NYC REMAC

Advisory No.	2017-10		
Title:	BLS Glucometry and Pulse-Oximetry **UPDATED: 09/15/2017**		
Issue Date:	August 9, 2017		
Effective Date:	September 1st, 2017		
Supersedes:	n/a	Page:	1 of 14

The Regional Emergency Medical Advisory Committee (REMAC) of New York City is responsible to develop, approve and implement prehospital treatment and transport protocols for use within the five boroughs of the City of New York. The Regional Emergency Medical Advisory Committee (REMAC) of New York City operates under the auspices of Article Thirty of the New York State Public Health Law.

The recently revised NYC REMAC Protocols (2017-05 REMAC Advisory 2017-05: Protocol Revisions), identify that finger sticks to obtain blood glucose level via Glucometer have been added as an option for EMTs. Although this is an option, the use of glucometers is strongly recommended. In order to support the direction of the NYC REMAC, the REMSCO has obtained Glucometers and Pulse Oximeters for distribution to non-municipal EMS Agencies operating in NYC.

The equipment to be distributed includes:

- Professional Monitoring Blood Glucose Meter (with 3-volt battery, carrying case, user's manual)
- Professional Monitoring Blood Glucose Test Strips (1-year supply)
- Push-Button Safety Lancets (23G Needle, 100/box)
- Control Solution (for calibrating Glucometer)
- Fingertip Pulse Oximeter (2 AAA batteries, Lanyard, instruction manual)

Attached to this advisory are the following educational materials:

- Training PPT
- NYS Department of Health BLS Altered Mental Status protocol (M-2)
- NYC REMAC BLS Altered Mental Status protocol (411)
- NYS Department of Health Clinical Laboratory Evaluation Program Limited Service Laboratory Registration Application (form DOH-4081) for blood testing licensure (blood glucometry only)
- NYS Department of Health Policy 05-04: Blood Glucometry for BLS EMS Agencies
- NYS Department of Health Policy 12-01: Blood Glucometry and Nebulized Albuterol for BLS Agencies

Josef Schenker, MD, FACEP
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Executive Director Operations, Regional Emergency Medical Services Council of New York City

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?

No

Yes

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

BG: **<** 60 mg/dl

BG: **>** 60 mg/dl

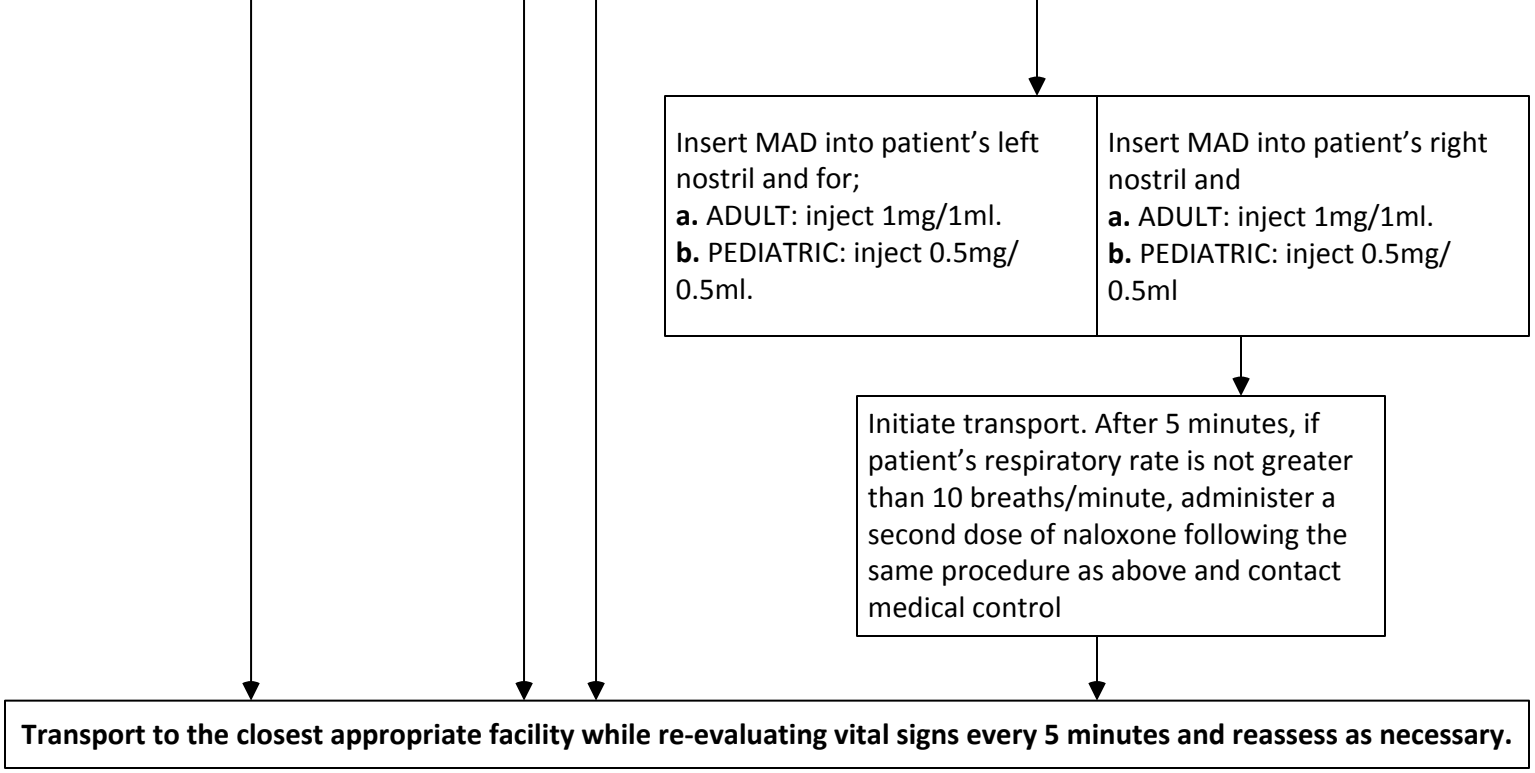
A) If the patient has a known history of diabetes controlled by medication, is conscious and is able drink without assistance, provide an oral glucose solution, fruit juice or non-diet soda by mouth.

