NEW YORK STATE OF OPPORTUNITY. Department of Health | Wadsworth Center

Oversight of Clinical Laboratories in New York State

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The Wadsworth Center

New York State's Public Health Laboratory

- Performs clinical and environmental testing for public health purposes such as pathogen surveillance and outbreak investigations, Newborn Screening, (bio)monitoring for environmental contaminants.
- Serves as a reference laboratory for rare and difficult to identify pathogens.
- Performs externally-funded applied and basic research.
- Supports graduate education
- Acts as a regulatory entity for clinical laboratories, environmental laboratories, tissue banks.

The Division of Laboratory Quality Certification is the division of the Wadsworth Center that carries out regulatory functions including the oversight of clinical laboratories.

Oversight of Clinical Laboratories

NYS Public Health Law and NYS Regulations

- Provides DOH the authority to permit clinical laboratories located in, or accepting specimens from New York state.
- Describes requirements that need to be met to obtain or maintain a permit to operate a clinical laboratory.

Oversight of Clinical Laboratories

The Centers for Medicare and Medicaid Services (CMS) has determined that New York State's laws and regulations for the oversight of clinical labs are equal or more stringent than Federal requirements (i.e., CLIA88).

Because of this, NYS has been granted exempt status and we act as an agent of CMS to provide oversight of NYS clinical labs. If a lab in NYS is issued a NYS permit, they will automatically meet the Federal requirements to carry out testing.

If an out-of-state laboratory accepts specimens from New York state, they are also required to be permitted by NYS and meet our requirements.

Oversight of Clinical Laboratories

Clinical Laboratory Evaluation Program (CLEP)

CLEP is the program that is responsible for the oversight of clinical laboratories.

~1,000 comprehensive clinical laboratories
~900 patient service centers
~3,500 certificates of qualification (CQ) holders that act as directors/assistant directors of clinical laboratories
~5,000 limited service laboratories (waived testing)

How we carry out oversight

- On-site inspection of clinical laboratories
- Review of proficiency testing results
- Evaluate laboratory director qualifications
- Investigate complaints and incidents
- Review non-FDA cleared or approved laboratory developed tests (LDTs).

CLEP works closely with scientific staff at the Wadsworth Center that provide expertise in all disciplines of clinical laboratory medicine.

The scientific subject matter experts play a primary role in the review of laboratory developed tests (LDTs).

Oversight of Laboratory Developed Tests

What are Laboratory Developed Tests (LDTs)?

- Non-FDA cleared or approved tests that are developed and validate by the laboratory offering the assay.
- Tests that include a combination of reagents and/or kits prepared by the laboratory, labeled as Analyte Specific Reagents (ASR), Research Use Only (RUO), or Investigational Use Only (IUO).
- Modified FDA-approved tests where there has been a change in intended use. For example, a change in the specimen type; the type of analysis (e.g., qualitative vs. quantitative); the purpose of the assay (e.g., screening, diagnosis, prognosis, monitoring, and /or confirmation); or the target population(s).

Oversight of Laboratory Developed Tests

What information is a laboratory required to submit?

- Standard operating procedures
- Data supporting the analytical validity of the assay
- Data supporting the clinical validity of the assay

Oversight of Laboratory Developed Tests

Over the last 20 years, Wadsworth has reviewed more than 11,000 laboratory LDTs covering a wide range of categories of testing.

Additional Information

Clinical Laboratory Evaluation Program (CLEP)
https://www.wadsworth.org/regulatory/clep

CLEP Program Guide
https://www.wadsworth.org/regulatory/clep/clinical-labs

Information on Laboratory Developed Tests
https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval