



## CLIA Authorization Policy For Research

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA)<sup>1</sup>.

Pathology's CLIA license covers Point Of Care Testing (POCT) performed in the DHMC clinics as Pathology provides the oversight, ensures competencies of users and approves/validates the POCT devices that are being used for patient testing. If a POCT device being used in a DHMC research study has already been validated and approved by the clinical laboratory, the laboratory can provide and document training and competency assessment of staff performing lab testing for research. The laboratory can then grant approval to any such research sponsor if so required.

If a research study requires POCT on test kits/devices not sanctioned by Pathology then no such CLIA authorization will be granted. For questions concerning CLIA or CLIA licensure please contact the POCT office @ 650-7198

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