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.**

411

ALTERED MENTAL STATUS

NOTE: Emotionally disturbed patients must be presumed to have an underlying medical or traumatic condition causing an altered mental status.

Assess such patients for an underlying medical or traumatic condition causing an altered mental status and treat as necessary.

1. Assess the situation for potential or actual danger and establish a safe zone, if necessary.

NOTE: 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 and/or others.

2. If an underlying medical or traumatic condition causing an altered mental status is not apparent; the patient is fully conscious, alert, and able to communicate; and an emotional disturbance is suspected, see Protocol #430.

3. Monitor the airway.

4. Administer oxygen.

NOTE: IF OVERDOSE IS SUSPECTED, USE HIGH FLOW OXYGEN.

5. Request Advanced Life Support assistance, if appropriate.

6. If an overdose is strongly suspected, and the patient's respiratory rate is less than 10/minute, administer intra-nasal (IN) Naloxone, ~~if available~~, via:

a. Mucosal Atomizer Device (MAD)~~, as follows~~:

i. **ADULT** patient: 1mg/ml in each nostril. Total of 2 mg/2ml

ii. **PEDIATRIC** patient: 0.5 mg/0.5 ml in each nostril. Total of 1 mg/1 ml.

OR

b. **Narcan® Nasal Spray**

i. **Adult AND Pediatric patients:** 4 mg/0.1ml in ONE nostril. If, after 2- 3 minutes if there is no or minimal response, repeat administration of 4mg/0.1ml with a second device into OTHER nostril.

Relative Contraindications:

- Cardiopulmonary Arrest,
- Active seizure,
- Evidence of nasal trauma, nasal obstruction and/or epistaxis.

7. Initiate transport.

8. If after 5 minutes, the patient's respiratory rate is not greater than 10 breaths/minute, administer a repeat dose of naloxone, following the same procedure described in #6.

NOTE: A GLUCOMETER (IF AVAILABLE) SHOULD BE USED TO DOCUMENT BLOOD GLUCOSE LEVEL PRIOR TO ADMINISTRATION OF GLUCOSE, FRUIT JUICE OR SODA.

IF THE GLUCOMETER READING IS ABOVE 60 MG/DL, WITHHOLD TREATMENT FOR HYPOGLYCEMIA.

DIABETIC PATIENTS WITH A BLOOD GLUCOSE LEVEL READING BETWEEN 60-80 MAY STILL BE EXPERIENCING HYPOGLYCEMIA, AND IF THEY DISPLAY SUCH SIGNS AND SYMPTOMS SHOULD BE TREATED ACCORDINGLY.

9. If the patient is conscious, can swallow, and can drink without assistance, provide a glucose solution, fruit juice, or non-diet soda by mouth.

   a. Do **not** give oral solutions to unconscious patients.

   b. Do **not** give oral solutions to patients with head injuries.

