GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook., Commissioner

Nathan Deal, Governor

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia,gov

Enclosed is the clinical laboratory licensure packet you requested. Please fill out the appropriate forms carefully and completely and return to this office with the **licensure fee of $500.00**. Please make the check payable to the **GEORGIA DEPARTMENT OF COMMUNITY HEALTH**

Each facility must have a licensed laboratory director. If your laboratory director is not currently licensed, please complete the appropriate form and submit to this office along with a **$10.00 fee.**

The following documents can be obtained online under the licensure requirements and initiating the appropriate form(s) necessary for licensure:

_ 1. "Rules" for Licensure of Clinical Laboratories (Chapter 290-9-8)- Please see website: **www.dch.georgia.gov. Current Rules and Regulations.**
_ 2. Application For a Clinical Laboratory License
_ 3. Application For Laboratory Director License, if applicable
_ 4. Guidelines for licensing a Specimen Collection Station

Complete the appropriate forms and return them to this office. A survey will be conducted verifying compliance with State licensure requirements **prior to the opening of your facility** for patient testing or specimen collection.

If you have any questions, please do not hesitate to contact this office at (404)657-5450. Thank you for completing and returning these forms as soon as possible.

Sincerely,

Sheela E. Puthumana BS MT(ASCP)
Program Director
Diagnostic Services Unit
Healthcare Facility Regulation Division

NEWFAC.LTR
Revised 1/4/12

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook., Commissioner *Nathan Deal, Governor*

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia,gov

APPLICATION FOR STATE OF GEORGIA CLINICAL LABORATORY LICENSE

CLINICAL LABORATORY LICENSURE LAW, 1970

LAB LICENSE #	**YEAR**	**CLIA #**

PART I. GENERAL INFORMATION

Name of Laboratory:

Address:	City:	County:	State:	Zip Code:

Telephone #	Fax #	e-mail address

Name and Address of Owner / Management Group:	Administrator:

Type of Laboratory (check A, B, C, D)

A. Hospital Based
- ☐ Clinical
- ☐ Blood Bank
- ☐ Tissue Bank
- ☐ Specialty

B. Private
- ☐ Clinical
- ☐ Blood Bank
- ☐ Tissue Bank
- ☐ Specimen Collection Station

C. ☐ Official Public Health Agency

D. ☐ Point of Care

Categories For Which Annual License / Approval is Requested (place "X" in appropriate squares)

CLINICAL CHEMISTRY
- ☐ Routine
- ☐ Urinalysis
- ☐ Blood Gases
- ☐ Toxicology (medical)
- ☐ TDM
- ☐ Other _____

☐ **HEMATOLOGY**

IMMUNOHEMATOLOGY
- ☐ Group
- ☐ Type
- ☐ Crossmatch.
- ☐ Antibody Screen
- ☐ Identification
- ☐ Transfusion Services
- ☐ Pheresis
- ☐ Components
- ☐ Donor Services
- ☐ Storage

MICROBIOLOGY
- ☐ Bacteriology I
  Gram Stain / Kits
- ☐ Bacteriology II
- ☐ Mycobacteriology I
  AFB Stain
- ☐ Mycobacteriology II
- ☐ Mycology I
  Wet Prep
- ☐ Mycology II
- ☐ Parasitology
- ☐ Virology

CLINICAL IMMUNOLOGY AND SEROLOGY
- ☐ Syphilis
- ☐ Non-Syphilis
- ☐ Viral Serology
- ☐ HIV (Screen / Confirmation)

PATHOLOGY
- ☐ Exfoliative Cytology
- ☐ Anatomic Pathology
- ☐ Oral Pathology

☐ **H L A TESTING**

☐ **RADIOBIOASSAY** (in vivo)

☐ **TISSUE BANKING**

☐ **GENETICS / CYTOGENETICS**

☐ **INHERITED DISORDER TESTING**

☐ **POINT OF CARE TESTING**

☐ **SPECIMEN COLLECTION STATION(S)**

_____

_____

_____

*Attach extra sheet if necessary

☐ **OTHER** (Identify)

DO NOT COMPLETE - FOR ADMINISTRATIVE USE ONLY

☐ License Fee Receive Check # _____ Date _____

All applicants complete Section **A**, **B**, **C, D,** and **E** (and sign form). Attach appropriate supplements.

PART II. IDENTIFICATION OF LABORATORY

A. PUBLIC HEALTH LABORATORY

1. Type of Laboratory: ☐ STATE ☐ DISTRICT ☐ COUNTY

B. INDEPENDENT TESTING LABORATORY

1. Name of Owner / Management Group:

2. Type of Ownership / Management Group:

☐ Individual ☐ Corporation ☐ Partnership ☐ Other (Specify) _____

C. HOSPITAL LABORATORY

1. Type of Hospital:

☐ General ☐ State ☐ Private ☐ Other _____

3. Name of Administrator:

ACCREDITATION OF LABORATORY

Is this laboratory licensed or accredited by any professional or governmental agency (except business license)

☐ YES ☐ NO

List the Accrediting Body:

_____

_____

_____

_____

Date of Last Inspection: _____

PROFICIENCY TESTING:

