WREMAC

Western Regional Emergency Medical Advisory Committee

ALLEGANY, CATTARAUGUS, CHAUTAUQUA, ERIE,
GENESEE, NIAGARA, ORLEANS, AND WYOMING COUNTIES

WREMAC Blood Glucose Monitoring for Basic EMTs

TABLE OF CONTENT

- ☐ Purpose, Policy & Education
- ☐ Steps to complete approval process
- ☐ WREMAC Blood Glucose Protocol for EMT
- ☐ NYS BLS Hypoglycemia Protocol
- ☐ Limited Laboratory Registration Instructions and Application *(Attachment 1)*
- ☐ Policies and Procedures sample *(Attachment 2)*
- ☐ WREMAC BLS Agency Application to Perform Blood Glucose Monitoring *(Attachment 3)*
- ☐ Medical Director Verification DOH-4362 *(Attachment 4)*

WREMAC
Western Regional Emergency Medical Advisory Committee
ALLEGANY, CATTARAUGUS, CHAUTAUQUA, ERIE,
GENESEE, NIAGARA, ORLEANS, AND WYOMING COUNTIES

WREMAC 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 60 mg/dL and the patient has an altered mental status, confirm ALS is enroute and monitor the A, B, C's.

6. If hypoglycemic (<60 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 60 mg/dL.
Altered Mental Status – GCS of 14 or less and not alert and oriented.

Altered Mental Status

(including, but not limited to hypoglycemia and opioid overdose)

Assess the situation for potential or actual danger. If the scene/situation is not safe, retreat to a safe location, create a safe zone and obtain additional assistance from a police agency.

1) Perform primary assessment. Assure that the patient's airway is open and that breathing and circulation are adequate. Suction as necessary.
2) Administer high concentration oxygen. In children, humidified oxygen is preferred.
3) Obtain and record patient's vital signs, including determining the patient's level of consciousness. Assess and monitor the Glasgow Coma Scale.

Is the patient conscious? (A,V)

Yes

History of Diabetes?

Yes

If regionally approved and available, obtain patient's blood glucose (BG) level. If not refer to A below.

BG: **<** 60 mg/dl

A) If the patient has a known history of diabetes controlled by medication, is conscious and is able drink without assistance, provide an oral glucose solution, fruit juice or non-diet soda by mouth.

