Hudson Valley Regional
Emergency Medical Services Council

33 Airport Center Drive, Suite 204, Second Floor
New Windsor, NY 12553
Phone - (845) 245-4292 ~ Fax: (845) 245-4181
www.hvremsco.org

BLS Glucometry Application

Agency Information

Agency Name Agency Code	( ) Telephone Number
Name of Primary Contact (Please Print)	E-Mail Address
Address City State Zip Code	( ) Fax Number

Agency Medical Director

Agency Medical Director Name	( ) Telephone Number
Address City State Zip Code	( ) Fax Number

Authorization Names and Signatures

CEO or Designee (Please Print)	Signature	Date
Agency Medical Director (Please Print)	Signature	Date

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COLLABORATIVE AGREEMENT

BLS Glucometry

As per Hudson Valley Regional Medical Advisory (HVREMAC) requirements,

Agency Name: _____ and
(Hereafter referred to as the Agency)

Medical Director: _____
(Hereafter referred to as the Agency Medical Director)

enter into this collaborative agreement in which;

1. The Agency will possess and operate one or more glucometers according to written policies and procedures which have been developed as recommended by New York State Department of Health Policy Statement 05-04 “Blood Glucometry for Basic Life Support EMS Agencies”;
2. The Agency will ensure that the New York State Basic Life Support Adult and Pediatric Treatment Protocols are utilized by all participating personnel for the proper utilization of BLS Glucometry;
3. The Agency will ensure that the Glucometer will only be utilized by authorized EMT(s) who have successfully completed a training program which includes lesson 4-4 of the New York State Department of Health Emergency Medical Technician – Basic Curriculum, agency specific Blood Borne Pathogens and Sharps Safety training, manufacturer specific glucometer utilization in-service, and the HVREMAC approved BLS Glucometry Training Curriculum;
4. The Agency will require that all BLS glucometer utilizations are documented appropriately by utilizing the New York State approved Patient Care Report (PCR);
5. The Agency agrees to include the review of all BLS glucometer utilizations in the Agency’s quality improvement plan that is required by Article 30 of the New York State Public Health Law;
6. The Agency will review this agreement on an annual basis and will file a new Collaborative Agreement and updated BLS Glucometry Application with the Hudson Valley Regional EMS Council if the Agency Medical Director, or any of the contents of this agreement, changes.

_____ _____
Name of Authorized Agency Representative (Print) **Title**

_____ _____
Signature **Date**

_____ _____
Agency Medical Director’s Signature **Date**

_____
New York State Medical License Number

New York State
Department of Health
Bureau of Emergency Medical Services

POLICY STATEMENT

Supercedes/Updates: ***New***

No. 05-04

Date: Sept. 23, 2005

Re: Blood Glucometry for Basic Life Support EMS Agencies

BACKGROUND

At the January, 2005 meeting of the New York State Emergency Medical Advisory Committee (SEMAC), the use of glucometers by Emergency Medical Technicians (EMT) in Basic Life Support (BLS) EMS agencies was approved. The SEMAC approval was granted with the specific condition that the EMS service wishing to use a glucometer at the BLS level, be granted approval by the local Regional Emergency Medical Advisory Committee (REMAC), each EMT complete an approved training program and the service apply and be granted a Limited Laboratory Registration.

The purpose of this policy is to explain the approval process for agencies wishing to implement a glucometry program. The addition of prehospital blood sugar evaluation is intended to assist in the recognition of hypoglycemia and improve the speed with which proper treatment is received.

AUTHORIZATION

Each REMAC, interested in allowing their BLS EMS agencies to participate, will adopt protocols which will allow a basic EMT to obtain a blood sample, using a lancet device, or equivalent and test the blood sample in a commercially manufactured electronic glucometer. The REMAC will also determine the type and level of record keeping and quality assurance required for this procedure.

To be authorized to use an electronic glucometer, the EMS agency must make written request to the local Regional Emergency Medical Advisory Committee (REMAC). The request must include, but not be limited to the following items and possess the necessary Clinical Laboratory authorizations required by Public Health Law.

- Include a letter from the service medical director supporting the request and indicating an understanding of their role in the Clinical Laboratory requirements and quality assurance process.

- Complete the NYS Department of Health Clinical Laboratory Limited Laboratory Registration application (DOH-4081) for blood testing licensure.
- Develop written policies and procedures for the operation of the glucometer that are consistent with local protocol. This shall include at least the following:
  - written policies and procedures for the training and documentation of authorized users;
  - a defined quality assurance program, including appropriateness review by the medical director;
  - documentation of control testing process; and
  - written policies and procedures for storage of electronic glucometer, and proper disposal of sharps devices.

