SmartNotes

Understanding CLIA Complexity: Obtaining the Correct Designation for Your Laboratory

Traditionally, physician offices and treatment centers often send out specimens to hospitals or reference labs for drugs of abuse testing. Today, health care providers are increasingly seeing the advantages of testing on-site in the office, with immediate access to patient test results. Establishing a laboratory that has a Clinical Laboratory Improvement Amendments (CLIA) moderate complexity certification may be an attractive option for those practices or facilities that want to maximize patient care, reduce testing costs, and create additional revenue opportunities for their practice or facility.

Labs currently designated as high complexity, on the other hand, are finding that the reimbursement reductions implemented in 2016 by the Centers for Medicare & Medicaid Services (CMS) no longer make that designation financially sustainable; a CLIA moderate complexity designation may be an ideal alternative worth consideration for these practices or facilities.

What does a manufacturer need to do to be approved as moderate complexity?

- **Perform extensive studies to prove that the analyzer parameters designed for that assay produce accurate results**

  Analyzer parameter optimization studies include:

  – Linearity: Accuracy by % Recovery

  – Precision: 20 day Within-run and Total

  – 14-day Calibration Stability

  – 30-day Reagent On-Board Stability

  – Method Comparison: Immunoassay and LC-MS/MS

- **Document and submit results to the FDA for clearance**

CLIA Program

CLIA is a federal program that set standards, regulates laboratories and ensures that accurate and reliable test results are produced. Laboratories that test patient specimens must follow the CLIA Program for in-office testing and are required to be certified by their state and the CMS before they can accept human samples for diagnostic testing.[1]

CLIA Test System Complexity

Under CLIA, the FDA categorizes clinical laboratory test systems as a high, moderate or waived complexity. These test systems include the assay and instrument combination approved for use together.

ThermoFisher SCIENTIFIC

CLIA waived tests for drugs of abuse, also called point-of-care tests, include cups or strips that require looking for a colored line to appear, as positive or negative, once the test comes in contact with urine or oral fluid. While easy to perform, they are not as accurate as automated tests and may require repeats to accurately interpret the results.[2]

Automated drugs of abuse immunoassays are a more accurate and potentially cost-effective alternative. They can be designated as either moderate or high complexity but default to highly complex unless the manufacturer performs the necessary studies to gain FDA clearance for a moderate complexity designation.

Without a CLIA moderate complexity designation, highly complex laboratories would have to do the studies themselves and moderately complex laboratories would not be allowed to run the assay.

CLIA Laboratory Complexity

The type of tests you wish to conduct and the CLIA complexity of each test included on your instrument's menu will dictate the applicable CLIA requirements for your laboratory. In general, the more complicated the test, the more stringent the requirements under CLIA; this is mainly due to the type of personnel needed.[3]

Compared to the requirements of a moderate complexity lab, a high complexity lab requires more investment due to the required credentials of those overseeing and operating the lab.[3] A high complexity lab requires a medical director and a licensed Medical Technologist to be on site at all times, whereas a moderate complexity lab requires a Technical Consultant and non-licensed technologist. The table below compares these key requirements.[4]

Table 1: Comparison of CLIA Complexity Requirements

	High Complexity Laboratory	Moderate Complexity Laboratory
Oversight	Medical Director	Technical Consultant
Staffing	Minimum of 1 licensed Medical Technologist or Technician on site at all times the lab is open. BS in a scientific field is also acceptable	Licensed tech is not required.* On the job training is acceptable
Equipment	LC-MS/MS, Clinical Analyzers, Lab Developed Test and Presumptive Optical Tests (i.e. lab strips)	All equipment must have minimal oversight, nothing complex
Test Menu	Mixture of waived, moderate and high complex tests	Waived and moderate only as determined for each assay application by the FDA

Reimbursement Facts

Prior to 2016, CMS reimbursed high complexity immunoassay tests at a higher rate than moderate complexity tests. Today, **both high and moderate complexity immunoassays are reimbursed at the same rate.** The government provides the upper limit for reimbursement; however, each state determines the actual reimbursement for the area where the laboratory is located.[5] Due to the investment requirements of a high vs moderate complexity lab, if your drugs of abuse testing needs only require moderate complexity assays, this may be a more financially viable option.

Implementing a Moderate Complexity Laboratory in Your Practice or Facility

Whether you are adding a moderate complexity laboratory to your practice or facility, or shifting from a high to a moderate complexity laboratory, it is not difficult and there are resources available to assist your transition. Understanding the requirements to successfully implement a CLIA moderate complexity lab in your office is a key first step.