BG: **>** 60 mg/dl

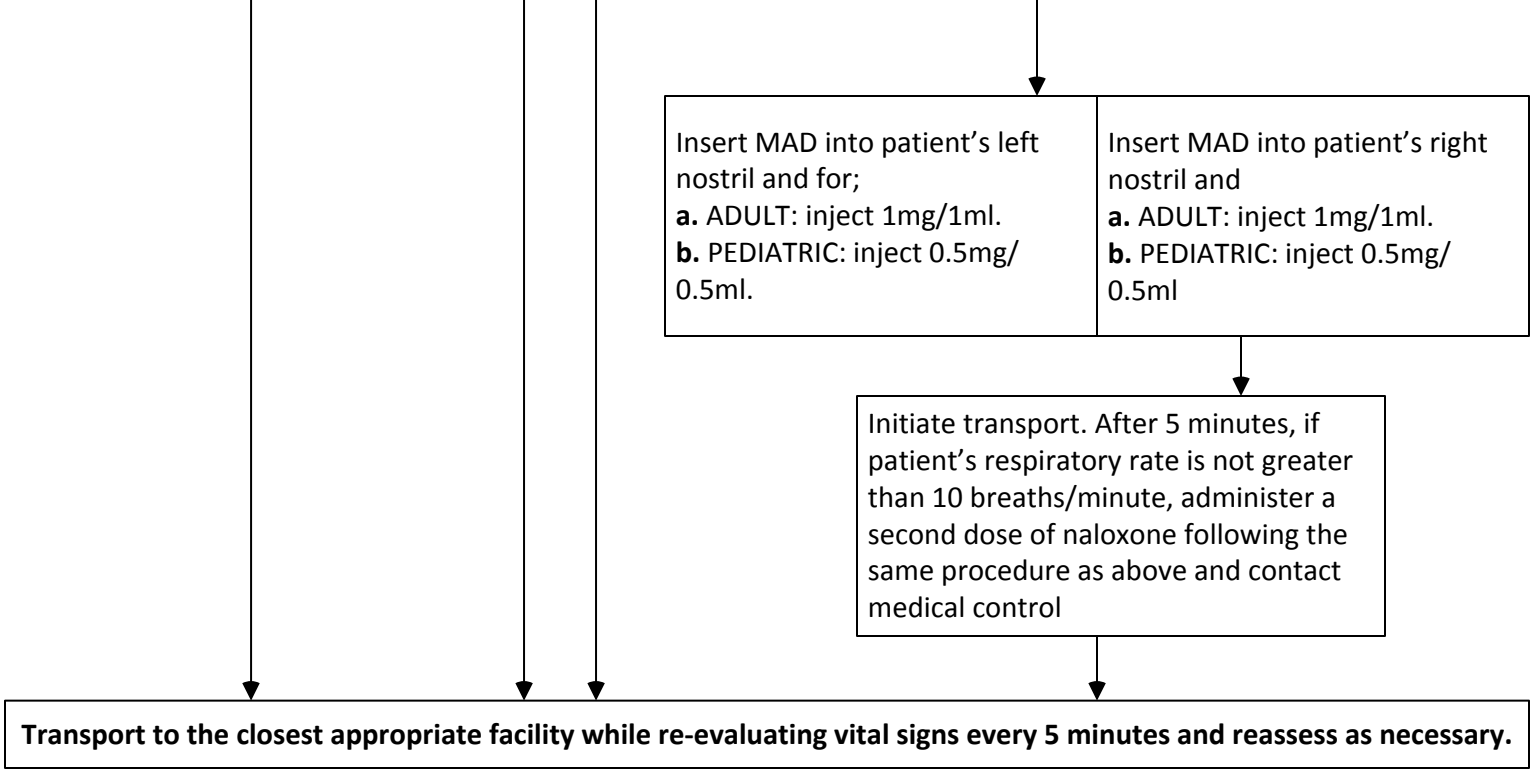
No

No

If regionally approved and available, obtain patient's blood glucose (BG) level and document findings and continue transport

If patient has a suspected opioid overdose:
i. If patient does not respond to verbal stimuli, but either responds to painful stimuli or is unresponsive; and
ii. Respirations less than 10/minute and signs of respiratory failure or respiratory arrest, refer to appropriate respiratory protocol and continue with this protocol.

Administer naloxone (Narcan®) via a mucosal atomizer device (MAD). Or other Regionally approved FDA commercially prepared metered dose device**



Caution:

- **All suicidal or violent threats or gestures must be taken seriously. These patients should be in police custody if they pose a danger to themselves or others.**
- **If the patient poses a danger to themselves and/or others, summon police for assistance**.

NOTES:

- **Request Advanced Life Support if available. Do NOT delay transport to the appropriate hospital.**
- **Emotionally disturbed patients must be presumed to have an underlying medical or traumatic condition causing the altered mental status.**
- **If underlying medical or traumatic condition causing an altered mental status is not apparent; the patient is fully conscious, alert (A) and able to communicate; and an emotional disturbance is suspected, proceed to the Behavioral Emergencies protocol.**
- **This protocol is for patients who are NOT alert (A), but who are responsive to verbal stimuli (V), responding to painful stimuli (P), or unresponsive (U).**
- **** Current approved alternative FDA approved commercially prepared metered dosing units are 4mg/0.1ml and are approved for full dosing in Adult and Pediatric patients.**

ATTACHMENT

1

NEW YORK STATE DEPARTMENT OF HEALTH
Wadsworth Center
Clinical Laboratory Evaluation Program
Empire State Plaza, P.O. Box 509
Albany, New York 12201-0509
Telephone: (518) 402-4253 Fax: (518) 449-6902
E-mail: CLEPLtd@health.ny.gov
Web: www.wadsworth.org/regulatory/clep/limited-service-lab-certs

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 with your application. 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. This fee is non-refundable.