All licensed laboratories must satisfactorily participate in one of the State approved Proficiency Testing Programs for each category in which they are licensed. **A COPY OF YOUR PROFICENCY TESTING ORDER CONFIRMATION OR APPLICATION FOR ENROLLMENT MUST BE ATTACHED TO <u>THIS</u> APPLICATION.**

A copy of your results must be sent by the proficiency testing agency to:

Georgia Department of Human Resources, Health Care Section, Diagnostic Services Unit,
Two Peachtree Street, N.W., Suite 33-250, Atlanta, GA 30303-3142

PART III. DIRECTOR INFORMATION

Laboratory Director Name: Last	First	Middle		
Address:	City:	County:	State:	Zip Code:
Degrees:	Specialty:	No. Hours per week Director Spends in This Lab?	Does the Director also Serve as Supervisor ☐ YES ☐ NO	

Director listed in (A) above is Director of the Following Laboratories	**LAB License #**
1. _____	**1.** _____
2. _____	**2.** _____
3. _____	**3.** _____

B. Consultant: Last First Middle

Address:	City:	County:	State:	Zip Code:

Certified In:	Is the Following Provided?	Number of Hours Per Week Consultant Spends in Laboratory ?
□ Anatomic Pathology □ Clinical Pathology □ Other _____	On-Site Consultation □ YES □ NO In-Service Training □ YES □ NO	

D. . Supervisory and Technical Personnel *(Pathologist / Managers / Technologist) attach extra sheet if necessary*

Name (Last, First, Middle)	Degree / Major Field CERTIFICATION	Years of Experience	Position – Title and Primary Responsibility	Hours per Week
a.				
b.				
c.				
d.				
e.				
f.				
g.				
h.				
i.				
j.				
k.				

E. Non-Supervisory Technical Personnel (Do not include any persons listed above in Parts A, B, C and D)

Total Number Assigned To	General Laboratory		Anatomical Laboratory	
	Full Time	Part Time Hrs./Week	Full Time	Part Time Hrs./Week
a. Technologists				
b. Technicians				
c. Trainees				
d. Other				
Total				

ATTESTATION:

I hereby attest that all of the statements made in this application are true, complete and correct to the best of my knowledge.

Signature of Laboratory Director: _____Date:_____

Name and Title of Designee (Authorized Person) _____

(Print)

Signature: _____

Designee e-mail address: _____

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GUIDELINES FOR THE APPLICATION

LICENSURE AS A CLINICAL LABORATORY DIRECTOR

1. Clearly print your name the way it should appear on your license:
   If you do not use your full middle name, print only your middle initial.

2. Check the categories and subcategories which you plan to direct.

3. Enclose a copy of your current Georgia physician's license, if applicable.

4. List board certification and date certified, or check eligibility and note specialization for board certification.

5. Submit a copy of board certification or letter of notification from designated board of passing certification examination. For board eligibility submit a copy of the letter of eligibility from designated board.

6. Education – give name and location of college / university, major, dates attended. (month and year) and degree(s) received.

7. Laboratory Training – List laboratory training and experience. If applying as director of a laboratory specialty / sub-specialty laboratory, as a restricted director, or as a director of a plasmapheresis / whole blood donor center, be specific as to laboratory training and experience.

8. List the laboratory or laboratories which you plan to direct. You must be licensed as a laboratory director **before** you take over the directorship of any laboratory.

9. Sign and date the application and enclose a **check or money order** for the fee **($10.00) made payable to Georgia Department Community Health).**

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook., Commissioner

Nathan Deal, Governor

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia,gov

APPLICATION FOR CLINICAL LABORATORY DIRECTOR

UNDER THE CLINICAL LABORATORY LICENSURE LAW, 1970

1. Name of Applicant as Preferred on License (please print)

Address #	Street	City	State	Zip Code

Telephone #	Fax #	e-mail address

2. Check those categories or subcategories which you plan to direct.

CLINICAL CHEMISTRY
- ☐ Routine
- ☐ Urinalysis
- ☐ Blood Gases
- ☐ Toxicology (medical)
- ☐ TDM
- ☐ Other _____

☐ **HEMATOLOGY**

IMMUNOHEMATOLOGY
- ☐ Group
- ☐ Type
- ☐ Crossmatch.
- ☐ Antibody Screen
- ☐ Identification
- ☐ Transfusion Services
- ☐ Pheresis
- ☐ Components
- ☐ Donor Services
- ☐ Storage

MICROBIOLOGY
- ☐ Bacteriology I
  Gram Stain / Kits
- ☐ Bacteriology II
- ☐ Mycobacteriology I
  AFB Smears
- ☐ Mycobacteriology II
- ☐ Parasitology
- ☐ Mycology I
  Wet Preps
- ☐ Mycology II
- ☐ Virology

CLINICAL IMMUNOLOGY AND SEROLOGY
- ☐ Syphilis
- ☐ Non-Syphilis
- ☐ Viral Serology
- ☐ HIV (Screen / Confirmation)

PATHOLOGY
- ☐ Exfoliative Cytology
- ☐ Anatomic Pathology
- ☐ Oral Pathology

- ☐ **H L A TESTING**
- ☐ **RADIOBIOASSAY** (in vivo)
- ☐ **TISSUE BANKING**
- ☐ **GENETICS / CYTOGENETICS**
- ☐ **INHERITED DISORDER TESTING**
- ☐ **POINT OF CARE TESTING**
- ☐ **SPECIMEN COLLECTION STATION(S)**
  _____
  _____
  _____
- ☐ **OTHER** (Identify)
  _____

3. ☐ **M.D.** Licensed in Georgia to Practice: ☐ Medicine ☐ Osteopathy ☐ Dentistry
Georgia License Number _____(attach copy of current card)

☐ **Ph.D.** Field of Study _____

If you have not previously been licensed as a Laboratory Director in Georgia, please submit to this office documentation attesting to your qualifications.

