Blood Glucose Monitoring for Basic EMTs

**Purpose:** To establish a uniformed procedure to determine a safe and effective manner for Basic EMT's to become authorized to evaluate blood-glucose levels using a glucometer in the Pre-Hospital setting.

**Policy:**
The New York State Department of Health Bureau of Emergency Medical Services (NYS DOH BEMS) Policy Statement 05-04 allows the use of glucometers by Emergency Medical Technicians (EMT) in Basic Life Support (BLS) EMS agencies to check patient blood glucose levels. This approval was given under the conditions that the EMS service wishing to use a glucometer at the BLS level, be granted approval by WREMAC, each EMT complete an approved training program and the service apply and be granted a Limited Laboratory Registration. BLS providers in Advanced Life Support (ALS) agencies must also complete the training prior to performing this skill. In order to provide this additional care, a BLS or ALS agency must complete the following items and be approved by WREMAC before allowing their BLS providers to perform this skill. BLS and ALS agencies that already have their CLIA authorization numbers are able to skip to Step 1 C.

**Education:**
EMT’s who wish to become authorized shall attend a blood-glucose monitoring training session instructed by a NYS DOH CIC, CLI, EMS Program Agency Representative or the Agency Medical Director (or designee) utilizing the Power Point presentation titled “Diabetes for the EMS Provider” or similar presentation as adopted by the WREMAC.

A practical evaluation with a signed attendance roster will be filed in the agencies training files. Providers shall complete annual glucometry training which shall include, at a minimum, review of glucometry equipment and the approved protocol in this policy. Documentation of this training shall be maintained by the agency for a period of three years.

Any provider who does not complete the initial training and subsequent training shall not be authorized to evaluate blood-glucose levels using a glucometer in the Pre-Hospital setting.
STEPS TO COMPLETE APPROVAL PROCESS

Procedure

Step 1: Designate an individual who will complete and maintain records of quality control testing.

Step 2: Complete the DOH-4081 “Limited Laboratory Registration Form” (ATTACHMENT 1).

Step 3: Send this document and registration fee to:
   NYS DOH Quality Control
   Wadsworth Center
   Clinical Laboratory Evaluation Program
   P.O. Box 509
   Albany, NY 12201-0509

   **Please note** - A CLIA authorization number must be received from the Wadsworth Center and included with your completed packet before the application will be processed by the REMAC.

Step 4: Write up agency Policies and Procedures to include the following:
   1. Training Program and documentation of authorized users.
   2. Quality Assurance program, include appropriateness review by Agency Medical Director.
   3. Documentation of control testing process.
   4. Storage of glucometer and proper disposal of sharps.

   **NOTE:** ATTACHMENT 2 is a sample policy & procedure that may be incorporated into the final version of your agency’s policies & procedures.

Step 5: Complete ATTACHMENT 3: “WREMAC BLS Agency Application to Perform Blood Glucose Monitoring”.

Step 6: Complete ATTACHMENT 4: “Medical Director Verification Form” (DOH-4362). Be sure to check off all approvals including “Blood Glucometry”.

Step 7: All providers must review the WREMAC Blood Glucometry PowerPoint Presentation found on the WREMAC Web site: www.WREMAC.com. It is strongly suggested that a NYS CLI or CIC provide the in-service. Complete a sign-in sheet!

Step 8: Submit the completed documents (from above) to your regional Program Agency. A complete packet includes the following:
   1. WREMAC BLS Agency Application to Perform Blood Glucose Monitoring (Attachment 3).
   2. Letter of support from the Agency Medical Director to engage in blood glucose monitoring.
   3. Copy of the “Limited Laboratory Registration Form” (Attachment 1) along with the CLIA authorization number received from the DOH.
   4. Copy of Policies and Procedures (sample provided in Attachment 2).
   5. Updated Medical Director Verification Form DOH-4362 (Attachment 4).
   6. Sign-in sheet of all providers who completed the WREMAC In-Service (Step 7).
Western Regional Emergency Medical Advisory Committee Blood Glucose Monitoring Protocol for EMT-Basic

1. If patient presents with an altered mental status, request ALS.


3. Obtain a complete set of Vital Signs; include O₂ saturation if available.

4. Check Blood Glucose and place lancet in an approved sharps container.

5. If Blood Glucose is greater than 80 mg/dL and the patient has an altered mental status, confirm ALS is enroute and monitor the A, B, C’s.

6. If hypoglycemic (<80 mg/dL) and awake (A or V on AVPU) with the ability to maintain their airway; administer oral glucose consistent with NYS BLS Protocol. Repeat Vital Signs and AVPU after 5 minutes. (including a repeat D-stick)

7. If completely alert and oriented, request medical control approval to cancel ALS.

8. Continue on going assessment consistent with current NYS BLS Protocols.

DO NOT DELAY TRANSPORT!

Definitions:
Basic EMT – defined in Article 30 of the New York State Public Health Law.
Hypoglycemia – Blood Glucose level that is less than 80 mg/dL.
Altered Mental Status – GCS of 14 or less and not alert and oriented.
ATTACHMENT

1
Please follow the instructions carefully since submission of incomplete applications will delay processing and issuance of the registration. **NOTE:** You must enclose a $200.00 application fee payment. Your check or money order should be made payable to: New York State Department of Health. The check or check stub should indicate the laboratory’s name.

A. BACKGROUND AND GENERAL INFORMATION

The New York State Department of Health’s Clinical Laboratory Evaluation Program has been authorized under Section 579 of Article 5, Title V of the Public Health Law to provide oversight to facilities performing waived and/or provider-performed microscopy procedures in New York State. These facilities are considered Limited Service Laboratories and must register with the Department as described in this registration package in order to obtain a federal CLIA number and authorization to perform patient testing. **Not-for-profit, state or local government laboratories or programs engaged in limited public health testing not exceeding fifteen types of test per registration may be eligible to apply for a multi-site CLIA number.**

B. PHYSICIAN OFFICE EXCEPTION

The only facilities that are exempt from Limited Service Laboratory Registration are private physician office laboratories (POLs) operated by individual practitioners or as part of a legally constituted, independently owned and managed partnership or group practice, or the independent practice of a nurse practitioner operating under a practice agreement with a licensed physician. The tests performed must be conducted by the providers or by their own employees, utilizing their own reagents and instrumentation, solely as an adjunct to the practice of medicine for their patients. Laboratories that meet the criteria above for a POL must apply to the Physicians Office Laboratory Evaluation Program (POLEP) in order to receive a CLIA number. Information and applications may be obtained by calling POLEP at 518-485-5352.

Laboratories which are set up as a joint venture of several practitioners, partnerships or practices and practices which are owned, managed and/or operated by managed care organizations, hospitals or consulting firms do not qualify for the POL exemption and must obtain a Limited Service Laboratory Registration. If you have any question about whether a permit is required, contact our program at 518-402-4253 (voice), 518-485-5414 (fax), or via e-mail at: clepltd@wadsworth.org.

C. ADDITIONAL RESOURCES

Technical support is available from our program to assist Limited Service Laboratory staff in implementing a quality testing program within these facilities. An additional resource available to Limited Service Laboratory staff is a document published by the Centers for Disease Control and Prevention (CDC) in November 2005 entitled “Good Laboratory Practices for Waived Testing Sites.” This publication is available on the CDC website at: [http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf).

COMPLETING THE REGISTRATION APPLICATION

Please note that the authority for the New York State Department of Health, Wadsworth Center, Clinical Laboratory Evaluation Program to request personal information from you, including identifying numbers such as federal Employer Identification Number (EIN), and the authority to maintain such information, is found in Section 5 of the New York State Tax Law. **Disclosure of this information by you is mandatory.** These numbers are routinely used only as identifiers within our Program. They may only be released for tax administration purposes and other purposes authorized by the Tax Law. The Administrator of the Clinical Laboratory Evaluation Program is responsible for maintaining the records of such information. The administrator can be reached by writing to the Clinical Laboratory Evaluation Program at the address indicated at the top of this page.
1. CLIA STATUS AND APPLICATION TYPE

**CLIA Number:** If you have already obtained a CLIA certification number, please indicate the number in the area provided. If you do not already have a CLIA certification number, one will be assigned to your facility.

**Multi-Site Registration:** Not-for-profit, state or local government laboratories or programs engaged in limited public health testing not exceeding fifteen types of tests per registration may be eligible to apply for a multi-site CLIA number. One location must be designated as the primary location; this application should be completed for that site. To include secondary locations, complete and include with this application a Limited Service Laboratory Registration Notification to Add Permanent Testing Location to Multi-Site Registration (form, DOH-4081MS). Note that the laboratory director listed on this application will be responsible for all sites operating under a multi-site CLIA number.

2. GENERAL LABORATORY INFORMATION (Note: If you are completing this application for the primary site in a multi-site network, provide the information for that site).