Volunteer ambulance services as defined in Article 30 of the Public Health Law and operated under Section 209-B of the General Municipal Law shall be exempt from the requirement to pay the $200.00 application fee. Volunteer ambulance services seeking a fee waiver must submit a copy of the most recent *Application for EMS Operating Certificate, form DOH-206* that was filed with the Bureau of EMS, as well as a copy of your current EMS Operating Certificate. The document may be obtained through the Bureau of EMS Central Office Operations Unit at 518-402-0996, or through the Bureau of EMS website at: http://www.health.ny.gov/professionals/ems/

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), 518-449-6902 (fax), or via e-mail at: CLEPLtd@health.ny.gov

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 Network 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 Limited Service Laboratory Multi-Site Network Registration and 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 Network Registration (form, DOH-4081MS). Note that the laboratory director listed on this application will be responsible for all sites operating under a Limited Service Laboratory Multi-Site Network Registration and 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 Certificate.

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 network 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 off-site community screening events. Laboratories seeking approval to operate off-site 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 Limited Service Laboratory Multi-Site Network Registration and 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.

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 designated as responsible for the technical and clinical direction of the laboratory testing within your facility and/or laboratory network.

The laboratory director designee must be a licensed health care practitioner (Physician, Dentist, PA, NP, or CNM only) or a Ph.D. holding a certificate of qualification. Be reminded that a Ph.D. is not a licensed health care practitioner and may not act as laboratory director in sites performing Provider-performed Microscopy Procedures (PPMP).

Indicate if the individual holds a certificate of qualification. If the individual is a health care practitioner, a license number must be provided. ****NOTE: The laboratory director must include a copy of their current New York State Professional License with the completed Limited Service Laboratory Registration Reapplication package.***

Indicate whether the individual is employed at the facility and/or laboratory network on a full-time, or part-time basis.

8. WAIVED TEST PROCEDURES REQUESTED

Indicate the *Waived* tests that you wish to perform and provide the combined estimated annual test volume for all *Waived* test procedures indicated. **Waived* testing includes tests performed using a kit, device or procedure, which has been designated by the Food and Drug Administration (FDA) as *Waived* for the purposes of CLIA '88. Non-DOT breath alcohol testing must be performed using an FDA approved IVD Over-The-Counter device. 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
To Search FDA's IVD Over-The-Counter Lab Test Database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm

IMPORTANT NOTE: Limited Service Laboratories seeking approval to perform lead screening(s) must provide CLEP with a written protocol detailing how testing is performed in accordance with the manufacturer's requirements.

Additional guidance with protocol development for lead, and/or rapid HIV testing is available at the following websites:

For Lead Testing: www.wadsworth.org/regulatory/clep/limited-service-lab-certs
For HIV Testing: www.health.state.ny.us/diseases/aids/testing/rapid/index.htm

9. PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES REQUESTED

Indicate the *Provider-performed Microscopy (PPM) Procedures* that you wish to perform and provide the combined estimated annual test volume for all PPM Procedures indicated. ***Provider-performed Microscopy (PPM) Procedures** 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 *PPM Procedures* 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.

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). **Please Note: All signatures must be original. SIGNATURE STAMPS WILL NOT BE ACCEPTED.**

OUR MAILING ADDRESS

Application documents must be returned to our office at the address below:

Regular Mail
Clinical Laboratory Evaluation Program
Wadsworth Center
New York State Department of Health
Empire State Plaza, P.O. Box 509
Albany, NY 12201-0509

Express Mail
Clinical Laboratory Evaluation Program
David Axelrod Institute
Wadsworth Center
New York State Department of Health
120 New Scotland Avenue
Albany, NY 12208

LIMITED SERVICE LABORATORY REGISTRATION

Once the Limited Service Laboratory Registration application is approved, an initial registration certificate will be issued. The certificate 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 network registration, registration certificates for all locations in the network will be sent to the primary location. Certificates are valid for two years from the date issued. Approximately three months before the registration expires, you will receive materials to renew your registration or multi-site network registration.