Attach Money Order or check for **$ 10.00** (biennial License Fee)
Make payable to: **Georgia Department of Community Health** (NO CASH)

DO NOT COMPLETE - FOR ADMINISTRATION USE ONLY

☐ License Fee Received ☐ Check # _____ ☐ Date Issued _____

4. ATTESTATION:

I hereby attest that all of the statements made in this application are true, complete and correct to the best of my knowledge.

SIGNATURE OF APPLICANT: _____DATE_____

5. CERTIFICATIONS and / or REGISTRATIONS (Attach copies of certificates or Letter of Eligibility)

CERTIFYING AUTHORITY	DATE CERTIFIED	BOARD ELIGIBLE	SPECIALIZATION
		☐	
		☐	
		☐	

6. EDUCATION

NAME and LOCATION of College or University	MAJOR	Dates Attended (mo. / yr) FROM	TO	DEGREE

7. LABORATORY TRAINING (complete in detail) **MOST RECENT**

A. ☐ Medical Technology (Certification _____) ☐ Research ☐ Internship ☐ Residency ☐ Other (specify) _____

Name and Address of Institution	Laboratory Specialty In Which you Trained
Training Dates	Name and Degree of Immediate Supervisor during Training

B. ☐ Medical Technology (Certification _____) ☐ Research ☐ Internship ☐ Residency ☐ Other (specify) _____

Name and Address of Institution	Laboratory Specialty In Which you Trained
Training Dates	Name and Degree of Immediate Supervisor during Training

8. LABORATORY EXPERIENCE (complete in detail)

A. Name and Address of Institution	Dates Employed
Name and Degree of Laboratory Director	Your Job Title

Experience was in the following: (if more than one, give length of time in each)

☐ Clinical Chemistry ☐ Immunology & Serology ☐ Cytogenetics
☐ Hematology ☐ Pathology ☐ Metabolic Disorder
☐ Immunohematology ☐ Radiobioassay ☐ Other _____
☐ Microbiology ☐ Tissue Banking

Description of duties: _____

_____
_____
_____
_____

B. Name and Address of Institution	Dates Employed

Name and Degree of Laboratory Director	Your Job Title

Experience was in the following: (if more than one, give length of time in each)

□ Clinical Chemistry □ Immunology & Serology □ Cytogenetics
□ Hematology □ Pathology □ Metabolic Disorder
□ Immunohematology □ Radiobioassay □ Other _____
□ Microbiology □ Tissue Banking

Description of duties: _____
_____

9. LABORATORY (IES) for which you will serve as licensed director:

A. Name and Address:	Telephone #

Number of hours per week devoted to the Directorship of this laboratory: _____

Do you also serve as supervisor ? □ YES □ NO

Supervisor / Manager (s):	Categories	Hours / Week
1. Name:		

B. Name and Address:	Telephone #

Number of hours per week devoted to the Directorship of this laboratory: _____

Do you also serve as supervisor ? □ YES □ NO

Supervisor / Manager (s):	Categories	Hours / Week
1. Name:		

C. Name and Address:	Telephone #

Number of hours per week devoted to the Directorship of this laboratory: _____

Do you also serve as supervisor ? □ YES □ NO

Supervisor / Manager (s):	Categories	Hours / Week
1. Name:		

INSTRUCTIONS FOR COMPLETING AFFIDAVIT
REQUIRED TO BECOME LICENSED

In order to obtain a license from the Department of Community Health to operate your business, Georgia law requires every applicant to complete an affidavit (sworn written statement) before a Notary Public that establishes that you are lawfully present in the United States of America. This affidavit is a material part of your application and must be completed truthfully. Your application for licensure may be denied or your license may be revoked by the Department if it determines that you have made a material misstatement of fact in connection with your application to become licensed. If a corporation will be serving as the governing body of the licensed business, the individual who signs the application on behalf of the corporation is required to complete the affidavit. Please follow the instructions listed below.