**Laboratory Name:** Indicate the legal name exactly as you wish it to appear on the Limited Service Laboratory Registration.

**Federal Employer ID Number:** Under the New York State Tax Law, you are required to provide your federal Employer Identification Number. A CLIA registration number cannot be issued without this information.

**County/Borough:** Indicate the New York State county or borough that the laboratory is physically located in.

**Laboratory Address:** The laboratory address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable.

**Mailing Address:** Indicate if the laboratory has a separate mailing address. Our office will use the mailing address for all correspondence with your facility.

**Contact Person Name, Telephone Number and E-Mail Address:** The contact person is the individual designated by the Laboratory Director as the liaison with our Program. This is the individual that you would like us to direct correspondence to and/or follow-up with should questions arise regarding any of the answers provided in your registration materials. If you are applying for a multi-site registration, this individual will be the point of contact for all sites within the network.

**Laboratory Telephone and Fax Numbers, E-mail Address:** These sections are self-explanatory.

**Days & Hours of Testing:** Indicate the days and hours when laboratory testing will be performed.

**Community Screening:** Indicate whether your laboratory or laboratory network will perform community screening events. Laboratories seeking approval to operate community screening events must maintain a protocol describing in detail how laboratory testing will be performed.

Permanent off-site locations performing testing should be registered under a multi-site CLIA number using form DOH-4081MS.

3. LABORATORY TYPE

This information is needed to assign and maintain your CLIA certification. Indicate your laboratory type from the list provided. Please check the type that is most descriptive of your facility.
4. OWNERSHIP INFORMATION

All applications must list the name and address of the individual, partnership or corporation that owns or operates the laboratory or laboratory network. “Address of Principal Office” refers to the address of the principal office of the corporation, partnership or government entity, which owns or operates the laboratory. Government-operated facilities should identify the sponsoring county, city or municipality and provide the name, title, and address of the administrator.

Laboratories indicating not-for-profit status must provide proof by submitting a copy of the organization’s IRS letter of determination for nonprofit status or a copy of the organization’s NYS Charities Registration Filing. Please note that the form used for making a tax-exempt purchase is not acceptable proof of not-for-profit status.

Small Business: A small business is defined as one, which is located in New York State, independently owned and operated, and employs 100 or fewer individuals. This includes all employees, both technical and non-technical.

5. AFFILIATION

If your facility is affiliated with a laboratory holding a New York State permit, please provide the name, address, and NYS laboratory permit PFI Number (if known). Affiliation refers to actual involvement in the technical performance of the testing performed at your facility, or common staff, supplies, etc. Do not report the name of your reference laboratory.

6. MANAGEMENT

If the laboratory testing performed under this registration is provided under a management or consulting contract, indicate the name and address of the company that you contract with to perform this testing. Do not report the name of your reference laboratory.

7. LABORATORY DIRECTORSHIP

Supply information concerning the individual who provides technical and clinical direction of your laboratory testing (i.e. the medical director). The laboratory director designee must be a licensed health care practitioner (Physician, Dentist, PA, NP, or CNM only) or an individual holding a New York State Certificate of Qualification as a laboratory director. Indicate if the individual holds a Certificate of Qualification. If the director is a health care practitioner, a license number must be provided. Indicate whether the individual is employed at the laboratory on a full-time or part-time basis.

8A. WAIVED TEST PROCEDURES REQUESTED

Indicate the Waived tests that you wish to perform. *Waived* testing includes tests performed using a kit, device or procedure, which has been designated by the Food and Drug Administration as Waived for the purposes of CLIA ‘88. Sites performing these tests shall maintain a copy of the documentation that the tests in use have been so designated. Listings of waived tests are available at the following websites:

To Search By Test System: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/testswaived.cfm
To Search By Analyte: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/analyteswaived.cfm
To Search a Particular Kit/Mfr.: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

IMPORTANT NOTE: Limited Service Laboratories seeking approval to perform lead and/or rapid HIV screening(s) must provide CLEP with a written protocol detailing how testing is performed in accordance with the manufacturer’s requirements. Guidance with protocol development for lead and/or rapid HIV testing is available at the following websites:

For HIV Testing: www.health.state.ny.us/diseases/aids/testing/rapid/index.htm
For Lead Testing: www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm
8B. PROVIDER-PERFORMED MICROSCOPY PROCEDURES REQUESTED

Indicate the Provider-performed Microscopy Procedure(s) that you wish to perform. *Provider-performed Microscopy Procedures (PPMP) includes tests personally performed as part of physical examinations by health care providers, licensed and currently registered in New York State, including physicians, dentists, podiatrists, physician assistants, nurse practitioners and certified midwives operating within the scope of practice for their profession and which have been designated as PPMP by the Centers for Disease Control. Sites performing these tests shall maintain a copy of the documentation that the tests in use have been so designated.