Registrants may only perform the tests listed on the registration certificate issued by the Department. Multi-site network registrants may only perform the tests listed on the registration certificate 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.). 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: www.wadsworth.org/regulatory/clep/limited-service-lab-certs

SPECIAL NOTICE

The submission of incomplete and/or incorrect application materials will delay processing. Required information includes, but is not limited to the following:

- $200.00 Application Fee (*Volunteer Ambulances Services Refer to Page - 1 of the Instructions*);
- A Working E-Mail Address;
- A Copy of Laboratory Director's Current New York State Professional License;
- Estimated Annual Test Volumes for Waived and/or PPM Procedures;
- Name & Original Signature of Laboratory Director and Individual Completing Application. Signature stamps will not be accepted.

NEW YORK STATE DEPARTMENT OF HEALTH
Wadsworth Center
Clinical Laboratory Evaluation Program
Empire State Plaza, P.O. Box 509
Albany, New York 12201-0509
Telephone: (518) 402-4253 Fax: (518) 449-6902
E-mail: CLEPLtd@health.ny.gov
Web: www.wadsworth.org/regulatory/clep/limited-service-lab-certs

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. **This fee is non-refundable.**

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: (Note: If applying for a multi-site registration, complete this information for the primary 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 off-site 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
- ☐ 05-*26* Blood Bank
- ☐ 06-*3A* Community Clinic
- ☐ 07-*04* Comprehensive Outpatient Rehabilitation Facility
- ☐ 23-*06* Correctional Facilities
- ☐ 08-*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 Number: _____)
- ☐ 17-*13* Insurance
- ☐ 18-*14* Intermediate Care Facility for the Mentally Retarded
- ☐ 19-*15* Mobile Laboratory
- ☐ 20-*16* Pharmacy
- ☐ 21-*19* Physician Office
- ☐ 22-*20* Practitioner Other
- ☐ 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-*28* Tissue Bank/Repositories
- ☐ 29-*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 (Check Only <u>One</u> Box 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 laboratory 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 (Indicate CQ Code): _____ ☐ No

Check Degree(s) and License(s) Held (Include a Copy of Current New York State Professional License):

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

Indicate New York State Professional 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

8. WAIVED TEST PROCEDURES REQUESTED: Check off all waived tests that you intend to perform and indicate the estimated annual test volume for all waived tests to be performed.

☐ Adenovirus	☐ Erythrocyte Sedimentation Rate *(ESR)*	☐ Occult Blood
☐ Aerobic/Anaerobic Organisms-Vaginal	☐ Ethanol	☐ Ovulation Tests
☐ Alanine Aminotransferase *(ALT)*	☐ Follicle Stimulating Hormone (*FSH*)	☐ pH
☐ Albumin	☐ Fructosamine	☐ Phosphorous
☐ Alkaline Phoshatase *(ALP)*	☐ Gamma Glutamyl Transferace *(GGT)*	☐ Platelet Aggregation
☐ Amylase	☐ Glucose	☐ Potassium
☐ Aspartate Aminotransferase *(AST)*	☐ Glycosylated Hemoglobin	☐ Pregnancy Test (*Urine*)
☐ B-Type Natriuretic Peptide *(BNP)*	☐ HDL Cholesterol	☐ Protime
☐ Bacterial Vaginosis, Rapid	☐ Helicobacter Pylori	☐ RSV *(Respiratory Syncytial Virus)*
☐ Bladder Tumor Associated Antigen	☐ Hematocrit	☐ Saliva Alcohol
☐ Blood Urea Nitrogen *(BUN)*	☐ Hemoglobin	☐ Sodium
☐ Breath Alcohol *(FDA OTC Devices Only)*	☐ HCV, Rapid	☐ Strep Antigen Test (*Rapid*)
☐ Calcium	☐ HIV, Rapid	☐ Thyroid-Stimulating Hormone *(TSH)*
☐ Calcium, Ionized	☐ Influenza	☐ Total Bilirubin
☐ Carbon Dioxide	☐ Ketones	☐ Total Protein
☐ Catalase *(Urine)*	☐ Lactic Acid *(Lactate)*	☐ Trichomonas, Rapid
☐ Chloride	☐ LDL Cholesterol	☐ Triglycerides
☐ Cholesterol	☐ Lead *(*Submit Protocol w/App.)*	☐ Urinalysis
☐ Creatine Kinase *(CK)*	☐ Microalbumin	☐ Other: _____
☐ Creatinine	☐ Mononucleosis	
☐ Drugs of Abuse	☐ Nicotine	