1. **Review the list of Secure and Verifiable Documents under O.C.G.A. §50-36-2 which follows these instructions. This list contains a number of identification sources to choose from that are considered secure and verifiable that you can use to establish your identity, such as a U.S. driver's license or a U.S. passport. Locate one original document on the list to bring to the Notary Public to establish your identity.**

2. **Print out the affidavit. (If you do not have access to a printer, you can go to your local library or an office supply store to print out the document for a small fee.)**

3. **Fill in the blanks on the Affidavit above the signature line only—<u>BUT DO NOT SIGN THE AFFIDAVIT at this time.</u> (You will sign the affidavit in front of the Notary Public.) Fill in the name of the secure and verifiable document (for example, Georgia driver's license, U.S. passport) that you will be presenting to the Notary Public as proof of your identity. <u>CAUTION: Put your initials in front of only ONE of the choices listed on the affidavit and described here below:</u>**

   - **Option 1) is to be initialed by you if you are a United States citizen; or**

   - **Option 2) is to be initialed by you if you are a legal permanent resident of the United States. You are not a U.S. citizen but you have a green card; or**

   - **Option 3) is to be initialed by you if you are a qualified alien or non-immigrant (but not a U.S. citizen or a legal permanent resident) with an alien number issued by the Department of Homeland Security or other federal immigration agency. Fill in the alien number, as well.**

4. **Find a Notary Public in your area. Check the yellow pages, the internet or with a local business, such as a bank.**

5. **Bring your affidavit and the identification you selected (from the list of Secure and Verifiable Documents) to appear before the Notary Public.**

6. **Show the Notary Public your secure and verifiable identification (anything on List that follows these instructions) and state under oath in the presence of the Notary Public that you are who you say you are and that you are in the United States lawfully. Then sign your name.**

7. **Make certain that the Notary Public signs and dates the affidavit and puts when the notary commission expires.**

8. **Make a copy of the affidavit and the identification that you presented to the Notary Public for your own records.**

9. **Attach the ORIGINAL SIGNED AFFIDAVIT and a copy of the identification you presented to your application for licensure. DO NOT SEND US YOUR AFFIDAVIT SEPARATELY. IT MUST BE INCLUDED IN THE COMPLETE APPLICATION PACKET WHICH YOU <u>MAIL</u> TO US.**

Secure and Verifiable Documents Under O.C.G.A. § 50-36-2

Issued August 1, 2011 by the Office of the Attorney General, Georgia

The Illegal Immigration Reform and Enforcement Act of 2011 ("IIREA") provides that "[n]ot later than August 1, 2011, the Attorney General shall provide and make public on the Department of Law's website a list of acceptable secure and verifiable documents. The list shall be reviewed and updated annually by the Attorney General." O.C.G.A. § 50-36-2(f). The Attorney General may modify this list on a more frequent basis, if necessary.

The following list of secure and verifiable documents, published under the authority of O.C.G. A. § 50-36-2, contains documents that are verifiable for identification purposes, and documents on this may not necessarily be indicative of residency or immigration status.

- A United States passport or passport card [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]
- A United States military identification card [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]
- A driver's license issued by one of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Marianas Islands, the United States Virgin Island, American Samoa, or the Swain Islands, provided that it contains a photograph of the bearer or lists sufficient identifying information regarding the bearer, such as name, date of birth, gender, height, eye color, and address to enable the identification of the bearer [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]
- An identification card issued by one of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Marianas Islands, the United States Virgin Island, American Samoa, or the Swain Islands, provided that it contains a photograph of the bearer or lists sufficient identifying information regarding the bearer, such as name, date of birth, gender, height, eye color, and address to enable the identification of the bearer [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]
- A tribal identification card of a federally recognized Native American tribe, provided that it contains a photograph of the bearer or lists sufficient identifying information regarding the bearer, such as name, date of birth, gender, height, eye color, and address to enable the identification of the bearer. A listing of federally recognized Native American tribes may be found at: http://www.bia.gov/WhoWeAre/BIA/OIS/TribalGovernmentServices/TribalDirectory/ind/ex.htm [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]
- A United States Permanent Resident Card or Alien Registration Receipt Card [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]
- An Employment Authorization Document that contains a photograph of the bearer [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]
- A passport issued by a foreign government [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]

- A Merchant Mariner Document or Merchant Mariner Credential issued by the United States Coast Guard [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]

- A Free and Secure Trade (FAST) card [O.C.G.A. § 50-36-2(b)(3); 22 CFR § 41.2]

- A NEXUS card [O.C.G.A. § 50-36-2(b)(3); 22 CFR § 41.2]

- A Secure Electronic Network for Travelers Rapid Inspection (SENTRI) card [O.C.G.A. § 50-36-2(b)(3); 22 CFR § 41.2]

- A driver's license issued by a Canadian government authority [O.C.G.A. § 50-36-2(b)(3); 8 CFR § 274a.2]

- A Certificate of Citizenship issued by the United Stated Department of Citizenship and Immigration Services (USCIS) (Form N-560 or Form N-561) [O.C.G.A. § 50-36-2(b)(3); 6 CFR § 37.11]

- A Certificate of Naturalization issued by the United States Department of Citizenship and Immigration Services (USCIS) (Form N-550 or Form N-570) [O.C.G.A. § 50-36-2(b)(3); 6 CFR § 37.11]

- In addition to the documents listed herein, if, in administering a public benefit or program, an agency is required by federal law to accept a document or other form of identification for proof of or documentation of identity, that document or other form of identification will be deemed a secure and verifiable document solely for that particular program or administration of that particular public benefit. [O.C.G.A. § 50-36-2(c)]

O.C.G.A. § 50-36-1(e)(2) Affidavit

By executing this affidavit under oath, as an applicant for a **license, permit or registration**, as referenced in O.C.G.A. § 50-36-1, from the **Department of Community Health, State of Georgia**, the undersigned applicant verifies one of the following with respect to my application for a public benefit:

1) _____ I am a United States citizen.

2) _____ I am a legal permanent resident of the United States.

3) _____ I am a qualified alien or non-immigrant under the Federal Immigration and Nationality Act with an alien number issued by the Department of Homeland Security or other federal immigration agency.

My alien number issued by the Department of Homeland Security or other federal immigration agency is:_____.

The undersigned applicant also hereby verifies that he or she is 18 years of age or older and has provided at least one secure and verifiable document, as required by O.C.G.A. § 50-36-1(e)(1), with this affidavit.

The secure and verifiable document provided with this affidavit can best be classified as: _____.

In making the above representation under oath, I understand that any person who knowingly and willfully makes a false, fictitious, or fraudulent statement or representation in an affidavit shall be guilty of a violation of O.C.G.A. § 16-10-20, and face criminal penalties as allowed by such criminal statute.

Executed in _____ (city), _____(state).

_____
Signature of Applicant

_____
Printed Name of Applicant

SUBSCRIBED AND SWORN
BEFORE ME ON THIS THE
___ DAY OF _____, 20____

_____
NOTARY PUBLIC
My Commission Expires:

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook, Commissioner

Nathan Deal, Governor

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia,gov

INSTRUCTIONS FOR COMPLETING SCREENING & MONITORING EXEMPTION APPLICATION

Enclosed is an application and instructions to request initial or renewed Georgia Clinical Laboratory licensure exemption status for the purpose of performing specific laboratory tests or techniques designated by the Department that are used for screening and monitoring purposes only. The currently approved tests that can be used for screening and monitoring purposes are listed on the enclosed application.

We have enclosed the Department's exemption guidelines in a check-list format to facilitate the application and review process. Please review the checklist to ensure your facility/agency has all the guidelines in place. If your agency/facility complies with the guidelines, sign and date the attestation statement at the bottom of the guidelines.

The Healthcare Facility Regulation Division within the Department of Community Health is responsible for the Clinical Laboratory Licensure program and staff from HFRD will review your exemption application and notify you of your exemption status by letter.

Approval letters will authorize a screening and monitoring testing time frame and testing locations. Please note that approval must be obtained before testing can be performed. Routine inspections by HFRD will not be conducted; however, HFRD will investigate any complaints alleging failure to follow exemption guidelines.

For your information, the Department has defined screening and monitoring tests as follows:

- **Screening tests** mean those simple laboratory tests, approved by the Department as screening tests, used to aid in the detection of previously undiagnosed conditions.
- **Monitoring tests** mean those simple laboratory tests, approved by the Department as monitoring tests, with performance characteristics (accuracy and precision) that allow the tests to be used for evaluation of the status of previously diagnosed conditions.

If the Department does not grant exemption approval or you fail to follow exemption guidelines, you will be required to be licensed as a clinical laboratory and must meet applicable requirements of the Rules and Regulations for Clinical Laboratories, Chapter 290-9-8.

Return the signed and dated application along with the signed and dated guidelines checklist to the Diagnostic Unit at the address above. If you have questions, you can contact staff in the Diagnostic Unit, Health Care Section of HFRD at 404- 657-5450.

Authority: **The Georgia Clinical Laboratory Licensure Law** (O.C.G.A. 31-22-2)

2/3/2010

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook, Commissioner *Nathan Deal, Governor*

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia.gov

APPLICATION FOR LICENSURE EXEMPTION (SCREENING AND MONITORING PROCEDURES)

O.C.G.A. 31-22 and Chapter 290-9-8-.29)

☐ INITIAL APPLICATION ☐ RENEWAL APPLICATION

Facility / Agency Name		**Telephone Number:**
Facility / Agency Address:		**Contact e-mail address:**
Name and Address of owner:		**Fax Number:**
Type of Facility:		**Telephone Number:**
Area where testing will occur:	**Duration of Time for Testing** ☐ Once Time (Only) ☐ Periodic (Specific Time) _____ ☐ On Going	**Fax Number:**

Tests for which approval is requested (check all applicable):

___ Urine Reagent Strip
___ Visually Read
___ Strip Reader

___ Urine Pregnancy

___ Urine Specific Gravity

___ Whole Blood Glucose
___ Visual
___ Strip Reader

___ Microhematocrit

___ Hemoglobin

___ Hemoglobin A1C

___ Lipid Profile (Cholesterol Screen)
CLIA Waived (Only)
___ Total Cholesterol
___ HDL
___ Triglycerides
___ LDL (calculated)

___ ** HIV Screening Test
CLIA Waived (Only)

___ Fecal / Gastric Occult Blood

** **GA Code 31-22-9.2.d** The health care provider ordering a HIV test shall provide medically appropriate counseling to the person tested with regard to the test results. All positive test results must be confirmed by additional testing (i.e. Western Blot), and reported to the state.

