

Email sent to all permitted CLEP laboratories on 07/28/11

Subject: Management of non-permitted laboratory requests

Dear Laboratory Director and Management Staff,

New York State Public Health Law (Article 5, Title V, Section 574) and regulations (Part 58-1.10 (g) of 10NYCRR) require that all specimens obtained within New York State be tested by a laboratory that holds a New York State clinical laboratory permit, including test-specific approval when required. Due to the rarity of many diseases, testing for all potential conditions may not be available from permit-holding laboratories or there may be adequate justification for use of a specific laboratory that does not hold a permit. In these cases, the department's approval must be received prior to submitting a specimen collected in New York State for testing by a non-permitted laboratory or a permitted laboratory that does not hold approval for that particular test. The Clinical Laboratory Evaluation Program (CLEP) administers this process and monitors the volume and frequency of requests. The attached policy and algorithm is proposed to manage the non-permitted laboratory (NPL) test request process.

The proposed policy and algorithm is open for review and comment. Please respond with comments by September 12, 2011. Comments can be submitted in writing by mail to the Wadsworth Center, N.Y. State Department of Health, Empire State Plaza, P.O. Box 509 Albany, N.Y. 12201-0509, or by e-mail to [CLEP@health.state.ny.us](mailto:CLEP@health.state.ny.us). Please use the keywords Management of non-permitted laboratory requests in the subject line.

Thank you for your assistance.

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