9A. TECHNICAL INFORMATION: WAIVED TEST PROCEDURES

For each Waived test indicated in Section 8A-Waived Test Procedures Requested, complete the appropriate Technical Information section(s) on page 4.

- Indicate the test procedure (i.e. blood glucose, dipstick urinalysis, fecal occult blood, etc.);
- Indicate the name of the kit and/or instrument, and manufacturer;
- Provide an estimate of the total number of tests performed annually (i.e. How many tests do you do per year?).

9B. TECHNICAL INFORMATION: PROVIDER-PERFORMED MICROSCOPY PROCEDURES

For each Provider-performed Microscopy Procedure indicated in Section 8B-Provider Performed Microscopy Procedures Requested, complete the appropriate Technical Information section(s) on page 4.

- Indicate the test procedure (i.e. Wet Mounts, KOH Preps, etc.);
- Provide an estimate of the total number of tests performed annually (i.e. How many tests do you do per year?).

10. CERTIFICATION

This section must be completed & signed by the individual indicated in Section 7–Laboratory Directorship as responsible for the technical and clinical direction of your laboratory testing and the individual completing the application (if different from the Laboratory Director).

CLIA REGISTRATION

Once your application is approved, we will issue an initial CLIA registration number. You will be sent a registration document, which will serve to verify your enrollment with this program and will also provide documentation of your CLIA registration number. If you are applying for a multi-site registration, registration documents for all locations in the network will be sent to the primary location. Registrations are valid for two years from the date issued. Approximately three months before the registration expires, you will receive an application to renew your registration or multi-site registration.

Registrants may only perform the tests listed on the registration document issued by the Department. Multi-site registrants may only perform the tests listed on the registration document issued to the Primary Site.

CHANGES IN STATUS

Once approved, you must keep our Program informed of any changes which may affect your registration status (i.e. laboratory name, address, director, test menu, owner, additional testing sites, etc.). Please be advised that Limited Service Laboratory registrations are void upon change in the laboratory location or the owner. In addition, registrants must inform our Program of any change in location or laboratory director within 30 days of the change. Limited Service Laboratory Change forms may be downloaded from our website at:

http://www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm
**INITIAL LIMITED SERVICE LABORATORY REGISTRATION APPLICATION**

Please follow the instructions carefully since the submission of incomplete applications will delay the processing and issuance of the registration. **NOTE:** You must enclose a $200.00 application fee payment with your application. Your check or money order should be made payable to: New York State Department of Health.

1. **CLIA STATUS AND APPLICATION TYPE:**
   - If your laboratory already has a CLIA number, please indicate here: ____________________________________________
   - Type of Limited Service Laboratory Registration Requested (Select One):
     - Single-Site Registration
     - Multi-Site Registration (if you wish to add secondary testing sites, please complete form, DOH-4081MS)
   - If this is a new facility, indicate the projected opening date: ________________________________________________

2. **GENERAL INFORMATION:** If applying for a multi-site registration, complete this information for the main site.
   - **Laboratory Name (Limited to 70 Characters):**
   - **Federal Employer ID Number:**
   - **County/Borough:**
   - **Laboratory Address (Physical Location of Laboratory):**
     - **City:**
     - **State:**
     - **ZIP Code:**
   - **Mailing Address (If Different From Physical Location):**
     - **City:**
     - **State:**
     - **ZIP Code:**
   - **Telephone Number:**
   - **FAX Number:**
   - **Contact Person Name (If Not the Laboratory Director):**
     - **Telephone Number:**
     - **E-mail Address:**
   - **Laboratory E-mail Address:**

Indicate the Days & Hours when testing will be performed (Please clarify hours as AM and/or PM):

- MO _______ to _______  TU _______ to _______  WE _______ to _______  TH _______ to _______
- FR _______ to _______  SA _______ to _______  SU _______ to _______

Indicate whether your laboratory or laboratory network will perform community screening events:  □ No  □ Yes
3. LABORATORY TYPE: Select one from the list below that best describes your laboratory.