Testing Personnel:

M.D. ___ R.N. ___ L.P.N. ___ ++Medical Asst. _____
Physician Asst. ___ Nurse Midwife___ Med. Technologist ___ Other _____ (specify)
Pharmacist ___ Nurse Practitioner___ Med. Technician ___

++Medical Assistant / Clinical Laboratory Assistant / Patient Care Tech / Clinical Nursing Assistant

I hereby certify that the screening and monitoring laboratory tests requested for exemption from licensure will be performed utilizing acceptable laboratory standards for safety, quality and infection control, that manufacturer's test guidelines will be followed, and that the information reported within this application is true, accurate, and complete to the best of my knowledge.

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook, Commissioner

Nathan Deal, Governor

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia.gov

APPLICATION FOR LICENSURE EXEMPTION (SCREENING AND MONITORING PROCEDURES)

Name of responsible person(s) **Title**

Signature of Responsible Person **Date**

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook, Commissioner

Nathan Deal, Governor

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia.gov

GUIDELINES FOR SCREENING & MONITORING TESTS

Please use the following checklist to ensure you have complied with all the guidelines for screening and monitoring tests.
If your agency/facility complies with the guidelines, sign and date the attestation statement and return the signed copy with your application to:
Diagnostic Unit, HealthCare Facility Regulation Division,
Two Peachtree Street, N. W., Suite 31-447,
Atlanta, GA 30303.

_____	**290-9-8-.29** The facility/agency must submit complete applications for initial and renewal approvals for screening and monitoring testing. 1. A *completed* Application for a Licensure Exemption to perform Screening and Monitoring Procedures to include: ▪ All sites where testing will occur (attach additional pages as needed); ▪ Check test/s requested for approval; ▪ If requesting approval for HIV screening, must have a procedure describing how compliance with required counseling, reporting, and referrals will be accomplished; ▪ Specify testing personnel and have training and competency evaluation available; and ▪ Read, sign, and date the certification statement at the bottom of the application.
_____	**290-9-8-.29** The facility/agency must develop and implement an employee training and competency evaluation program that includes testing procedures, quality controls, quality assurance, and safety measures. 2. Training policy and procedures include at a minimum the following topics: ▪ Specimen collection and handling; ▪ Test procedures; ▪ Quality Controls; ▪ Quality Assurance; ▪ Safety, Infection Control, and Hazardous waste disposal; and ▪ Competency evaluations.

_____	**290-9-8-.29** The facility/agency must follow published manufacturers' guidelines for quality control. 3. Quality control procedures for screening and monitoring tests shall include: ▪ Controls and control frequency; and ▪ Maintenance and calibration.
_____	**290-9-8-.29** The facility / agency must follow accepted laboratory standards for reporting laboratory test results. 4. Procedures for reporting tests results: ▪ Reports provided to non-physicians must contain a recommendation that results be reviewed by a physician or that medical advice be obtained; ▪ Reports must identify the screening and monitoring tests as being performed by a non-licensed laboratory; and ▪ Abnormal rests results must include a recommendation that the individual seek medical advice and that the abnormal results be confirmed by a definitive laboratory tests at a licensed laboratory.
_____	**290-9-8-.29** The facility / agency must follow accepted laboratory standards for record keeping and maintenance. 5. Records must be maintained for two years and must include: ▪ Quality control records; ▪ Testing records must include test date, time, patient's full name or unique identifier, test site, control/calibration results, lot numbers of reagents / controls, and identification of testing personnel; ▪ Maintenance records; and ▪ Procedure manuals.
_____	**290-9-8-.29** The facility/agency must follow accepted infection control standards as applicable for laboratory settings. 6. Infection Control procedures: ▪ Standard Precautions; ▪ Disposal of potentially infectious waste and sharps; ▪ Packaging, labeling, and transportation of potentially hazardous materials; and ▪ Handling employee needle / sharps injuries.

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook, Commissioner

Nathan Deal, Governor

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia.gov

	I hereby attest that _____ is in compliance with the above guidelines for performing Name of Facility/Agency Screening and monitoring tests. I further acknowledge that failure to follow the above exemption guidelines may require my Facility / agency to meet applicable licensure requirements of the Rules and Regulations for Clinical Laboratories, Chapter 290-9-8. _____ _____ Signature Date

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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STATE LABORATORY LICENSE

Change of Location Check List

Lab License # _____ Date of Move: _____

Facility Name:_____

New Address: _____

_____

_____

_____1. Documentation of compliance with local and state building, safety, and fire codes
Check all that apply:

- ☐ Certificate of Occupancy
- ☐ Post construction Inspection
- ☐ Electrical Inspection
- ☐ Fire Inspection

_____2. Separate employees hand washing and toilet facilities included in new construction or major renovations.

_____3. Documentation of pre and post move instrument correlations and post move Calibrations and quality control results.

