. If you have questions regarding the application, please call (334) 206-5175.

(Revised 12/2021)

APPLICATION INSTRUCTIONS
Independent Clinical Laboratory

Changes in the ownership of a licensed Independent Clinical Laboratory are reviewed on a case-by-case basis by the Alabama Department of Public Health. A license application for a change of ownership in an Independent Clinical Laboratory may be required in the circumstances described below (see also 42 C.F.R. § 489.18 and State Operations Manual Section 3210.1D); however, changes of ownership may not be limited to these situations. Please consult the Licensure Division for a determination as to whether a Change of Ownership License Application is required if the applicable transaction is not described.

Unincorporated Sole Proprietorship. If a provider entity is owned by a single individual, approval for a change of ownership is required when transferring title of that provider entity to another person or firm, regardless of whether the transaction includes transfer of title to the real estate. Approval for a change of ownership is also required if the former owner becomes one of the members of a partnership or corporation succeeding him/her as the new owner.

Partnership. The removal, addition, or substitution of an individual as a partner in the provider entity dissolves the old partnership, creates a new partnership, and constitutes a change of ownership, unless expressly provided otherwise in the transaction. Questions regarding the applicability of this requirement under Alabama law will be submitted to the CMS Regional Office for final determination.

Corporation. A change in the members of the governing body of the provider entity's owner corporation, regardless of whether ownership of the corporation stock is transferred, would not constitute a change of ownership as long as the same corporation continues to be the legal entity responsible for operation of the provider entity.

- A merger of one or more corporations into the provider corporation, with the Medicare-participating provider corporation surviving, does not constitute a change of ownership.
- If the corporation that survives the merger is not the former owner of the provider corporation, a change of ownership has occurred.
- Consolidation or merger of two or more corporations that results in the creation of a new corporate entity having ownership control over a provider constitutes a change of ownership.
- Transfer of corporate stock does not constitute a change of ownership.

Leasing. The lease of all or part of a provider facility constitutes a change of ownership of the leased portion. If only part of the provider facility is leased, the original provider agreement remains in effect only with respect to the unleased portion. The Department does a survey and prepares a certification covering the leased portion as a new provider. Documents must be provided to the Department that indicate which individual or entity has first level authority over, and responsibility for, the provider located within the leased premises.

Management Firm. A firm that contracts with the owners to manage a provider entity, subject to the owners' general approval of operating decisions, is an agent of the owners rather than a

partner or successor. If management in that sense is turned over to a management firm, this would not constitute a change of ownership, even though the management firm may appear to have wide latitude in making decisions, and even though its fee may be based on the net revenue or profit the provider entity receives from furnishing services.

The only time an operation under a management agreement would constitute a change of ownership is when the owner has relinquished all authority and responsibility for the provider entity. Questionable cases will be submitted to the CMS Regional Office for a final determination.

Franchise. If a provider entity states it is a franchisee of another entity which is the owner of the provider, a determination must be reached concerning which entity is the provider that CMS will hold legally responsible for complying with all applicable law and regulations before the change of ownership can be processed.

Item 1: Applicant. The applicant should be the legal name of the individual, partnership, corporation or other entity who will become the governing authority of the Hospital upon the change of ownership and in whose name the license will be issued. The applicant's name as stated on the application must be identical to the name reflected on the corporate documents submitted with the application. If the Independent Clinical Laboratory is operated by another entity pursuant to a lease agreement, the lessee should be listed as the applicant, and a copy of the lease agreement must be submitted with the application.

NOTE - The applicant must be the operator of the Independent Clinical Laboratory, the entity that makes employment decisions concerning the Independent Clinical Laboratory's Director, determines patient care issues, makes payment for the Independent Clinical Laboratory's financial obligations, etc.

The Department does not recognize fictitious business names (d/b/a's) as such or require their disclosure. Businesses are not required to register a d/b/a or trade name with the Alabama Secretary of State. If a d/b/a is included as part of the applicant's legal name in Item 1, the d/b/a will be reflected on the license. If the d/b/a will be utilized as the facility name, it should be entered in Item 7.

Item 5: Laboratory Director. A copy of the current license and credentials or resume for the applicant's qualified Director must be attached.

Item 6: Facility Name. The information provided on this line will be entered in the Department's Provider Services Directory, and the Independent Clinical Laboratory will be referred to by this name. This same name should be reflected on all of the Independent Clinical Laboratory's advertisements, letterhead, signage and certification information. The name must be unique to the Independent Clinical Laboratory - 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 Department staff, it could create any confusion in the mind of the public.

Governing authorities operating more than one facility may give the facilities they operate similar, but not identical, names. The facility name may be abbreviated if the abbreviation is also used on all advertisements, letterhead, signage and certification information.

Item 8: Facility's Mailing Address. The Independent Clinical Laboratory's mailing address or post office box must be within the same postal service area as its street address.

Item 13: Specimen Collection Station. A specimen collection station is a facility that collects specimens and packages them for transportation.

Item 14: Waived Tests. Waived tests are defined as simple laboratory examinations and procedures which (1) are cleared by the U.S. Food and Drug Administration for home use; (2) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or (3) pose no reasonable risk of harm to the patient if the tests are performed incorrectly.

