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CLIA Waived Tests: An Overview

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Oversight of Clinical Laboratory Testing at the Federal and State Level

In 1988, Congress passed the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) establishing quality standards for all clinical laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992.

The Centers for Medicare and Medicaid Services (CMS) has the primary responsibility for the operation of the CLIA Program.

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Oversight of Clinical Laboratory Testing at the Federal and State Level

CMS determined that New York State's laws and regulations for the oversight of clinical labs are equal to or more stringent than CLIA 88.

Because of this, NYS was first granted exempt status in 1995 and more recently in 2015. As a result of this exemption, we are responsible for providing oversight of NYS clinical labs. If a lab in NYS has a NYS permit they will automatically meet the Federal requirements to carry out testing.

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Oversight of Clinical Laboratory Testing at the Federal and State Level

"But we are a nursing home not a laboratory….."

The statutory definition of a clinical laboratory is the following:

"A clinical laboratory means a facility for the… examination of materials derived from the human body, for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of a health condition."

So, yes, a nursing home can be considered to be a laboratory if nursing home staff are performing clinical testing on the residents.

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Oversight of Clinical Laboratory Testing at the Federal and State Level

There are over 500 skilled nursing facilities in New York State that are considered to be laboratories because they perform waived testing on-site.

In order to understand what a waived test is, you need to understand the CLIA complexity model.

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The CLIA Complexity Model

Clinical laboratory tests are assigned a level of complexity.

There are three categories:

- High complexity tests
- Moderate complexity tests
- Waived tests

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The CLIA Complexity Model

In general, the more complicated the test, the more stringent the requirements.

CLIA waived tests are those tests that have been determined to be simple tests with insignificant risk of an erroneous result.

If a laboratory is only performing waived testing, it is not subject to more stringent regulatory requirements that laboratories performing high and moderate complexity testing must meet. Therefore, they are "waived" from the more stringent level of oversight.

CLIA Waived Tests

Who determines if a laboratory test is a waived test?

It is the Food and Drug Administration (FDA) that categorizes diagnostic tests by their complexity based on criteria outlined in CLIA regulations.

How do I determine if a test is categorized as waived?

CLIA Waived Tests

The FDA has a searchable database that can be used to determine if a test is waived.

Use the following link to search for waived tests:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

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CLIA Waived Tests

When searching, you may want to click "show drop down" under analyte name and use the drop down under "complexity" to choose "waived" to limit the search.

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CLIA Waived Tests

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

(DEMO)

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Obtaining Approval to Perform Waived Testing

The Department of Health's Clinical Laboratory Evaluation Program (CLEP) has been authorized under Section 579 of Article 5, Title V of the Public Health Law to provide oversight of facilities performing waived testing.

Any facility performing waived testing is required to be registered by CLEP as a Limited Service Laboratory (LSL).

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Obtaining Approval to Perform Waived Testing

To become registered by CLEP as a LSL, you will need to submit a complete application. The application provides CLEP with information such as:

- the name, location and type of facility
- ownership information
- the individual who will act as the laboratory director
- the types of waived tests that will be performed
- the estimated volume of testing that will be performed

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Obtaining Approval to Perform Waived Testing

Application materials and other information can be found at : https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs

The LSL Application Process Video Series provides additional guidance.

For additional information on Limited Laboratory Registration contact CLEP by phone at (518) 402-4253 or by email at CLEPLTD@health.ny.gov.

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Requirements of a LSL Director

Each LSL must identify an individual who will be designated as the laboratory director.

Who is authorized to be a laboratory director?

- A NYS licensed health care practioner including medical doctors, doctors of osteopathy, dentists, physician assistants nurse practioners, or certified nurse midwives.
- A Ph.D. that holds a certificate of qualification issued by CLEP.

Responsibilities of a LSL Director

The LSL Director is responsible for the technical and clinical direction of the testing within the facility. The LSL director needs to:

- Establish and approve policies and producers; update policies and procedures as needed.
- Train staff performing tests and perform annual evaluation to demonstrate continued ability and knowledge to perform the test (competency assessment).
- Establish a comprehensive quality assurance system designed to monitor and evaluate the ongoing and overall quality of the total testing process.