_____4. Updated policy and procedure manuals.

_____5. Proficiency testing agency notified of change of address.

_____6. Records for the past 2 / 5 / 10 years must be available

Signed: _____ Date _____

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PERSONNEL LIST

Facility Name: _____

DIRECTOR _____ ADDRESS _____

MANAGER / SUPERVISOR _____ _____

CLIA LICENSE # _____ _____

STATE LICENSE # _____ CITY / STATE _____

NAME	** CERTIFICATION	SHIFT	DATE HIRED	SURVEYOR COMMENT

****CERTIFICATION:** MLT / MT (ASCP) (AMT) (NCA) (HEW) etc. **or** CT (ASCP) **or** HT (ASCP) etc.

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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Atlanta, GA 30303-3159
www.dch.georgia,gov

MAIL ALL STATE CLINICAL LABORATORY APPLICATIONS TO :

Department Of Community Health
Healthcare Facility Regulation Division
Diagnostic Services Unit
2 Peachtree Street, N.W.
Suite 31-447
Atlanta, GA 30303-3142

ATTN: STATE LABORATORY PROGRAM

Because Faxed copies may not be clear and may distort your information,
we ask that all original paperwork be mailed to the above address.

After we have reviewed your application,
if we request additional documentation, you may fax any additions / changes and or supporting documents to:

404-657-5442

PLEASE MAKE CHECKS PAYABLE TO:
Department Of Community Health

Contact Personnel:

Sheela E. Puthumana
Program Director
Phone: 404-657-5447
Fax 404 – 657 - 5442

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook, Commissioner *Nathan Deal, Governor*

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia.gov

Instructions for Completing the Laboratory Self Report Form
State of Georgia
Healthcare Facility Regulation Division
Diagnostic Services Unit

Reportable Laboratory Incidents

This form is designed for notifying the Healthcare Facility Regulation Division (HFRD) of reportable sentinel incidents and for the action taken by the facility to identify and address any opportunity to improve care/procedures related to the incident. A separate letter to notify HFRD of such incidents is NOT required.

Directions for completing the Laboratory Incident Reporting Form
Please type or print the information. Be as complete as you can: complete information may allow our staff to review the incident without contacting you for more information. Use a separate report for each incident: a transfusion reaction fatality/serious health damage is one incident; erroneous test results resulting in or having the potential to threaten the health and safety of the patient is a separate incident.

What should be reported:

1. Fatal transfusion reactions or transfusion complications affecting the patients
2. Laboratory testing errors which have resulted in the death or serious injury to a patient or employee.
3. Significant interruptions in service vital to the continued safe operation of the facility, such as the loss of electricity, gas or water services.

Facility Information:
Include the name, address, phone number, fax number, e-mail address, of the laboratory or physician office The license number is on your facility license/permit. The contact person(s) listed will be the person(s) HFRD will contact should a follow-up phone call be needed.

Reporting Information:
Record the date and time the incident occurred, the date and time you became aware of the incident, and the date and time you are reporting the incident to HFRD, circling am or pm. Check which event you are reporting on the form or hand write it.

Summary of Incident:
Provide a brief summary of the reportable incident: describe what happened, who was involved (i.e.: MT, MLT, phlebotomist, RN, etc) and what action was taken at the time of the event. For example:

"The patient was in the process of receiving a unit of B positive blood. The floor RN noted a rise in temperature, rapid breathing and shaking twenty minutes after the unit of blood was hung. The RN immediately stopped the transfusion and notified the laboratory of a possible transfusion reaction. The lab came and collected blood and urine from the patient and on checking the armband, found that the name on

the unit did not match the armband of the patient. The lab performed pre and post reaction and found that the patient was Type A Rh negative which is incompatible with B positive blood."

Immediate Corrective or Preventative Action Taken:
Provide a brief narrative of your evaluation of the actions taken in regard to the incident. For example:

"Internal investigation revealed that the RN received the correct unit of blood that matched the requisition but gave it to a phlebotomy team member who gave the blood to the wrong patient."

Include any action you will take as a result of this review, which could include but is not limited to: inservice & monitoring, revision of policy/procedure, development of policy/procedure, no action required, etc.

Sign and date the form and print your name and title. Return the form via fax to 404-657-5442. Do not put any information in the box entitled "For Department Use Only".

Thank you for your cooperation.

GEORGIA DEPARTMENT OF COMMUNITY HEALTH
Healthcare Facility Regulation Division
Health Care Section
Diagnostic Services Unit
2 Peachtree Street, N.W. Suite 31-447
Atlanta, Georgia 30303
Tel: 404.657.5450 Fax: 404.657.5442

REQUIRED LABORATORY SELF REPORTS – INCIDENTS

(Please Type or Print Form)

For Confidentiality see 290-9-8-.27(6)

FACILITY INFORMATION

Name of Laboratory: _____

Georgia License #: _____ - _____

Address: _____

City: _____ **State:** _____ **Zip Code:** _____

Contact Person(s): _____ **Title:** _____

Phone Number of Contact: _____ **Fax #:** _____

Email Address: _____

PATIENT/ REPORTING INFORMATION

Date _____ **Time** _____ **a.m./p.m.** **Incident Occurred**

Date _____ **Time** _____ **a.m./p.m.** **Facility was aware that reportable May have occurred**

Date _____ **Time** _____ **a.m./p.m.** **Reported to ORS Agency**

COMPLETE IF APPLICABLE

_____ _____ _____ **M/F** _____
Patient Name **Age** **Sex** **Date of Birth**

_____ _____
Medical Record # **Date of Admission**

Diagnosis (*all*) (Use Narrative Format, Not ICD-9 Coding):