Item 19: Director's Signature. The Laboratory Director designated in Item 5 to run the Independent Clinical Laboratory on behalf of the applicant must sign the application and make the attestation in this section.

Item 20: Attestation of Responsible Person. A company officer, board member, administrator or other responsible person of the applicant must sign the application and make the attestation in this section.

Item 21: Current Licensee's Signature. A company officer, board member, administrator or other responsible person of the current licensee must sign the application and make the attestation in this section.

Application Fee. The application fee for an Independent Clinical Laboratory is $240. Application fees are not refundable. Checks or money orders must be made payable to the Alabama Department of Public Health and submitted with the application.

Attachments. Each attachment to the application must be specifically referenced within the application and labeled accordingly. For example, an attachment to Item 15(d) should be referenced in the application and labeled as such.

(Revised 12/2021)

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)

CHANGE OF OWNERSHIP APPLICATION TO OPERATE AN INDEPENDENT CLINICAL LABORATORY

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

1. _____
Applicant
(see instructions on page 4)

2. _____
Applicant Address

3. _____
City State Zip Code

4. _____
Applicant Telephone Number

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

_____
Laboratory Director's Email Address

6. _____
Facility Name
(see instructions on page 4)

7. _____
Facility Physical Address

8. _____
Facility Mailing Address
(see instructions on page 5)

9. _____
City Zip Code County

10. _____
Facility Telephone Number

11. _____
Facility ID Number

12. This application is to apply for (check one):

a. Change of Ownership ☐ b. Change of Ownership and name change ☐

The facility is currently licensed as _____.
(Facility Name)

13. Laboratory Classification

☐ Clinical (also complete 14b, 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 solely as a specimen collection station and will not perform other clinical procedures. Do not check this box if the "Clinical" box has been checked.

Provide the address and phone number of the laboratory where the clinical procedures will be Performed on the specimens collected at this station.

_____.

14. a. Will this facility operate only as a mobile unit? YES ☐ NO ☐
Check YES if testing will not be performed at the physical address provided in Item 7.

b. Will this facility operate only as a waved test facility? YES ☐ NO ☐
If YES, please attach a list of the tests, the manufacturer of the tests, and the specimen type, when Necessary, to determine the level of CLIA complexity.

15. 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). Attach a schematic depicting both the pre-transaction and post-transaction organizational structure of the governing body and Independent Clinical Laboratory.

_____ _____

_____ _____

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

16. Are there any outstanding citations of deficiency, either Federal or State, that have not been corrected? YES ☐ NO ☐
If yes, has the plan of correction for these deficiencies been accepted by the Division of Health Care Facilities? YES ☐ NO ☐

Note: The new operator will be responsible for correcting all outstanding deficiencies and may be subject to sanctions imposed for past or present deficiencies, including payment of any uncollected civil monetary penalties. Approval of applications for changes of ownership of Independent Clinical Laboratories with outstanding deficiencies remains subject to the sole discretion of the Department.

17. 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 any professional license, held by him/her, such as a license as a nursing home administrator, attorney, nurse, or physician? YES ☐ NO ☐

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

If the answer is yes to a, b, c, or d, please attach an explanation.

18. Provide the name, phone number, and email address for a knowledgeable person that can provide additional information about this application.

    Name (print) _____

    Phone _____

    Email _____

19. Laboratory Director's Signature:

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

    _____ _____
    Signature Date

    _____
    Printed Name

    NOTARIZED:

    Sworn to and subscribed before me this _____day of _____20_____.

    _____
    (Notary Public)

    (Seal)

    My commission expires_____.

20. 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 the statements made herein are true and correct, to the best of my knowledge and belief. To the best of my knowledge, neither the applicant nor any of its owners or principals, including myself, nor the Laboratory Director, has operated, or allowed the operation of, this or any other facility without a license. I certify that I am authorized to make this representation on behalf of the applicant.

    _____ _____
    Signature Date

    _____ _____
    Printed Name Title/Position

NOTARIZED:

Sworn to and subscribed before me this _____day of _____20_____.

_____
(Notary Public)

(Seal)

My commission expires_____.

21. Current Licensee's Signature

I declare, under penalty of perjury, that the current licensee of this facility concurs with this change of ownership and recommends that this application for a change of ownership be granted. I certify that I am authorized to make this representation on behalf of the current licensee.

_____
Name of Currently Licensed Facility

_____ _____
Signature Date

_____
Printed Name

_____
Title/Position

NOTARIZED:

Sworn to and subscribed before me this _____day of _____20_____.

_____
(Notary Public)

(Seal)

My commission expires_____.

MANDATORY ACKNOWLEDGMENT NOTICE

Pursuant to *Alabama Code* section 30-3-194, every applicant seeking a license, certificate, permit, or authorization from a state agency to engage in 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 any legal business entity. Failure to provide this social security number will result in the denial of the application.

Print or Type Name of Person Signing Application
On Behalf of the Applicant: _____

Social Security Number of Person Signing Application: _____

Print or Type the Facility Name: _____

THIS PAGE **IS NOT** PUBLIC RECORD