- [ ] 01-24 Ambulance
- [ ] 02-3B Ambulatory Surgery Center
- [ ] 03-02 Ancillary Testing Site in Health Care Facility/Hospital Extension Clinic
- [ ] 04-25 Assisted Living Facility
- [ ] 06-3A Community Clinic
- [ ] 07-04 Comprehensive Outpatient Rehabilitation Facility
- [ ] 23-06 Correctional Facilities
- [ ] 07-3C End Stage Renal Disease Dialysis Facility
- [ ] 09-3D Federally Qualified Health Center
- [ ] 10-08 Health Fair
- [ ] 11-07 Health Maintenance Organization
- [ ] 12-08 Home Health Agency
- [ ] 13-09 Hospice
- [ ] 14-01 Hospital
- [ ] 15-11 Independent
- [ ] 16-12 Industrial* (Indicate Bureau License No.: __________________)
- [ ] 17-13 Insurance
- [ ] 18-14 Intermediate Care Facility for the Mentally Retarded
- [ ] 19-15 Mobile Laboratory
- [ ] 20-16 Pharmacy
- [ ] 24-27 Public Health Laboratory
- [ ] 25-3D Rural Health Clinic
- [ ] 26-17 School/Student Health Service
- [ ] 27-18 Skilled Nursing Facility or Nursing Facility
- [ ] 28-99 Other (Indicate): __________________________________

4. OWNERSHIP INFORMATION: List the name and address of the individual, partnership or corporation owning or operating the laboratory or laboratory network. “Address of Principal Office” refers to the address of the principal office of the corporation, partnership or government entity, which owns or operates the laboratory or laboratory network.

Type of Control/Ownership (Select Only One From the List Below):
- [ ] For-Profit (indicate): Individual
- [ ] For-Profit (indicate): Partnership
- [ ] For-Profit (indicate): Corporation
- [ ] Not-For-Profit (indicate): Religious Affiliation
- [ ] Not-For-Profit (indicate): Private
- [ ] Government (indicate): City
- [ ] Government (indicate): County
- [ ] Government (indicate): State
- [ ] Government (indicate): Federal

Name of Owner (if Sole Proprietorship) or Corporation:

Street Address of Principal Office of Owner (if Sole Proprietorship) or Corporation:

- City:
- State:
- ZIP Code:

This Facility: A small business is defined as one, which is located in New York State, independently owned and operated, and employs 100 or fewer individuals. This includes all employees, both technical and non-technical.
- [ ] Is a small business
- [ ] Is not a small business

5. AFFILIATION: If your laboratory is affiliated with a laboratory holding a NYS permit, provide the name, address, and NYS laboratory permit PFI Number (if known). Do not provide the name and PFI Number of your reference laboratory.

PFI Number:

Name of Affiliated Laboratory:

Street Address:

- City:
- State:
- ZIP Code:

6. MANAGEMENT: If the laboratory testing performed on-site in your facility is provided under a management or consulting contract, indicate the name, and address of the company you contract with to perform this testing. Do not provide the name and PFI Number of your reference laboratory.

Name of Management/Consulting Company:

Street Address:

- City:
- State:
- ZIP Code:
7. LABORATORY DIRECTORSHIP: Complete this section in its entirety for the individual providing technical and clinical direction of your laboratory testing.

<table>
<thead>
<tr>
<th>First Name:</th>
<th>M.I.:</th>
<th>Last Name:</th>
</tr>
</thead>
</table>

Do you currently hold a NYS Laboratory Director Certificate of Qualification?
- [ ] Yes  CQ Code: ____________________________  [ ] No

Check Degree(s) and License(s) Held & Indicate License Number Below:

Provide License Number: _______________________________________

Indicate whether the Laboratory Director is employed at the laboratory on a full-time or part-time basis (Select One):

Director Status:  [ ] Full-Time  [ ] Part-Time

8A. WAIVED TEST PROCEDURES REQUESTED: Check off all waived tests that you intend to perform. *NOTE: This is not a complete list of waived tests. For a more comprehensive list, refer to the attached registration instructions Section 8A – Waived Test Procedures Requested for links to several FDA websites. Complete Section 9A-Technical Information: Waived Test Procedures for each test checked in this section.