	Indicate the combined estimated annual test volume for <u>all</u> Waived Test Procedures indicated above:

9. PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES 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.

- ☐ 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

	Indicate the combined estimated annual test volume for <u>all</u> PPM Procedures indicated above:

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. Registration under this subdivision may be denied, limited, suspended, revoked or annulled by the Department upon a determination that a laboratory services registrant: (i) failed to comply with the requirements of this subdivision; (ii) provided services that constitute an unwarranted risk to human health; (iii) intentionally provided any false or misleading information to the Department relating to registration or performing laboratory services; or (iv) has demonstrated incompetence or shown consistent errors in the performance of examinations or procedures. 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.

Laboratory test registrants shall: (i) provide only the tests and services listed on the registration issued by the Department hereunder; (ii) advise the Department of any change in the registrant's name, ownership, location or qualified health care professional or laboratory director designated to supervise testing within thirty days of such change; (iii) provide the department with immediate access to all facilities, equipment, records, and personnel as required by the Department to determine compliance with this subdivision; (iv) comply with all public health law and federal requirements for reporting reportable diseases and conditions to the same extent and in the same manner as a clinical laboratory; (v) perform one or more tests as required by the department to determine the proficiency of the persons performing such tests; and (vi) designate a qualified health care professional or qualified individual holding a certificate of qualification pursuant to section five hundred seventy-three of this title, who shall be jointly and severally responsible for the testing performed.

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 tests indicated in Section(s) 8. Waived Test Procedures Requested and/or 9. Provider-Performed Microscopy (PPM) 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

SPECIAL NOTICE

The submission of incomplete and/or incorrect application materials will delay processing. Required information includes, but is not limited to the following:

- $200.00 Application Fee (*Volunteer Ambulances Services Refer to Page - 1 of the Instructions*);
- A Working E-Mail Address;
- A Copy of Laboratory Director's Current New York State Professional License;
- Estimated Annual Test Volumes for Waived and/or PPM Procedures;
- Name & Original Signature of Laboratory Director and Individual Completing Application. Signature stamps will <u>not</u> be accepted.

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 # _____
(xxx)xxx-xxxx

Agency QA/QI Coordinator**:**

Name: _____ Contact Phone #: _____
(xxx)xxx-xxxx

==========

_____ 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 _____
xx/xx/xxxx

Date of approval by WREMAC _____

ATTACHMENT

4

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Emergency Medical Services

Medical Director Verification

Notice to Service

Please identify the physician providing Quality Assurance oversight to your individual agency. If your agency 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 agency has more than one 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 Central Office for filing with your service records.

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

☐ Defibrillation / PAD (BLS Level Services)
☐ Epi Pen
☐ Albuterol
☐ Blood Glucometry
(Epi / Albuterol / Blood Glucometry per regional protocol)
☐ Naloxone

☐ Paramedic Level of Care
☐ Critical Care Level of Care
☐ AEMT Level of Care
☐ Controlled Substances (BNE License on file)

EMS Agency (Please Type or Print Legibly)

Agency Name _____

Agency Code Number _____

Agency Type ☐ Ambulance ☐ ALSFR ☐ BLSFR

Agency CEO _____
Name

Medical Director _____
Name

_____
NYS Physician's License Number

Ambulance/ALSFR Agency Controlled Substance License # if Applicable: 03C – _____

Ambulance/ALSFR Agency Controlled Substance License Expiration Date: _____

Medical Director Affirmation of Compliance

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

If the service I provide oversight to is not certified EMS agency 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.

Medical Director _____
Signature

_____
Date of Signature