Responsibilities of a LSL Director

- Ensure that tests are performed in accordance with the manufacturers' instructions.
- Maintain complete and accurate records of the tests performed, including but not limited to, the patient's name, results, person performing the test, and quality control data.
- Ensure that persons who are involved in making decisions about diagnosis or treatment decisions are authorized by law to make these decisions.

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Requirements for Testing Personnel

Personnel that perform waived testing in a LSL DO NOT need to be a licensed health care practioner.

Any individual that has been trained and competency assessed can perform waived testing.

The goal of training and competency assessment is to ensure that the testing procedures described in the manufacturers instructions are being performed consistently and accurately so that the patient test results are accurate.

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Additional Information and Guidance

Ready Set Test Booklet
https://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/ReadySetTestBooklet.pdf

Good Laboratory Practices for Waived Testing Sites
https://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf

Standard Practices in Laboratory Medicine for Limited Service Laboratories
https://www.wadsworth.org/sites/default/files/WebDoc/1697462341/FINAL_Guidance%20FAQ%20document%2011_01_13_revised.pdf

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Point-of-Care Testing (POCT)

POCT refers to testing at or near the site of patient care.

The testing is intended to provide quick results to facilitate treatment decisions or further testing.

There are a variety of waived point of care tests that can be performed by nursing homes as a LSL.

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Point-of-Care Testing (POCT)

Single Analyte Testing Devices
(e.g. glucose, occult blood, HCV)

From: https://www.acepnow.com/emergency-physicians-role-point-care-testing-postexposure-prophylaxis/

From: https://www.cliawaived.com

From: https://www.cliawaived.com

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Point-of-Care Testing (POCT)

Multi-analyte Testing Devices
(e.g., chemistry panels, coagulation, hematology panels)

From: http://www.totalhomeheal thinc.com/pdf/pt-inr.html

From: https://www.abaxis.com/medical/piccolo-xpress

From: http://pages.sysmex.com/XW-100_Waived_CBC_landing.html

From: https://www.pointofcare.abbott/us/en/home

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Waived Hematology Point-of-Care Tests

- White Blood Cell Count
- Red Blood Cell Count
- Hemoglobin
- Hematocrit
- Mean Corpuscular Volume
- Platelet Count
- Neutrophil Count
- Lymphocyte Count
- Other White Blood Cell Count
- Neutrophil Percentage
- Lymphocyte Percentage
- Other White Blood Cell Percentage
- Protime/INR
- Erythrocyte sedimentation rate
- Platelet aggregation

Waived Chemistry Point-of-Care Tests

Cholesterol
HDL
LDL
Glycosylated hemoglobin
Triglyceride
VLDL
Alkaline phosphatase (ALP)
Aspartate Aminotransferase (AST)
Alanine aminotransferase (ALT)
Amylase
Urinalysis
Anion gap
Thyroid stimulating hormone (TSH)
BUN (blood urea nitrogen)
creatinine
glucose
albumin
tCO_2
calcium
sodium
potassium
Chloride
total bilirubin
Gamma glutamyltransferase
Occult blood
eGFR
Troponin
Pregnancy tests
Lactic acid
Ketones
Uric acid
Total protein

Waived Microbiology Point-of-Care Tests

- Influenza A
- Influenza B
- Mononucleosis (EBV)
- Strep A
- HIV
- HCV
- Borrelia burgdorferi (Lyme)
- Parainfluenza
- Rhinovirus
- Adenovirus
- Bordetella pertussis
- Mycoplasma pneumoniae
- Respiratory syncytial virus
- Treponema pallidum (syphilis)

Point-of-Care Testing (POCT)

Although a device may be considered to be a point of care test, this does not automatically mean that the test is considered to be a waived test!

If you will be operating as a LSL, you will need to ensure that the test is a CLIA waived test and that you are following the manufacturer's instructions.

