APPLICATION FOR STATE OF GEORGIA CLINICAL LABORATORY LICENSE
CLINICAL LABORATORY LICENSURE LAW, 1970

<table>
<thead>
<tr>
<th>LAB LICENSE #</th>
<th>YEAR</th>
<th>CLIA #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

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
  - Clinical
  - Blood Bank
  - Tissue Bank
  - Specimen Collection Station

- D. Point of Care
  - Clinical
  - Blood Bank
  - Tissue Bank
  - Specimen Collection Station

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

**CLINICAL CHEMISTRY**

- ☐ Routine
- ☐ Urinalysis
- ☐ Blood Gases
- ☐ Toxicology (medical)
- ☐ TDM
- ☐ Other _____________

**MICROBIOLOGY**

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

**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

**IMMUNOHEMATOLOGY**

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

**CLINICAL IMMUNOLOGY AND SEROLOGY**

- ☐ Syphilis
- ☐ Non-Syphilis
- ☐ Viral Serology
- ☐ HIV (Screen / Confirmation)

**SPECIMEN COLLECTION STATION(S)**

*Attach extra sheet if necessary

Equal Opportunity Employer
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 PROFICIENCY TESTING ORDER CONFIRMATION OR APPLICATION FOR ENROLLMENT MUST BE ATTACHED TO THIS 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
1. ____________________________________________________________________________________________

2. ____________________________________________________________________________________________

3. ____________________________________________________________________________________________

<table>
<thead>
<tr>
<th>LAB License #</th>
<th>LAB License #</th>
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<tbody>
<tr>
<td>1. ____________</td>
<td>1. ____________</td>
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<td>2. ____________</td>
<td>2. ____________</td>
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<tr>
<td>3. ____________</td>
<td>3. ____________</td>
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</tbody>
</table>
B. Consultant:

<table>
<thead>
<tr>
<th>Name (Last, First, Middle)</th>
<th>Address:</th>
<th>City:</th>
<th>County:</th>
<th>State:</th>
<th>Zip Code:</th>
</tr>
</thead>
</table>

Certified In:
- ☐ Anatomic Pathology
- ☐ Clinical Pathology
- ☐ Other

Is the Following Provided?
- On-Site Consultation ☐ YES ☐ NO
- In-Service Training ☐ YES ☐ NO

Number of Hours Per Week Consultant Spends in Laboratory?

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

<table>
<thead>
<tr>
<th>Name (Last, First, Middle)</th>
<th>Degree / Major Field</th>
<th>Years of Experience</th>
<th>Position – Title and Primary Responsibility</th>
<th>Hours per Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
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<tr>
<td>b.</td>
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<td>c.</td>
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<td>d.</td>
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<td>i.</td>
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<td>j.</td>
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<td>k.</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Total Number Assigned To</th>
<th>General Laboratory</th>
<th>Anatomical Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Full Time</td>
<td>Part Time</td>
</tr>
<tr>
<td>a. Technologists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Technicians</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Trainees</td>
<td></td>
<td></td>
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<tr>
<td>d. Other</td>
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</tbody>
</table>

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: __________________________

02/04/2010 2:28 PM
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.
APPLICATION FOR CLINICAL LABORATORY DIRECTOR

UNDER THE CLINICAL LABORATORY LICENSURE LAW, 1970

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

<table>
<thead>
<tr>
<th>Address #</th>
<th>Street</th>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
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<tbody>
<tr>
<td></td>
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<table>
<thead>
<tr>
<th>Telephone #</th>
<th>Fax #</th>
<th>e-mail address</th>
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</table>

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

**CLINICAL CHEMISTRY**
- [ ] Routine
- [ ] Urinalysis
- [ ] Blood Gases
- [ ] Toxicology (medical)
- [ ] TDM
- [ ] Other ______________

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

**HEMATOLOGY**
- [ ] HLA TESTING
- [ ] RADIOBIOASSAY (in vivo)
- [ ] TISSUE BANKING
- [ ] GENETICS / CYTOGENETICS
- [ ] INHERITED DISORDER TESTING
- [ ] POINT OF CARE TESTING

**IMMUNOHEMATOLOGY**
- [ ] Group
- [ ] Type
- [ ] Crossmatch
- [ ] Antibody Screen
- [ ] Identification
- [ ] Transfusion Services
- [ ] Pheresis
- [ ] Components
- [ ] Donor Services
- [ ] Storage

**CLINICAL IMMUNOLOGY AND SEROLOGY**
- [ ] Syphilis
- [ ] Non-Syphilis
- [ ] Viral Serology
- [ ] HIV (Screen / Confirmation)