LIMITED LABORATORY REGISTRATION

The law requires that any EMS service testing blood glucose, whether by electronic glucometer or chemstrip, be required to possess a **Limited Laboratory Registration**. In order to obtain the Registration, EMS agencies must complete and submit the following documents:

- **Limited Service Laboratory Registration (DOH-4081)**
- **Disclosure of Ownership and Controlling Interest Statement (DOH-3486)**

The information and appropriate application paperwork is available at:

http://www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm

No EMS service may engage in the testing of blood glucose without a registration permit.

NOTIFICATION

Once the EMS service has received written approval from the REMAC, the EMS Service must provide the Bureau of EMS with a new **Medical Director Verification Form (DOH-4362)**, indicating the Limited Laboratory Registration permit number and authorization by the service medical director.

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
CLINICAL LABORATORY EVALUATION PROGRAM
P.O. BOX 509
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E-mail: clepltd@wadsworth.org
Web: www.wadsworth.org/labcert/limited/

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.

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@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 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 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 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 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 a Ph.D. holding a New York State Department of Health Certificate of Qualification.*** Indicate if the individual holds a Certificate of Qualification. If the director 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 Application package.*** Indicate whether the individual is employed at the laboratory 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, 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.

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

For Lead Testing: www.wadsworth.org/labcert/limited/index.htm
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).

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
Wadsworth Center
New York State Department of Health
Empire State Plaza
P1 South – Loading Dock J
Albany, NY 12237

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:

http://www.wadsworth.org/labcert/limited/

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Web: www.wadsworth.org/labcert/limited/

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

Indicate the combined estimated annual test volume for all 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 all 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

Hudson Valley Regional
Emergency Medical Services Council

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BLS Glucometer Training Curriculum

BLS Glucometer training must, at a minimum, include the following components to be approved by the Hudson Valley Regional EMS office:

1. Lesson 4-4 of the NYS EMT-B Curriculum entitled Diabetic Emergencies/Altered Mental Status (Two hours)

2. Agency specific OSHA BBP and Sharps Safety (Didactic and Clinical Session must be included)*

3. Manufacturer specific glucometer utilization training/in-service

Medical / Behavioral and Obstetrics / Gynecology

Lesson 4-4
Diabetic Emergencies / Altered Mental Status

OBJECTIVES

Objectives Legend
C= Cognitive P = Psychomotor A = Affective
1 = Knowledge level
2 = Application level
3 = Problem-solving leve

COGNITIVE OBJECTIVES

At the completion of this lesson, the EMT-Basic student will be able to:

4-4.1 List causes of Altered Mental Status.
4-4.2 Describe the general steps for emergency care of a patient with altered mental status.
4-4.3 Identify the patient taking diabetic medications with altered mental status and the implications of a diabetes history.
4-4.4 State the steps in the emergency medical care of the patient taking diabetic medicine with an altered mental status and a history of diabetes.(C-1)
4-4.5 Establish the relationship between airway management and the patient with altered mental status.(C-3)
4-4.6 State the generic and trade names, medication forms, dose, administration, action, and contraindications for oral glucose.(C-1)
4-4.7 Explain the relationship between insulin and glucose.
4-4.8 Evaluate the need for medical direction in the emergency medical care of the diabetic patient.(C-3)
4-4.9 Define seizures
4-4.10 Identify possible causes of a seizure.
4-4.11 State the emergency care of a seizure.

AFFECTIVE OBJECTIVES

4-4.12 Explain the rationale for administering oral glucose.(A-3)

PSYCHOMOTOR OBJECTIVES

4-4.13 Demonstrate the steps in the emergency medical care for the patient taking diabetic medicine with an altered mental status and a history of diabetes.(P-1,2)
4-4.14 Demonstrate the steps in the administration of oral glucose.(P-1,2)
4-4.15 Demonstrate the assessment and documentation of patient response to oral glucose.(P-1,2)
4-4.16 Demonstrate how to complete a prehospital care report for patients with diabetic emergencies.(P-2)

PREPARATION

Motivation:	Diabetes is a prevalent disease in American society with estimates between 2-5% of the total population having either diagnosed or undiagnosed diabetes mellitus.
Prerequisites:	BLS, Preparatory, Airway and Patient Assessment.

MATERIALS

AV Equipment:	Utilize various audio-visual materials relating to diabetic emergencies. The continuous design and development of new audio-visual materials relating to EMS requires careful review to determine which best meet the needs of the program. Materials should be edited to assure meeting the objectives of the curriculum.
EMS Equipment:	Exam gloves, stethoscope (6:1), blood pressure cuff (6:1), penlight, tube of glucose, suitable glucose substitute.

