



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.
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CLINICAL LABORATORY EVALUATION PROGRAM Policy Update

October 22, 2010

Dear Laboratory Director:

Please note the following policy update -

POLICY FOR THE APPROVAL OF COMMERCIALY AVAILABLE AND LABORATORY-DEVELOPED TESTS (LDT) IN THE PERMIT CATEGORIES OF CLINICAL TOXICOLOGY, FORENSIC TOXICOLOGY AND/OR THERAPEUTIC SUBSTANCE MONITORING/QUANTITATIVE TOXICOLOGY (TSM/Q)

Please note that laboratories holding a permit in the categories of Clinical and Forensic Toxicology (Initial and Comprehensive) and/or Therapeutic Substance Monitoring/Quantitative Toxicology are no longer required to submit validation materials when adding commercially available tests and LDTs performed in whole blood, plasma, serum, oral fluid, urine or sweat. Laboratories must seek prior approval for the use of LDTs when analyzing matrices other than whole blood, plasma, serum, oral fluid, urine or sweat. Laboratories must continue to notify the Clinical Laboratory Evaluation Program (CLEP) when new tests are added to the laboratory's menu. The department reserves the right to request validation documentation at our discretion.

Laboratories holding permits in these categories have successfully demonstrated an effective quality management system, personnel competency in the design and validation of laboratory developed tests and successful performance in proficiency testing, when available.

WHAT THIS MEANS FOR PERMITTED LABORATORIES -

- Validation packages that have been submitted to CLEP by permitted laboratories have been reviewed and are herewith approved.
- Notification of additions to the laboratory test menu can be made using the [Notification to Add/Delete Analyte Form](#). Please indicate the methodology, specimen matrices, and attach sample reports for all outcomes. Forms are available on our website at www.wadsworth.org/clep
- Should you have questions, please contact the CLEP Validation Unit at CLEPVAL@health.state.ny.us