**PATHOLOGY**
- [ ] Exfoliative Cytology
- [ ] Anatomic Pathology
- [ ] Oral Pathology
- [ ] 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 ____________________________

Equal Opportunity Employer
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)

<table>
<thead>
<tr>
<th>CERTIFYING AUTHORITY</th>
<th>DATE CERTIFIED</th>
<th>BOARD ELIGIBLE</th>
<th>SPECIALIZATION</th>
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6. **EDUCATION**

<table>
<thead>
<tr>
<th>NAME and LOCATION of College or University</th>
<th>MAJOR</th>
<th>Dates Attended (mo./yr)</th>
<th>DEGREE</th>
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<tbody>
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<td>FROM</td>
<td>TO</td>
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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
| 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                  |                                |

<table>
<thead>
<tr>
<th>Description of duties: ________________________________</th>
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<thead>
<tr>
<th>9. LABORATORY (IES) for which you will serve as licensed director:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Name and Address:</td>
</tr>
<tr>
<td>Number of hours per week devoted to the Directorship of this laboratory: ____________________________</td>
</tr>
<tr>
<td>Do you also serve as supervisor? □ YES □ NO</td>
</tr>
<tr>
<td>Supervisor / Manager(s):</td>
</tr>
<tr>
<td>1. Name:</td>
</tr>
<tr>
<td>B. Name and Address:</td>
</tr>
<tr>
<td>Number of hours per week devoted to the Directorship of this laboratory: ____________________________</td>
</tr>
<tr>
<td>Do you also serve as supervisor? □ YES □ NO</td>
</tr>
<tr>
<td>Supervisor / Manager(s):</td>
</tr>
<tr>
<td>1. Name:</td>
</tr>
<tr>
<td>C. Name and Address:</td>
</tr>
<tr>
<td>Number of hours per week devoted to the Directorship of this laboratory: ____________________________</td>
</tr>
<tr>
<td>Do you also serve as supervisor? □ YES □ NO</td>
</tr>
<tr>
<td>Supervisor / Manager(s):</td>
</tr>
<tr>
<td>1. Name:</td>
</tr>
</tbody>
</table>

Revised 02/04/2010 1:37 PM
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
**APPLICATION FOR LICENSURE EXEMPTION**
(SCREENING AND MONITORING PROCEDURES)
O.C.G.A. 31-22 and Chapter 290-9-8-.29)

☐ INITIAL APPLICATION  ☐ RENEWAL APPLICATION

<table>
<thead>
<tr>
<th>Facility / Agency Name</th>
<th>Telephone Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility / Agency Address:</td>
<td>Contact e-mail address:</td>
</tr>
<tr>
<td>Name and Address of owner:</td>
<td>Fax Number:</td>
</tr>
<tr>
<td>Type of Facility:</td>
<td>Telephone Number:</td>
</tr>
<tr>
<td>Area where testing will occur:</td>
<td>Duration of Time for Testing</td>
</tr>
<tr>
<td>☐ Once Time (Only)</td>
<td>☐ Periodic (Specific Time)</td>
</tr>
</tbody>
</table>

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

- ___ Urine Reagent Strip
- ___ Microhematocrit
- ___ ** HIV Screening Test
- ___ CLIA Waived (Only)

- ___ Visually Read
- ___ Strip Reader
- ___ Hemoglobin
- ___ Fecal / Gastric
- ___ Occult Blood

- ___ Urine Pregnancy
- ___ Hemoglobin A1C
- ___ Visual
- ___ Strip Reader

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

- ___ Urine Specific Gravity
- ___ Visual
- ___ Strip Reader

** 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. _____
- Physician Asst. _____
- Nurse Midwife _____
- Med. Technologist _____
- Pharmacist _____
- Nurse Practitioner _____
- Med. Technician _____
- Other _____ (specify)

- ++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.