PERSONNEL

Primary Instructor:	One EMT-Basic instructor knowledgeable in treatment of diabetic emergencies.
Assistant Instructor:	The instructor-to-student ratio should be 1:6 for psychomotor skill practice. Individuals used as assistant instructors should be knowledgeable in diabetic emergencies.
Recommended Minimum Time to Complete:	Two hours

PRESENTATION

Declarative (What)

I. Signs and symptoms associated with a patient with altered mental status with a history of diabetes controlled by medication.
   - A. Rapid onset of altered mental status.
     1. After missing a meal on a day the patient took prescribed insulin.
     2. After vomiting a meal on a day the patient took prescribed insulin.
     3. After an unusual exercise or physical work episode.
     4. May occur with no identifiable predisposing factor.
   - B. Intoxicated appearance, staggering, slurred speech to complete unresponsiveness
   - C. Elevated heart rate
   - D. Cold, clammy skin
   - E. Hunger
   - F. Seizures
   - G. Insulin in refrigerator or other medications found at scene.
     1. Diabinese™
     2. Orinase™
     3. Micronase™
   - H. Uncharacteristic behavior
   - I. Anxious
   - J. Combative

II. Emergency medical care of altered mental status with a history of diabetes.
   - A. Perform initial assessment.
   - B. Perform focused history and physical exam.
     1. Onset
     2. Duration
     3. Associated symptoms
     4. Evidence of trauma
     5. Seizures
     6. Fever
   - C. Performs baseline vital signs and SAMPLE history.
   - D. Determine history of diabetes (medical identification tags) Assure known history of diabetes (medical identification tags), etc.
   - E. Determine if patient can swallow.
   - F. Administer oral glucose in accordance with local or state medical direction or protocol.

III. Altered Mental Status
   - A. Caused by a variety of conditions
     1. Hypoglycemia
     2. Poisoning
     3. Post seizure
     4. Infection
     5. Head trauma

6. Decreased oxygen levels

B. Emergency medical care
   1. Assure patency of airway.
   2. Be prepared to artificially ventilate/suction.
   3. Transport.
   4. Consider trauma, trauma can cause altered mental status.

IV. Seizures - Seizures are a sudden change in sensation, behavior or movement, usually related to brain malfunction that can be the result of disease, infection or injury to brain tissue. The more severe form of seizures are characterized by violent muscle contractions called convulsions. Epilepsy is a medical disorder characterized by episodic or sudden onset attacks of unconsciousness, with or without convulsions. Status epilepticus occurs when the patient has two or more convulsive seizures without regaining full consciousness.
   A. Chronic Seizures Disorders in children are rarely life-threatening. Seizures of unknown origin, however, including febrile, should be considered life-threatening by the EMT.
   B. May be brief or prolonged.
   C. Caused by fever, infections, poisoning, hypoglycemia, trauma, decreased levels of oxygen or could be idiopathic in children.
   D. Emergency medical care
      1. Assure patency of airway.
      2. Position patient on side if no possibility of cervical spine trauma. Protect patient from injury.
      3. Have suction ready.
      4. If cyanotic, assure airway and artificially ventilate.
      5. Transport.
         a. Although brief seizures are not harmful, there may be a more dangerous underlying condition.
         b. Rule out trauma, head injury can cause seizures.

V. Relationship to Airway Management
Assure that the patient's airway is open and that breathing and circulation are adequate and suction as necessary.

VI. Medication
   A. Oral Glucose
      1. Medication Name
         a. Generic - Glucose, Oral
         b. Trade - Glutose, Insta-glucose
      2. Indications - patients with altered mental status with a known history of diabetes controlled by medication.
      3. Contraindications
         a. Unresponsive.
         b. Unable to swallow.
      4. Medication form - Gel, in toothpaste type tubes
      5. Dosage - one tube

6. Administration
    a. Obtain order from medical direction either on-line or off-line.
    b. Assure signs and symptoms of altered mental status with a known history of diabetes.
    c. Assure patient is conscious and can swallow and protect their airway.
    d. Administer glucose.
    e. Perform ongoing assessment.
7. Actions - increases blood sugar
8. Side effects - none when given properly. May be aspirated by the patient without a gag reflex.
9. Administer Oxygen

SUGGESTED APPLICATION

Procedural (How)

1. Demonstrate the steps in emergency care for the patient with altered mental status and a history of diabetes who is on diabetic medication.
2. Demonstrate the steps in the administration of oral glucose.
3. Demonstrate the assessment and documentation of patient response.

Contextual (When, Where, Why)

Diabetes is a common disease affecting a large population. As the population ages, the number of people affected by diabetes will increase. Oral glucose given to a patient with an altered mental status and a known history of diabetes can make a difference between development of coma (unconsciousness) and ability to maintain consciousness.

STUDENT ACTIVITIES

Auditory (Hear)

None identified for this lesson.