If you modify the manufacturer's instructions, or the intended use of the test, the test will no longer considered to be waived and you will no longer be eligible to operate as a LSL.

Point-of-Care Testing (POCT)

Examples where changes in the manufacturer instructions of a waived test results in changes in the complexity designation of a test:

Abbot i-Stat CHEM8+ cartridge
Na, K, Cl, tCO2, Anion Gap, iCa, Glu, BUN, Crea, Hct, Hgb

Waived designation is only for venous whole blood samples collected in lithium heparin evacuated tubes (green top tubes).

If arterial, capillary, or other venous whole blood samples are used, it becomes a moderate complexity test.

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Point-of-Care Testing (POCT)

Examples where changes in the manufacturer instructions of a waived test results in changes in the complexity designation of a test:

Abaxis Piccolo xpress basic metabolic panel cartridge
Na, K, Cl, tCO2, iCa, Glu, BUN, Crea, eGFR

Waived designation is only for lithium heparinized whole blood samples.

If use lithium heparinized plasma or serum is used, it becomes a moderate complexity test.

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Point-of-Care Testing (POCT)

Examples where changes in the intended use result in changes in the complexity designation of a test:

Sysmex XW-100 Automated Hematology Analyzer
The manufacturer's instructions has a section "Intended Use" stating the following: the XW-100 Automated Hematology Analyzer is a quantitative automated hematology analyzer intended for *in vitro* diagnostic use to classify and enumerate the following parameters for venous whole blood anti-coagulated with K2/EDAT: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, other WBC%, NEUT%, LYM#, Other WBC#, NEUT#. **It is not for use in diagnosis or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of 2.**

If there are changes to the intended use it is no longer designated as waived.

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Phlebotomy

We are aware that clinical laboratories are reducing or eliminating phlebotomy services for nursing homes.

This has resulted in a number of inquires from nursing homes regarding requirements for performing phlebotomy at nursing homes.

We will be using a Q&A approach to educate you on requirements for phlebotomy.

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Phlebotomy Q&A

Q: The laboratory we use for testing will no longer be providing phlebotomy services for our nursing home. What options are available for obtaining phlebotomy services?

A: The nursing home can draw blood on the residents to forward to the laboratory. Alternatively, you could establish a contract with a mobile phlebotomy service that will come on-site and draw blood on the residents.

Phlebotomy Q&A

Q: If our nursing home staff will be performing phlebotomy, do they need to be approved or licensed by New York State?

A: No. Staff employed by the nursing home staff that will be performing phlebotomy do not need to be approved or licensed by New York State.

Phlebotomy Q&A

Q: Are there any educational requirements that our nursing home staff need to meet to perform phlebotomy?

A: Staff performing phlebotomy do not need to hold a specific educational degree. However, the nursing home is responsible for training the staff and for performing ongoing assessment of the staff to ensure they are following procedures (i.e., competency assessment). No additional approvals are required to draw blood on-site at your nursing home.

Phlebotomy Q&A

Q: Our nursing home is currently registered as a limited service laboratory that performs waived testing. We are going to begin performing phlebotomy on our residents. Do I need to amend my limited service laboratory registration to add phlebotomy as a new test?

A: No. Phlebotomy is not considered to be a test. It is the collection of the specimen. Therefore, there is no need to amend the limited service laboratory registration.

Contact Information

For additional information on Limited Laboratory Registration contact CLEP by phone at (518) 402-4253 or by email at CLEPLTD@health.ny.gov.

Michael Ryan
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Any Questions?

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NEW YORK STATE Department of Health

Statewide Health Information Network for NY (SHIN-NY) Overview and Data Exchange Incentive Program (DEIP)

The SHIN-NY in a Nutshell

- A secure network for sharing electronic clinical records
  - The SHIN-NY consists of eight Regional Health Information Organizations (also known as QEs)
- Records are accessed and exchanged securely between healthcare providers with appropriate consent
- Patients decide which entities can access or see their records
- Efficient access to clinical records helps providers better manage patient care
- The SHIN-NY can help reduce healthcare costs, improve healthcare coordination, and increase the quality of care for patients in New York State

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Qualified Entities (QEs)

The QEs are the backbone of the SHIN-NY, providing the services that make secure, vital access to a patient's health information possible statewide..