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Test Name</th>
<th>Test Name</th>
<th>Test Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine Aminotransferase (ALT)</td>
<td>LDL Cholesterol</td>
<td>Lead (*Note: Submit Testing Protocol w/Registration)</td>
<td>Lithium</td>
</tr>
<tr>
<td>Bladder Tumor Associated Antigen</td>
<td>Microalbumin</td>
<td>Mononucleosis</td>
<td>Nicotine (or its metabolites)</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Fructosamine</td>
<td>Occult Blood</td>
<td>Ovulation Tests</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Glucose (Fingerstick)</td>
<td>Pregnancy Test (Urine)</td>
<td>Protime</td>
</tr>
<tr>
<td>Drugs of Abuse</td>
<td>Glycosolated HGB</td>
<td>Strep Antigen Test (Rapid)</td>
<td>Thyroid-Stimulating Hormone (TSH)</td>
</tr>
<tr>
<td>Ethanol</td>
<td>HDL Cholesterol</td>
<td>Triglycerides</td>
<td>Urinalysis (Dipstick)</td>
</tr>
<tr>
<td>Follicle Stimulating Hormone (FSH)</td>
<td>Helicobacter Pylori</td>
<td>Hematocrit</td>
<td>HIV Antibody (*Note: Submit Testing Protocol w/Registration)</td>
</tr>
<tr>
<td></td>
<td>Hemoglobin</td>
<td>Hemoglobin</td>
<td>Influenza</td>
</tr>
<tr>
<td>Fructosamine</td>
<td>HIV Antibody</td>
<td>LDL Cholesterol</td>
<td>Lead (*Note: Submit Testing Protocol w/Registration)</td>
</tr>
<tr>
<td>Glucose (Fingerstick)</td>
<td>Microalbumin</td>
<td>Lithium</td>
<td>Nicotine (or its metabolites)</td>
</tr>
<tr>
<td>Glycosolated HGB</td>
<td>Mononucleosis</td>
<td>Occult Blood</td>
<td>Ovulation Tests</td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>Nicotine (or its metabolites)</td>
<td>Protime</td>
<td>Strep Antigen Test (Rapid)</td>
</tr>
<tr>
<td>Helicobacter Pylori</td>
<td>Other (Please Indicate): _____________________________</td>
<td>Thyroid-Stimulating Hormone (TSH)</td>
<td>Urinalysis (Dipstick)</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>Other (Please Indicate): _____________________________</td>
<td>Triglycerides</td>
<td>Other (Please Indicate): _____________________________</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Other (Please Indicate): _____________________________</td>
<td>Urinalysis (Dipstick)</td>
<td>Other (Please Indicate): _____________________________</td>
</tr>
<tr>
<td>HIV Antibody (*Note: Submit Testing Protocol w/Registration)</td>
<td>Other (Please Indicate): _____________________________</td>
<td>Urinalysis (Dipstick)</td>
<td>Other (Please Indicate): _____________________________</td>
</tr>
<tr>
<td>Influenza</td>
<td>Other (Please Indicate): _____________________________</td>
<td>Urinalysis (Dipstick)</td>
<td>Other (Please Indicate): _____________________________</td>
</tr>
</tbody>
</table>

8B. PROVIDER-PERFORMED MICROSCOPY PROCEDURES (PPMP) REQUESTED: Check off all PPM Procedures that you intend to perform. NOTE: Only providers (physicians, nurse practitioners, nurse midwives and physician assistants) may perform testing. Complete Section 9B - Technical Information: Provider-performed Microscopy Procedures for each test checked in this section.

<table>
<thead>
<tr>
<th>Procedure Name</th>
<th>Procedure Name</th>
<th>Procedure Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements</td>
<td>LDL Cholesterol</td>
<td>Lead (*Note: Submit Testing Protocol w/Registration)</td>
</tr>
<tr>
<td>Fecal Leukocyte examinations</td>
<td>Microalbumin</td>
<td>Mononucleosis</td>
</tr>
<tr>
<td>Fern tests</td>
<td>Nicotine (or its metabolites)</td>
<td>Protime</td>
</tr>
<tr>
<td>Nasal smears for granulocytes</td>
<td>Other (Please Indicate): _____________________________</td>
<td>Strep Antigen Test (Rapid)</td>
</tr>
<tr>
<td>Pinworm examinations</td>
<td>Thyroid-Stimulating Hormone (TSH)</td>
<td>Urinalysis (Dipstick)</td>
</tr>
<tr>
<td>Post-coital direct, qualitative examinations of vaginal or cervical mucous</td>
<td>Triglycerides</td>
<td>Other (Please Indicate): _____________________________</td>
</tr>
<tr>
<td>Potassium hydroxide (KOH) preparations</td>
<td>Urinalysis (Dipstick)</td>
<td>Other (Please Indicate): _____________________________</td>
</tr>
<tr>
<td>Qualitative semen analysis (limited to the presence/absence of sperm and detection of motility)</td>
<td>Other (Please Indicate): _____________________________</td>
<td>Other (Please Indicate): _____________________________</td>
</tr>
<tr>
<td>Urine sediment examinations</td>
<td>Other (Please Indicate): _____________________________</td>
<td>Other (Please Indicate): _____________________________</td>
</tr>
</tbody>
</table>
9A. TECHNICAL INFORMATION: WAIVED TEST PROCEDURES. The following information must be provided for each waived test indicated in Section 8A-Waived Test Procedures Requested. Make additional copies of table as needed and attach to the application.