Visual (See)

1. The student should see audio-visual aids or materials of patients with altered mental status with a known history of diabetes mellitus in the prehospital setting.
2. The student should see the administration of oral glucose (as a simulated paste) to a simulated patient.

Kinesthetic (Do)

1. The student will practice the steps in emergency care for the patient with an altered mental status and a history of diabetes and taking diabetic medication.
2. The student will practice the steps in the administration of oral glucose.
3. The student will practice documentation of assessment, treatment, and patient response to oral glucose.
4. The student will practice completing a prehospital care report for patients with diabetic emergencies.

INSTRUCTOR ACTIVITIES

Supervise student practice.
Reinforce student progress in cognitive, affective, and psychomotor domains.
Redirect students having difficulty with content (complete remediation forms).

EVALUATION

Written: Develop evaluation instruments, e.g., examinations, verbal reviews, handouts, to determine if the students have met the cognitive and affective objectives of this lesson.

Practical: Evaluate the actions of the EMT-Basic students during role play, practice or other skill stations to determine their compliance with the cognitive and affective objectives and their mastery of the psychomotor objectives of this lesson.

REMEDIATION

Identify students or groups of students who are having difficulty with this subject content. Complete remediation sheet from the instructor's course guide.

SUGGESTED ENRICHMENT

What is unique in the local area concerning this topic? Complete enrichment sheets from the instructor's course guide and attach with lesson plan.

HUDSON VALLEY REGIONAL EMS COUNCIL

Training & Education Programs

BLS Glucometer Utilization Practical Skills Evaluation

STATION BG

BLS Glucometer Utilization

Pass _____

Fail _____

Candidate _____

Examiner _____

Date _____ Start time _____ Stop time _____

	Possible	Awarded	Comments
Takes or verbalizes body substance isolation precautions prior to performing procedure	**C**		
Verbalizes indications for use of glucometry	**C**		
Requests Advanced Life Support (ALS)	**C**		
Ascertains patient's past medical history including allergies	**1**		
Selects appropriate site to obtain blood sample and prepares equipment	**1**		
Explains procedure to patient	**1**		
Cleanses site with antiseptic solution	**1**		
Utilizes lancet to pierce skin	**1**		
Discards lancet in sharps container	**C**		
Obtains blood sample	**C**		
Discards test strip in red-bag waste	**1**		
The examiner advises that the patient's blood glucose is less than 80 mg/dL.			
Confirms patient is conscious and able to swallow	**C**		
(Verbalized) Administers oral glucose	**1**		
Reassesses blood glucose after five minutes	**1**		
Ongoing assessment and transport	**1**		

Note: Candidate must complete all critical criteria (shaded areas) and receive at least 12 points to pass this station.

Total to pass 12 Total 15

COMMENTS:

HUDSON VALLEY REGIONAL EMS COUNCIL
Training & Education Programs

STATION
BG

BLS Glucometer Utilization

INSTRUCTIONS TO THE CANDIDATE

This station is designed to test your ability to perform BLS glucometry on a patient who has been identified as an appropriate candidate for this procedure. You are on scene with an EMT assistant. The assistant has completed the scene size-up and determined the scene safe. You are responsible for the direction and subsequent action of the EMT assistant. You may use any equipment available in this room. You have 5 minutes to complete this skill station. Do you have any questions?

NOTES

AMS: Altered Mental Status

Applies to adult and pediatric patients

CRITERIA

- Including, but not limited to, hypoglycemia
- For opioid (narcotic) overdose, see "Opioid (Narcotic) Overdose" protocol
- For behavioral emergencies, see also "Behavioral Emergencies" protocol

CFR AND ALL PROVIDER LEVELS

EMT

- Airway management and appropriate oxygen therapy
- Check pupils and, if constricted, consider "Opioid (Narcotic) Overdose" protocol
- Check blood glucose level, if equipped and safe to do so
    - If blood glucose is known or suspected to be below 60 mg/dL and patient can self-administer and swallow on command:
        - Give one unit dose (15-24 grams) of oral glucose, or another available carbohydrate source (such as fruit juice or non-diet soda)
    - If the patient is unable to swallow on command, or mental status remains altered following administration of oral glucose:
        - Do not delay transport
- Ongoing assessment of the effectiveness of breathing
    - Refer to "Extremis: Respiratory Arrest / Failure" or "Extremis: Pediatric Respiratory Arrest / Failure," protocol, if necessary

CFR AND EMT STOP

KEY POINTS/CONSIDERATIONS

- Assess the scene for safety and, if it is not, retreat to a safe location and obtain police assistance
- Consider closed head injury and non-accidental trauma, especially in children
- Consider drug ingestion, meningitis/encephalitis
- See also "Behavioral Emergencies" protocol, if indicated