While QEs are primarily established within geographical regions (Upstate more so than downstate), healthcare organizations may connect with the QE that best aligns with their business, operational, and service delivery needs.

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The SHIN-NY Core Services

Since March 2015, all RHIOs must provide the following **Core Services** to Participants:

- Statewide Patient Record Lookup*
- Statewide Secure Messaging (Direct)*
- Notifications (Alerts / Subscribe and Notify)*
- Provider & Public Health Clinical Viewers*
- Consent Management
- Identity Management and Security
- Public Health Reporting Integration
- Lab Results Delivery*

No charge for these services beyond initial setup

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Current Core Services Delivery and Participation

OVER 37 MILLION
Alerts Delivered

OVER 11 MILLION
Patient Record Returns
(Via EHR & Clinical Viewer)

Last 12 months as of August 2018

99% of Hospitals

65% of Diagnostic and Treatment Centers

52% of Physician Practice Sites

76% of Certified Home Health Agency*

89% of Long Term Home Healthcare Program*

77% of Residential Healthcare Facility – SNF*

75% of Hospice*

*Minimal data contribution due to not being traditional Meaningful Use providers; vast majority only have access to clinical viewer

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A Closer Look at Labs + the SHIN-NY

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Labs as SHIN-NY Data Contributors

- QEs are connected to a variety of hospital-based and independent labs
  - Examples include:
    - CapitalCare Lab Services
    - ACM Lab
    - BioReference
    - Quest Diagnostics
    - UHS
    - Lab Alliance of CNY
- In most cases, the labs contribute Laboratory Results and Pathology Reports to the HIE
- This clinical information can be viewed by providers
  - If provider is the ordering provider, consent is not needed
  - If provider is not the ordering provider, affirmative patient consent is required to view

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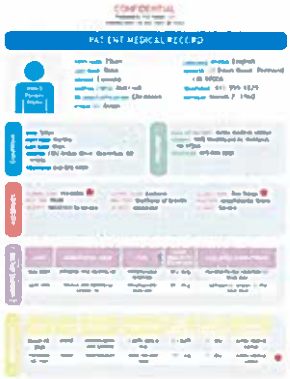
Patient Record Lookup

Patient record lookup allows healthcare providers to retrieve individual patient records from both the **local QE** and **across the statewide network** after receiving consent from the patient. This service makes information available to providers accessing the SHIN-NY via third party software (EHRs) and QE-provided clinical viewers. This data will include labs from any Laboratory that is connected to a QE.



Capabilities

- Search for existing patient records across all QEs
- Search within a QE's clinical viewer
- Search within third party software (EHR) supported by the QE

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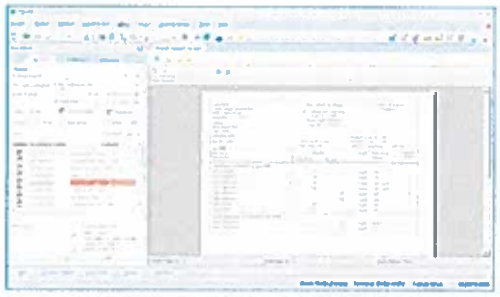
Results Delivery

This service allows for the delivery of diagnostic results and summary reports back to ordering providers and others designated to receive results. Primarily used to deliver Lab Results.



