



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

October 27, 2016

Dear Adult Care Facility Administrator:

This letter is to advise you about the regulatory requirements to perform laboratory testing on-site at your adult care facility. Adult care facilities that perform laboratory tests on materials obtained from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment must meet federal and state requirements to do so. Simple laboratory tests including, but not limited to **fingerstick glucose, urine dipstick, occult blood, and influenza testing** are subject to oversight by the New York State Department (Department) of Health's Clinical Laboratory Evaluation Program (CLEP). Adult care facilities performing these types of tests are considered Limited Service Laboratories and must register with the Department as described in the attached registration package in order to obtain authorization to perform patient testing. Please be reminded that testing on-site does not mean that the sample is collected and forwarded off-site to a reference laboratory that performs the testing.

Laboratory tests provide essential public health services in aiding the health care provider by furnishing information invaluable to the diagnosis and treatment of disease. The improper performance of a laboratory test may cause an erroneous diagnosis or contribute to an inappropriate treatment, resulting in prolonged or unnecessary hospitalization, injury or even death.

It is our understanding that it is standard of care to perform fingerstick glucose testing in addition to some other waived tests such as occult blood in adult care facilities. Please review the Limited Service Laboratory registration instructions and application available on our website at (<http://www.wadsworth.org/regulatory/clep/limited-service-labs-certs>). If any testing is performed at your adult care facility, please complete and submit the Limited Service Laboratory registration application.

Please be advised that Article 5, Title V of New York State Public Health Law provides the follows: "any person, partnership, corporation or other entity performing waived tests or provider-performed microscopy procedures without being authorized to do so shall be subject to a civil penalty of up to five hundred dollars for each test performed, not to exceed two thousand dollars per day for each day tests are performed.

If you have any questions, please contact me at (518) 402-2971 or Mr. James Holland at (518) 402-4141 or by e-mail at CLEPltd@health.ny.gov.

Sincerely,

A handwritten signature in dark ink, reading "Stephanie H. Shulman". The signature is fluid and cursive.

Stephanie H. Shulman, M.P.H., M.S., M.T. (ASCP)
Director, Clinical Laboratory Evaluation Program

Cc: V. Deetz
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