_____

_____

_____

Type of Incident: Please check appropriate boxes

[ ] Hemolytic Transfusion Reaction resulting in dealh/serious injury to internal organs
[ ] Erroneous test results that causes serious/life-threatening problems for the patient
[ ] Significant interruption in service vital to continued safe operation, such as the loss of electricity, gas or water services

Briefly describe circumstances of the incident: (attach additional sheet if necessary)

Immediate corrective or preventive Action taken: (attach additional sheet if necessary)

Note: If the incident involved a death, was the medical examiner notified? [ ] Yes [ ] No
Was an autopsy requested? [ ] Yes [ ] No
Name and contact number of Medical Examiner _____

Acknowledgement of Information Reported:

I certify that the information reported within this form is true, accurate, and complete to the best of my knowledge.

_____ _____ _____
Signature if person completing form ***Title*** ***Date Completed***

_____
Print name

For Department Use Only

Received in SA Date: _____

Reviewed By: _____

Date: _____

Reporting time frame of 24 hours/next-business day met? ( ) Yes ( ) No

Action Required: ( ) Yes ( ) No

Self Report ID #: _____ **Complaint #:** _____

This report is required as set forth in the Laboratory Rules 290-9-8-.27(6) and must be submitted to the Department within twenty four (24) hours or the next business day from when the incident occurred, or from when the facility has reasonable cause to suspect a reportable incident 290-9-8-.27(6)

For Confidentiality see 290-9-8-.27(6)

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook, Commissioner *Nathan Deal, Governor*

2 Peachtree Street, NW
Atlanta, GA 30303-3159
www.dch.georgia,gov

February 3, 2010

Laboratory Director

Dear:

Based on the information you provided regarding your request to obtain a license to operate a Specimen Collection Station, we have determined that a license will not be required because your proposed collection station does not meet the legal definition of a collection station. O.C.G.A. § 31-22-1 defines a "Specimen Collection Station" as a place having the **primary** purpose of either collecting specimens directly from patients or bringing specimens together after collection for the purpose of forwarding them either intrastate or interstate to a clinical laboratory for examination. The primary purpose of physician's offices is to provide medical care to patients. Therefore, physicians' offices do not meet the definition of a collection station. In addition, O.C.G.A. § 31-22-9(a)(4) exempts physicians' offices from licensure as a clinical laboratory when operated by duly licensed physicians exclusively in connection with the diagnosis and treatment of the physician's own patients.

Specimen collection sites operating within a physician's office are considered a part of the physician's practice and phlebotomists placed in physician's offices by reference laboratories will be considered to be working under a contractual agreement between the physician and the reference laboratory.

Please note that all physicians' offices that perform laboratory testing must be registered for with CLIA as a waived laboratory, certificate of compliance, or PPMP laboratory.

If you have questions regarding the information in this letter, you can contact me at 404-657-5447 or at tmsnelling@dhr.state.ga.us.

Sincerely,

Sheela E. Puthumana BS MT(ASCP)
Program Director, Diagnostic Services Unit
Health Care Section

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

David A. Cook, Commissioner

Nathan Deal, Governor

2 Peachtree Street, NW
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Sincerely,

Sheela E. Puthumana BS MT(ASCP)
Program Director, Diagnostic Services Unit
Healthcare Facility Regulation Division

GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

David A. Cook, Commissioner **Nathan Deal, Governor**

2 Peachtree Street, NW | Atlanta, GA 30303-3159 | 404-656-4507 | www.dch.georgia.gov

CLIA CERTIFICATION

HOW TO APPLY FOR A CLIA CERTIFICATE:

CERTIFICATE OF WAIVER

Please visit the CLIA web site: www.cms.gov/CLIA

1. **Click on "How to Apply for a CLIA Certificate"**
2. **Scroll down and find the CMS-116 FORM and print it out**
3. **Fill out the form thoroughly including your hours of operation. Make sure that the application is signed by the Director of the facility.**
4. **Mail your application to :**

   Department of Community Health
   Healthcare Facility Regulation Division
   Diagnostic Services Unit
   2 Peachtree Street NW.Suite 31-447
   Atlanta, GA 30303-3142
   Attn: Ms. Sharon Thomas

5. **Turn around time for processing a CLIA ID# is app. 4 weeks.**
6. **You may start testing as soon as you receive your CLIA ID# if you have Certificate of Waiver.**
7. **Around the same time you receive your CLIA ID # you will receive a fee coupon from CMS in Baltimore, Maryland: For Certificate of Waiver: $150.00/2 Years**
8. **Send your check as instructed to a bank in ATLANTA :**

   CLIA LABORATORY PROGRAM,
   P O BOX 530882,
   ATLANTA, GA 30353-0882
   Please enter your CLIA ID # at the bottom of the check

9. **As soon as your check is processed you will receive the CLIA Certificate from CMS in Baltimore, Maryland at the address in the CMS database at the time. You may start billing for tests performed when you receive your certificate.**
10. **Once you are in the CMS database you will receive renewal fee coupons approximately every 18 months.**
11. **Typically the renewal certificates are mailed very close to the expiration time even though the fees are paid well in advance.**