10. Transport.

11. Assess and monitor the Glasgow Coma score. (See Appendix E.)

    a. Do **not** delay transport.

Mandatory Quality Assurance Component

For every administration of intra-nasal (IN) Naloxone), the ACR/PCR documentation must be reviewed by the service medical director who is responsible for forwarding ACR/PCR data electronically to the NY REMAC via an online survey tool for system-wide QA purposes. Patient specific identifiers are omitted. This QA component is effective immediately. For the purposes of patient confidentiality, email mdiglio@nycremsco.org for directions on how to submit data electronically.

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.

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.

New York State
Department of Health
Bureau of Emergency Medical Services

POLICY STATEMENT

Supersedes/Updates: 09-13

No. 12-01

Date: January 10, 2012

Re: Blood Glucometry and Nebulized Albuterol for EMS Agencies

BACKGROUND

The New York State Emergency Medical Advisory Committee (SEMAC) has approved the use of glucometers and nebulized albuterol by Emergency Medical Technicians (EMT) who are employees/volunteers of an EMS agency (i.e. ambulance service, ALS-FR, BLS-FR). The SEMAC approval was granted with the specific condition that the EMS agency wishing to use a glucometer or nebulized albuterol, be granted approval by the Regional Emergency Medical Advisory Committee (REMAC), that each EMT from that EMS agency complete a REMAC approved training program, and that the EMS agency be granted a Limited Service Laboratory Registration (for blood glucometry only).

The purpose of this policy is to explain the approval process for EMS agencies wishing to implement a nebulized albuterol and/or blood glucometry program.

- Prehospital blood sugar evaluation is intended to assist in the recognition of hypoglycemia and improve the speed with which proper treatment is received.
- Nebulized albuterol, when administered under the Statewide BLS Adult and Pediatric Treatment Protocols has been shown to decrease respiratory distress in patients between one and sixty-five years of age who are experiencing an exacerbation of their previously diagnosed asthma.

AUTHORIZATION FOR BLOOD GLUCOMETRY AND/OR NEBULIZED ALBUTEROL

Each REMAC will adopt protocols which will allow an 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 determine the type and level of record keeping and quality assurance required for both blood glucometry and/or nebulized albuterol. Please note that a protocol for nebulized albuterol has been approved by SEMAC and is included in the Statewide BLS Adult and Pediatric Treatment Protocols for EMT-B and AEMT.

To be authorized to use an electronic glucometer or nebulized albuterol, the EMS agency must make written request to the appropriate REMAC. The request must include, but not necessarily be limited to, the following items:

- A letter from the EMS agency physician medical director supporting the request and indicating an understanding of their role in the Clinical Laboratory requirements (blood glucometry only) and quality assurance process.

- A completed NYS Department of Health Clinical Laboratory Evaluation Program Limited Service Laboratory Registration Application (form DOH-4081) for blood testing licensure (blood glucometry only).
- Written policies and procedures for the operation of the glucometer and storage and maintenance of nebulized albuterol that are consistent with applicable Regional and State protocols. These policies and procedures shall include, but not necessarily be limited to the following:
  - didactic and psychomotor objectives for training of authorized users including who will be authorized to conduct this training;
  - documentation and attendance records of the training of authorized users;
  - a defined quality assurance program, including appropriateness review by the EMS agency physician medical director;
  - documentation of control testing process (blood glucometry only);
  - written policies and procedures for storage of the glucometer and/or nebulized albuterol, and proper disposal of sharps devices (blood glucometry only);
  - notice to the EMS agency physician medical director of the use of the glucometer and/or nebulized albuterol, and;
  - requirements for documentation when the glucometer and/or nebulized albuterol is used for patient care.

LIMITED LABORATORY REGISTRATION FOR BLOOD GLUCOMETRY

New York State Public Health Law requires that any EMS agency testing blood glucose, whether by electronic glucometer or chemstrip, be required to possess a **Limited Service Laboratory Registration**. In order to obtain the Registration, EMS agencies must complete and submit the following document:

- **Limited Service Laboratory Registration Application (form DOH-4081)**

Information and application materials are available at:

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

No EMS agency may engage in the testing of blood glucose without a Limited Service Laboratory Registration Certificate.

NOTIFICATION

Once the EMS agency has received written approval for blood glucometry and/or nebulized albuterol from the REMAC, the EMS agency must provide BEMS with an updated and signed **Medical Director Verification Form (form DOH-4362)**, indicating the Limited Laboratory Registration permit number (if applicable) and authorization by the EMS agency physician medical director.

Issued and authorized by the Bureau of EMS Acting Director

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.