Capabilities

- Receive diagnostic results and summary reports for laboratory tests and radiology tests from laboratories and diagnostic centers and other facilities that have arranged to have the QE route results on their behalf
- Receive results when the Authorized User is the ordering provider or has been listed in the order to receive copies of results

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New York State Data Exchange Incentive Program (DEIP)

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DEIP Basics

- **Data Exchange Incentive Program (DEIP)** was established by the New York State Department of Health (NYSDOH), with support from the Centers for Medicare & Medicaid Services (CMS), to increase HIE adoption across the state by helping to defray the cost for an organization when connecting to their local QE
- The New York eHealth Collaborative (NYeC) is coordinating the rollout of the program and the incentive payments on behalf of the DOH
- Electronic Health Record (EHR) interfaces to New York State Qualified Entities (QEs) increases the quantity and quality of data in the SHIN-NY and build value for providers and patients at the point of care
  - In order to receive the full funding amount, $13,000, a provider needs to have a live connection of this type with their QE
- Organizations participating in DEIP are incentivized to contribute a pre-defined set of data elements to their local QE
- Limited funding is available and this program is operated on a first-come, first-served basis

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DEIP Eligibility Requirements

An organization must meet one of the following criteria:

Regulated Facilities*	Behavioral Health	EPs

• Be licensed as one of the following:
  • Article 28 Nursing Homes and Diagnostic & Treatment Centers
  • Article 36 Home Health agency/program
  • Article 40 Hospice
	• Be licensed by:
	  • OMH
	  • OASAS
	• Or be a designated HCBS provider
		• Have at least one provider who has attested to and been paid under Medicare MU or Medicaid MU (any year, any stage)

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*Will expand to include licensed clinical laboratories

DEIP Eligibility Requirements- continued

An organization must meet <u>all</u> of the following criteria:

EHR	Medicaid	Other

• Have an EHR that meets the Privacy & Security criteria set forth by NYeC and NYSDOH
• Have and EHR that is able to send data to the QE as either CCD or C-CDA
  • *EPs must send as C-CDA*
	• Organization must accept Medicaid, in one of the following forms:
	  • Fee-for-Service
	  • Managed Care
	  • HARP (for BH)
		• Organization/provider must not already be connected to/contributing data to a QE
		• Must not have received payment from any source for similar HIE activities

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DEIP Data Contribution Requirements

Regulated Facilities (Art. 28, 36, 40)

- Contribute the **Common Clinical Data Set** in CCD or C-CDA:
  - Name, sex, DOB, race, ethnicity, pref. language, smoking status, problems, meds, med. allergies, labs, lab results, vitals, care plan fields, procedures, care team members, immunizations
  - *Additional data elements, if available*: Incidents & Accidents (I&A), nurses notes, progress notes, orders, pain and skin assessment, advance directives/MOLST

Behavioral Health

- Contribute **five specified Core elements**, plus three additional data elements, as available:
  - *Core*: encounters, demographics, procedures/service, individualized service plans, diagnoses
  - *Additional*: Medications, labs, allergies

Medicare & Medicaid EPs

- Contribute the Common Clinical Data Set in CCD or C-CDA:
  - Name, sex, DOB, race, ethnicity, pref. language, smoking status, problems, meds, med. allergies, labs, lab results, vitals, care plan fields, procedures, care team members, immunizations,

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Program & Payment Milestones

Milestone/Activity	Deadline	Incentive Payment
Milestone 1: Sign a Participation Agreement with a QE	Participation Agreement must have been executed on or after 10/1/16 to receive payment against this milestone	$2,000 per organization
Milestone 2: Attest to the following: - Have the ability to **receive** a summary of care document in C-CDA - Have established a connection to the QE and that the organization is **contributing** the required clinical data as per the program requirements	No later than 9/30/2020 as long as funding is not exhausted before this time	$11,000 per connection

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RHIO/ QE Contacts

QE	Contact	Email
Bronx RHIO	Keela Shatzkin	keela@shatzkinsystems.com
HealtheConnections	Danielle Wert	dwert@healtheconnections.org
HEALTHeLINK	Stephen Gates	sgates@wnyhealthelink.com
Healthix	Olubunkola Ojeifo	oojeifo@healthix.org
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Rochester RHIO	Denise Dinoto	denise.dinoto@grrhio.org

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How to Get Started

- ✓ Check your organization's eligibility against the program requirements
- ✓ Contact your local QE
- ✓ Talk to your EHR vendor
- ✓ Contact NYeC or your local QE with any questions deip@nyehealth.org

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Overview Documents Available Online

Visit our Website:
http://www.nyehealth.org/deip

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