



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

Clinical Laboratory Evaluation Program – IMPORTANT TEST APPROVAL UPDATE

In an effort to streamline the Clinical Laboratory Evaluation Program's (CLEP) laboratory test validation review and approval process (for tests not cleared or approved by FDA), CLEP has changed its "material" requirements for submission of SOPM and method validation for review and approval.

This notification is to instruct laboratories that effective immediately, CLEP will require that laboratories provide **one hard copy and one electronic copy** (e.g., pdf version via email, on CD, or USB flash drive) of the materials (SOPM, validation, reports, references) required for review and approval as described in the applicable Submission Guidelines* on the CLEP Test Approval website: <http://www.wadsworth.org/labcert/TestApproval/index.htm>

CLEP had previously accepted hardcopy OR electronic copy. By providing CLEP with **hardcopy and electronic copy**, this will facilitate routing of the materials for review by eliminating the need for scanning/photocopying paper hardcopy.

PLEASE NOTE: Hardcopies should NOT contain STAPLES.

REMINDER: Submissions must be organized as labeled attachments (see Guidelines). Organized packages are critical to facilitating review by scientific staff that is not familiar with the details of your laboratory's routine processes. Including a Table Of Contents is also helpful. Also be reminded that inclusion of all laboratory raw validation data/printouts is NOT REQUIRED. Representative examples of test run documentation are requested, and validation data should be summarized in a tabular fashion.

*Submission Guidelines for Test Approval are being updated and the revisions will be available on the website soon.

We appreciate your assistance with our shared goal ensuring the quality of clinical laboratory testing. Should you have questions, please contact the CLEP Validation Unit at CLEPVAL@health.state.ny.us