



STATE OF NEW YORK DEPARTMENT OF HEALTH

Wadsworth Center

The Governor Nelson A. Rockefeller Empire State Plaza

P.O. Box 509

Albany, New York 12201-0509

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

February 2010

Re: Options for Point-of-Care Testing in Hospitals

Dear Laboratory Director:

As laboratory director, you are responsible under Hospital Code (10 NYCRR Section 405.16) for oversight of all laboratory testing within the facility, including point of care testing using federally waived test devices and practitioner-performed microscopy procedures (PPMP). Education Law requires that persons performing laboratory testing - including waived testing and PPMP – must be licensed professionals, including but not limited to clinical laboratory technology professionals, physicians, nurse practitioners, physicians' assistants, registered nurses (RNs), licensed practical nurses (LPNs), and respiratory therapists.

All testing services must comply with Article 5, Title V of the New York State Public Health Law. This advisory is to make you aware of a recent amendment to Public Health Law that established a streamlined registration process for point of care waived testing and PPMP, which allows laboratory and hospital management to designate distinct units within the hospital as a Limited Service Laboratory (LSL). Waived and PPMP testing performed on these units would not be held to the standards for a full clinical laboratory permit. Education Law exempts persons performing testing in LSLs from licensure as clinical laboratory practitioners. Please refer to the enclosed section of Public Health Law that describes LSLs.

The Department acknowledges hospitals' need to harmonize the statutory provisions, and has considered all the factors brought to our attention, as well as our primary goal of ensuring medically reliable testing. Accordingly, the Department will make available to hospitals **the option** to register as a single LSL all units within the hospital that conduct only waived and PPMP point-of-care testing. The self-identified settings (i.e. ancillary practice, delivery room,

cardiac catheterization, and nursing floors) must be distinct from and physically located outside the laboratory (ies) that operate under a full permit.

Hospitals are not obligated to register their point-of-care testing programs as LSLs. Each facility must consider the administrative burden of organizing separate but overlapping regulated testing systems. The Department encourages you to consult your hospital's Director of Nursing and Medical Director, as appropriate, when considering whether the LSL option is appropriate for your hospital. If you choose the LSL option, unlicensed personnel such as phlebotomists, patient care assistants and nurses' aides performing point-of-care testing must continue to be properly trained and provided an appropriate level of oversight. If you choose not to obtain an LSL registration for your point-of-care sites, licensed professionals (clinical laboratory technology professionals, physicians, nurse practitioners, physicians' assistants, RNs and LPNs, and respiratory therapists) may continue to conduct point-of-care testing (waived, non-waived and PPMP as appropriate) however, phlebotomists, patient care assistants, nurses aides and other unlicensed professionals who may currently be performing testing must cease doing so.

Point-of-care testing programs will continue to be surveyed as part of the routine on-site inspection of laboratory services whether or not the units are registered as an LSL. The requirement for licensed individuals to perform any waived testing conducted within the permit-holding laboratory would not be affected. The permit-holding laboratory must address point-of-care testing in its overall Quality Management System plan and will be held to standard **Validation S3: Multi-Systems Agreement**, for correlation of point-of-care test results with results for the same analyte generated by instrumentation used in the permit-holding laboratory. The Department plans to assist you in complying with the standards of practice for laboratory medicine by posting a guidance document on its website.

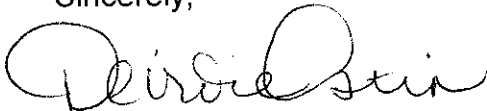
A pre-printed LSL registration form is enclosed for your convenience. All sites, programs, and specialty clinics within the hospital that will be performing point-of-care waived testing must be indicated on this form. The CLIA number of the main hospital laboratory will be used for the LSL registration.

An initial application fee of \$200 must be submitted with the form; registrations are renewable on a biennial basis. The director of the permit-holding laboratory must be identified as, and legally function as the director of the LSL; although he or she may delegate the day-to-day management of one or more point-of-care programs to another qualified person, the director is legally responsible for testing by the LSL units. If the director of the permit-holding laboratory is a Ph.D. and PPMP testing will be performed at the point-of-care, an assistant director who is a licensed M.D. must be identified to provide oversight for PPMP testing.

If you wish to register your facility's on-site point-of-care testing programs/units, please note that registrations will be accepted as of February 15, 2010. Effective July 1, 2010, unlicensed persons discovered to be performing testing other than pursuant to a LSL registration will be referred to the Education Department for investigation.

If you have any questions or we can assist you with this transition, you may contact a member of our staff to assist you. Questions can be directed to CLEP at (518) 485-5378 or by e-mail to CLEP@health.state.ny.us.

Sincerely,

A handwritten signature in cursive script that reads "Deirdre Astin".

Deirdre Astin, M.S., M.T. (ASCP)
Director, Clinical Laboratory Evaluation Program