<table>
<thead>
<tr>
<th>Name of responsible person(s)</th>
<th>Title</th>
</tr>
</thead>
</table>

Signature of Responsible Person

Date

S & M APPLICATION Revised 02/04/10
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

<table>
<thead>
<tr>
<th><strong>290-9-8-.29</strong></th>
<th>The facility/agency must submit complete applications for initial and renewal approvals for screening and monitoring testing.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>A completed Application for a Licensure Exemption to perform Screening and Monitoring Procedures to include:</td>
</tr>
<tr>
<td></td>
<td>▪ All sites where testing will occur (attach additional pages as needed);</td>
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<td></td>
<td>▪ Check test/s requested for approval;</td>
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<td></td>
<td>▪ If requesting approval for HIV screening, must have a procedure describing how compliance with required counseling, reporting, and referrals will be accomplished;</td>
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<td>▪ Specify testing personnel and have training and competency evaluation available; and</td>
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<td>▪ Read, sign, and date the certification statement at the bottom of the application.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>290-9-8-.29</strong></th>
<th>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.</th>
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<tbody>
<tr>
<td>2.</td>
<td>Training policy and procedures include at a minimum the following topics:</td>
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<td></td>
<td>▪ Specimen collection and handling;</td>
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<td></td>
<td>▪ Test procedures;</td>
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<td></td>
<td>▪ Quality Controls;</td>
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<td></td>
<td>▪ Quality Assurance;</td>
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<td></td>
<td>▪ Safety, Infection Control, and Hazardous waste disposal; and</td>
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<td></td>
<td>▪ Competency evaluations.</td>
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</table>

<table>
<thead>
<tr>
<th><strong>290-9-8-.29</strong></th>
<th>The facility/agency must follow published manufacturers’ guidelines for quality control.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>Quality control procedures for screening and monitoring tests shall include:</td>
</tr>
</tbody>
</table>
### 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 results 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.

I hereby attest that ________________________________ is in compliance with the above guidelines for performing 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.

_________________________  __________________________
Date                                                          Signature
STATE LABORATORY LICENSE
Change of Location Check List

Lab License # ____________________ Date of Move: ______________________

Facility Name: _______________________________________________________

New Address: __________________________________________________________

____________________________________________________________

____________________________________________________________

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

Revised 02/08/2010 10:02 AM

Equal Opportunity Employer
**Personnel List**

Facility Name: ____________________________________________

**DIRECTOR** ___________________________________   **ADDRESS** __________________________________________

**MANAGER / SUPERVISOR** __________________________             __________________________________________

**CLIA LICENSE #** ___________________________________            __________________________________________

**STATE LICENSE #** _____________________________   **CITY/STATE** __________________________________________

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

Revised 02/08/2010 10:00 AM
MAIL ALL STATE CLINICAL LABORATORY APPLICATIONS TO:

Diagnostic Services Unit
Health Care Section
Healthcare Facility Regulation Division
Department Of Community Health
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

MAIL STATE CLINICAL LABORATORY FEES & PAYMENT COUPON TO:

Georgia Department of Community Health
P O Box 741328
Atlanta, GA 30374-1328

Sheela E. Puthumana
Program Manager
Phone: 404-657-5447

Dinella Sears
Phone: 404-657-5450
Fax: 404-657-5442

Equal Opportunity Employer
Instructions for Completing the Laboratory Self Report Form
Diagnostic Services Unit, Health Care Section
Healthcare Facility Regulation Division

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.
REQUIRED LABORATORY SELF REPORTS
(Please Type Form)

FACILITY INFORMATION

Name of Laboratory:____________________________________License #:_____________________
Address: ___________________________________________________________________________
City: ________________________________ State: _________________ Zip Code:__________________
Person Reporting Incident: ___________________________________ Title:_______________________
Contact Person(s): _________________________ 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 incident may have occurred
Date______________ Time _________ a.m./p.m. Reported to HFRD

COMPLETE IF APPLICABLE

Patient Name          Age        Sex                Date of Birth
_____________________ _________________  __________________________
Medical Record #      Date of Admission      Reason for Admission
_____________________  ______________________  ______________________
Diagnosis (all): (Use Narrative Format, Not ICD-9 Coding)
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Type of Incident: Please check appropriate boxes. (Attach a copy of incident report if applicable)

[ ] Fatal transfusion reactions or transfusion complications affecting the patient(s)
[ ] Laboratory testing errors which have resulted in the death or serious injury to a patient or employee
[ ] Significant interruptions 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 Preventative 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 ____________________________

**Additional Required Reports: Please check appropriate boxes**

The Lab shall make a report of the event within 24 hours or by the next regular business day from when the reportable event occurred or from when the Lab has reasonable cause to anticipate that the event is likely to occur.

**Acknowledgement of Information Reported:**

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

Signature of Person Completing Form ____________________________
Title ____________________________
Date Completed ____________________________

Print Name

**For Department Use Only**

Received in S/A Date: ____________________________
Reviewed By: ____________________________
Date: ____________________________

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

Action Require ( ) Yes ( ) No

Self Report ID #: _______________ Complaint Number: _______________

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 by the next regular 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)

Revised 02/11/2010 9:20 AM