<table>
<thead>
<tr>
<th>Indicate Test Procedure (Ex: fingerstick glucose, dipstick urinalysis, etc.).</th>
<th>Indicate the Name of the Kit and/or Instrument, and the Name of the Manufacturer of the Device.</th>
<th>Estimate the Total Number of Tests Performed Annually.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9B. TECHNICAL INFORMATION: PROVIDER-PERFORMED MICROSCOPY PROCEDURES. The following information must be provided for each Provider-performed Microscopy test indicated in Section 8B-Provider Performed Microscopy Procedures Requested. Make additional copies of table as needed and attach to the application.

<table>
<thead>
<tr>
<th>Indicate Test Procedure.</th>
<th>Estimate the Total Number of Tests Performed Annually.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. CERTIFICATION. I understand that by signing this application form I agree to any investigation made by the Department of Health to verify or confirm the information provided herein or adjunctive to this application, and any investigation in connection with my laboratory registration, a complaint or incident report made known to the Department. If additional information is requested, I will provide it. Further, I understand that, should this application or my status be investigated at any time, I agree to cooperate in such an investigation.

I understand that under Section 579 of the Public Health Law the registration of this limited service laboratory may be revoked, suspended, limited or annulled if any fact is misrepresented in this application. Changes in any of the information in this application must be reported to the Clinical Laboratory Evaluation Program immediately by the laboratory director or owner. I also understand that additional penalties may apply if I misrepresent, conceal, or fail to disclose facts or information regarding my initial and continuing eligibility for said limited service laboratory registration. Further, I understand that misrepresentation may constitute offering a false instrument, which is a crime under New York State Penal Law.

By signing this application, I hereby attest that the information I have given the Department of Health as a basis for obtaining a limited service laboratory registration is true and correct, that I have read the relevant rules and regulations, and that I accept responsibility for the categories indicated in Section(s) 8A- Waived Test Procedures Requested and/or 8B- Provider Performed Microscopy Procedures Requested of this application.

<table>
<thead>
<tr>
<th>Print Name of Laboratory Director</th>
<th>Signature of Laboratory Director</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Print Name of Person Completing this Form</th>
<th>Signature of Person Completing this Form</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ATTACHMENT

2
It is the intent of (Organization Name) to provide Blood Glucometry testing.

This service is being offered in cooperation with ______________________(Physician).

Policies:
1. It is the policy of our organization that EMTS providing Blood Glucose testing (Glucometry) will be properly trained. Therefore, all persons providing Blood Glucose testing shall attend a blood-glucose monitoring training session instructed by a NYS DOH CIC, CLI, EMS Program Agency Representative or the Agency Medical Director (or designee) utilizing the Power Point presentation titled “Diabetes for the EMS Provider” or similar presentation. The provider will demonstrate competency in using the necessary equipment. All EMT’s will conduct skill proficiency as required by the WREMAC.

2. It is the policy of our organization to ensure the electronic glucometer is in a state of readiness at all times. Therefore, all regular maintenance and checkout procedures of the electronic glucometer will meet or exceed the manufacturer’s recommendations and the Clinical Laboratory Improvement Amendment (CLIA) License. Documentation of such inspections shall be dated and maintained in a secure file for a period of three (3) years. Inspections shall be the responsibility of the agency's EMS Captain or assigned person.

3. A portable sharps container will be stored with the device so that the lancets can be properly handled after use. The unused lancets will be stored in a device not to cause injury to providers.

4. It is the policy of our organization to ensure appropriateness in providing glucometry. Therefore, our agency shall participate in the required Quality Improvement program as determined by our Medical Director. The Medical Director will review some if not all PCR’s where the use of electronic glucometer was used.

