Advancing Patient Care through POCT and CLIA

Rapid evolution of point-of-care testing (POCT) continues, including its acceptance and use within health care settings. POCT is a form of testing in which the diagnostic analysis is performed where health care is provided, close to or near the patient, at the time and place of patient care. POCT incorporates medical devices that are regulated by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH).[i]

Doctors of optometry incorporate many tests during comprehensive eye examinations that are considered POCT. This includes visual field testing, optical coherence tomography (OCT), OCT-Angiography (A)[ii], electroretinography and visual evoked potential[iii] which are all common in optometry clinics. These and other medical devices and test results aid diagnosis of many disease states that affect the eye and vision system, providing diagnostic accuracy and analysis in the optometry clinic, close to or near the patient, at the time and place of patient care.

The doctor of optometry assumes the responsibility for developing procedures and interpreting results for POCT, while paraoptometric staff most frequently perform POCT. This scenario is common among other medical clinics but also raises additional responsibilities for the doctor. Further responsibilities include, but are not limited to, 1) quality control and assurance; 2) proficiency testing; 3) instrument maintenance; and 4) competency assessment.

Additionally, when the optometry clinic performs "laboratory" testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease, the doctor of optometry and the clinic are then regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[iv] If an entity performs tests (even just one) for these purposes, then it is considered under CLIA to be a laboratory and the doctor has an additional responsibility to register with the CLIA program.

The doctor must enroll the clinic (*with the appropriate tax ID number*) as a laboratory or testing site in the CLIA program and assign themselves the role of laboratory director. The CLIA application collects information about a laboratory's operation, which is necessary to determine the type of certificate to be issued and the fees to be assessed. There may be several types of POCT laboratory tests that the clinic intends to provide its patients, and each should be listed on the application. The most common POCT laboratory tests conducted in optometry settings are capillary blood glucose (CBG) testing (CPT code 82962) and osmolarity testing (CPT code 83861).[v] [vi] [vii] The information in Table 1.0[viii] would typically be collected in the CLIA application:

Table 1.0

Facility Name:
Name of Director:
Credentials: [Doctor of Optometry (OD)]
I General Information: [Initial Application]
II. Type of Certificate Requested: [Certificate of Waiver]
III. Type of Laboratory: [21 Physician Office]
IV Hours: [Add your hours]
V. Multiple Sites: [Yes or No]
VI. Waived testing to be performed: [For example, ACCU CHEK Inform II (Roche) CLIA Waived, TearLab Corporation TearLab Osmolarity System CLIA Waived or other (Specify)]

CLIA regulatory requirements classify testing into three categories: high complexity, moderate complexity and waived. Doctors of optometry as laboratory directors performing "waived testing" have already met education, training and experience requirements under CLIA. There are more than 1,400 test systems that have been waived as they employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible. The doctor of optometry serving as a laboratory director may want to verify that the waived CLIA test they intend to perform is consistent with their state optometry laws, license and insurance coverage. Additionally, they should check with their CLIA state agency for any other state-specific requirements. A listing of all state agency contacts for CLIA can be found here.

Extolled as a revolution in health care, POCT and CLIA are changing the face of clinical operations, providing an opportunity to improve patient care services by offering test results on a real-time basis.[ix] CLIA now covers approximately 260,000 laboratory entities, including many optometry clinics.[x] POCT and CLIA change the way health care professionals, including doctors of optometry, think about laboratory and clinical testing outside the central laboratory and hospital, for the betterment of patient-centered care.

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[i] https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health
[ii] https://www.optovue.com/oct
[iii] https://diopsys.com/visual-electrophysiology-products/electroretinography-visual-evoked-potential-devices/
[iv] https://www.cdc.gov/labquality/waived-tests.html
[v] Yum SI, Roe J. Capillary blood sampling for self-monitoring of blood glucose. Diabetes Technol Ther. 1999 Spring;1(1):29-37.
[vi] https://www.tearlab.com/?gclid=EAIaIQobChMIr6jJleXO8gIVaE1yCh0_qgBGEAAYASAAEgKdEfD_BwE
[vii] https://www.tearlab.com/pdfs/Reimbursement/950035_REV_A_-_FAQ.pdf
[viii] https://diagnostics.roche.com/us/en/landing-pages/accu-chek-inform-ii-glucose-total-soluton.html?gclid=EAIaIQobChMIvd7mufLM8gIVVDizAB17YQSaEAMYAiAAEgKAjfD_BwE (Accessed 8/26/2121)
[ix] https://watermark.silverchair.com/labmed29-0085.pdf
[x] https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA