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.

2. Follow NYS DOH BLS protocol for the General Approach to Medical Emergencies prioritizing and managing Airway, Breathing, and Circulation.

3. Obtain a complete set of Vital Signs; include O_2 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

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
CLINICAL LABORATORY EVALUATION PROGRAM
P.O. BOX 509
ALBANY, NY 12201-0509
Telephone: (518) 402-4253 Fax: (518) 485-5414
E-mail: clepltd@health.state.ny.us
Web: www.wadsworth.org/labcert

INITIAL LIMITED SERVICE LABORATORY REGISTRATION APPLICATION INSTRUCTIONS

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.

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

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
CLINICAL LABORATORY EVALUATION PROGRAM
P.O. BOX 509
ALBANY, NY 12201-0509
Telephone: (518) 402-4253 Fax: (518) 485-5414
E-mail: clepltd@wadsworth.org
Web: www.wadsworth.org/labcert

FOR OFFICE USE ONLY: ***I*** ____ ***R*** ____

Rec'd._____

_

Fee No._____

PFI: _____ Gaz Code: _____

CLIA No: _____

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):
Laboratory E-mail Address:		Telephone Number: 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 <u>One</u> From the List Below):

For-Profit (indicate):	☐ Individual	☐ Partnership	☐ Corporation	
Not-For-Profit (indicate):	☐ Religious Affiliation	☐ Private		
Government (indicate):	☐ City	☐ County	☐ State	☐ 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 <u>not</u> 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 <u>not</u> 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 <u>not</u> 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.

First Name:	M.I.:	Last Name:

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:

☐ M.D. ☐ D.O. ☐ D.D.S. ☐ Ph.D. ☐ D.Sc. ☐ NP ☐ PA ☐ CNM

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 <u>not</u> 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.

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

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.

- ☐ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ☐ Fecal Leukocyte examinations
- ☐ Fern tests
- ☐ Nasal smears for granulocytes
- ☐ Pinworm examinations
- ☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ☐ Potassium hydroxide (KOH) preparations
- ☐ Qualitative semen analysis (limited to the presence/absence of sperm and detection of motility)
- ☐ Urine sediment examinations

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.**

Indicate Test Procedure (Ex: fingerstick glucose, dipstick urinalysis, etc.).	Indicate the Name of the Kit and/or Instrument, and the Name of the Manufacturer of the Device.	Estimate the Total Number of Tests Performed Annually.

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.**

Indicate Test Procedure.	Estimate the Total Number of Tests Performed Annually.

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.

Print Name of Laboratory Director	Signature of Laboratory Director	Date
Print Name of Person Completing this Form	Signature of Person Completing this Form	Date

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 Labaortory 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

ATTACHMENT

3

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 _____

ATTACHMENT

4

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 ☐ Albuterol ☐ Blood Glucometry (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: _____