Agency Chief:

__________________________ ____________________________               ______________
Print       Sign       Date

Agency CEO:

__________________________ ____________________________             ______________
Print      Sign      Date

Agency Medical Director:

__________________________  ____________________________             _______________
Print       Sign      Date
Western Regional Emergency Medical Advisory Committee

BLS Agency Application to Perform Blood Glucose Monitoring

Agency Name _________________________________ Agency Code ____________

_____________________________________________________________________________

Mailing address City Zip

Contact ____________________________ Title _____________________________

Limited Lab Reg # __________ _

Daytime phone number _______________________________ Email__________________

Agency Medical Director ______________________________ # of trained providers _________

Representative responsible for BLS Glucometer Testing Care:

Name: ___________________________________________ Contact Phone # ______________

Agency QA/QI Coordinator:

Name: __________________________________________ Contact Phone #: ____________

=========================================================================

__________________________ requests authorization from REMAC to permit BLS providers to
perform Blood Glucose testing in compliance with NYS BLS Protocol and WREMAC Policy
Statement.

Attached to this application are the following items:

- A letter from the Agency Medical Director supporting the request and indicating an
  understanding of their role in the Clinical Lab requirements and quality assurance
  process.
- A copy of the completed NYS Department of Health Clinical Laboratory Limited
  Laboratory Registration application for blood testing licensure (DOH-4081 Limited
  Service Laboratory Registration), along with the authorizations from the Clinical
  Laboratory.
- Copies of written Policies and Procedures for the operation of the glucometer that are
  consistent with local protocols, to include:
  Training and documentation of authorized users
  Defined QA program, including appropriateness review by the Agency Medical
  Director
  Documentation of control testing process
  Storage of glucometer and proper disposal of sharps

As CEO of the above agency, I agree to the requirements set forth in the WREMAC Policy
Statement on blood glucose monitoring and will be responsible to make sure that the providers in
the agency follow those regional protocols. I also agree that all Blood Glucose monitor operators
will successfully complete the required training with an approved instructor and that
documentation of this training will be submitted to the Regional QA/QI Coordinator at least yearly.

Name _______________________________ Title ____________________ Date ____________

Date of approval by WREMAC _____________

WREMAC 2/09
**Notice to Service:**

Please identify the physician providing Quality Assurance oversight to your individual service. If your service provides Defibrillation, Epi-Pen, Blood Glucometry, Albuterol or Advance Life Support (ALS), you must have specific approval from your Regional EMS Council’s Medical Advisory Committee (REMAC) and oversight by a NY state licensed physician. If you change your level of care to a higher ALS level, you must provide the NYS DOH Bureau of EMS a copy of your REMAC’s written approval notice.

If your service wishes to change to a lower level of care, provide written notice of the change and the level of care to be provided, and the effective date of implementation, to your REMAC with a copy to the NYS DOH Bureau of EMS.

If your service has more than one Service Medical Director, please use copies of this verification and indicate which of your operations or REMAC approvals apply to the oversight provided by each physician. Please send this form to your DOH EMS Area Office for filing with your service records.

___________________________________________________________________________________

Check all special regional approvals and the single highest level of care applicable to your service:

- Defibrillation / PAD (BLS Level Services)
- Epi Pen (Epi / Albuterol / Blood Glucometry per regional protocol)
- AEMT– Paramedic Level of Care
- AEMT– Critical Care Level of Care
- AEMT– Intermediate Level of Care
- Controlled Substances (BNE License on file)

**Please Type or Print Legibly:**

Name of EMS Service: __________________________________________________________

Agency Code Number: _____________ Service Type: □ Amb □ ALSFR □ BLSFR

Name of Service CEO: ________________________________________________________

Name of Service Medical Director: _____________________________________________

NYS Physician’s License Number: _____________________________________________

Ambulance/ALSFR Service Controlled Substance License # if Applicable: 03C-___________

Ambulance/ALSFR Service Controlled Substance License Expiration Date: ____________

___________________________________________________________________________________

**Medical Director Affirmation of Compliance:**

I affirm that I am the Physician Medical Director for the above listed EMS service. I am responsible for oversight of the pre-hospital Quality Assurance/Quality Improvement program for this service. This includes medical oversight on a regular and on-going basis, in-service training and review of service policies that are directly related to medical care.

I am familiar with applicable State and Regional Emergency Medical Advisory Committee treatment protocols, policies and applicable state regulations concerning the level of care provided by this service.

If the service I provide oversight to is not certified and provides AED level care, the service has filed a Notice of Intent to Provide Public Access Defibrillation (DOH-4135) and a completed Collaborative Agreement with its Regional EMS Council.

Signature – Service Medical Director: _____________________________________________

Date of Signature: __________________________________________________________________________