Top considerations to make your decision may include:

Testing Volumes & Test Menu	Workflow and Space	Staff	Investment
• Does your test volume merit a positive ROI to adopt in-office testing? • What tests need to be run and are they moderate complexity assays?	• Do you have a dedicated space for a lab, such as a large closet or storage room? • Does your space allow for electrical outlets, running water, a table for an instrument, and a refrigerator close-by?	• Can you appoint someone to learn to run the instrument and follow the CLIA lab procedures?	• Can you invest in reasonable start-up costs to fuel longer-term revenue opportunity?

Steps to implement your CLIA moderate complexity lab in your practice or facility include:

Obtain a CLIA moderate complexity license and appropriate certificates[1]

Laboratories must enroll in the CLIA Program to be certified to run tests and apply for the right program certificates. There are five certificate options available.[1]

Employ appropriate personnel for a moderate complexity lab[6]

No lab technician is required and the person you choose to operate your lab can learn through on-the-job training. Note that a specialized CLIA consultant can often assist with understanding CLIA requirements and the process to become a CLIA certified laboratory.

Adopt lab instrumentation and assays to meet your test needs

Thermo Scientific™ Complete Automated Drugs of Abuse Testing Solution has a CLIA Moderate Complexity designation for our drugs of abuse tests on the Thermo Scientific™ Indiko™ and Indiko Plus chemistry analyzers, and the Beckman Coulter™ AU™ chemistry analyzers. Learn more from your local Thermo Fisher Scientific Sales Account Manager and distribution partners.

Enroll in a CLIA approved Proficiency Testing (PT) Program[7]

PT is the testing of unknown samples by a Health and Human Services (HHS)-approved program. You can use this to verify the accuracy and reliability of testing, and to validate the entire testing process.[7] Find PT providers at www.cms.gov.

Implement lab procedures and quality control standards

CLIA provides quality assurance lab procedures and standards that should be embedded into your workflow and standard operating procedures (SOPs). Your CLIA consultant can help you understand more.

The Thermo Scientific Complete Automated Drugs of Abuse Testing Solution

Thermo Fisher Scientific has more test systems approved for CLIA moderate complexity than any other brand.[8]

The Thermo Scientific™ Complete Automated Drugs of Abuse Testing Solutions allows you to comprehensively manage drug testing with more control, same-day turnaround time, accurate results, increased revenue, and while maximizing patient care.

Our drugs of abuse tests may be used with the Thermo Scientific™ Indiko™ and Indiko Plus chemistry analyzers and the Beckman Coulter™ AU™ chemistry analyzers. The chart below provides more detail about test systems approved for CLIA moderate complexity.

Table 2: CLIA Moderate Complexity Designations for the Thermo Scientific Drugs of Abuse Assays[8]

CLIA Moderate Complexity Designations for Thermo Scientific Indiko / Indiko Plus and Beckman Coulter AU Analyzers							
Thermo Fisher Scientific Assay	Indiko	Indiko Plus	AU400	AU480	AU640	AU680	AU5800
DRI Amphetamines	✓	✓	✓		✓		
DRI Barbiturates	✓	✓	✓	✓	✓	✓	✓
DRI Benzodiazepine	✓	✓	✓			✓	
CEDIA Buprenorphine	✓	✓		✓	✓	✓	✓
DRI Cannabinoids (THC)	✓	✓	✓	✓	✓	✓	✓
DRI Cocaine Metabolite	✓	✓	✓		✓	✓	
CEDIA Cocaine Metabolite	✓	✓					
DRI Cotinine	✓	✓	✓		✓		
DRI Ecstasy	✓	✓	✓				✓
DRI Ethyl Alcohol	✓	✓	✓	✓	✓	✓	✓
CEDIA Heroin Metabolite (6-AM)	✓	✓	✓	✓	✓	✓	✓
DRI Hydrocodone	✓	✓				✓	
DRI Methadone	✓	✓	✓		✓		
DRI Methadone Metabolite (EDDP)	✓	✓	✓	✓		✓	✓
DRI Opiates	✓	✓		✓	✓	✓	✓
DRI Oxycodone	✓	✓	✓	✓	✓	✓	✓
DRI Phencyclidine	✓	✓	✓		✓		
DRI Propoxyphene (PPx)	✓	✓	✓				
Specimen Validity Tests	CLIA complexity designation not required by the FDA						

Benefits of a CLIA Moderate Complexity Laboratory

Choosing to offer moderate complexity tests in your practice or facility is often driven by the benefit of faster turnaround time to strengthen quality of care, in-office efficiency, and potential to expand your services for additional income. A physician practice should carefully consider the requirements and benefits associated with becoming a CLIA moderate complexity laboratory before making a decision.

Benefits of adding a moderate complexity laboratory to your practice or facility include:

- Improve patient care by having immediate access to test results, and discussing these results with your patient while they are in the office
- Differentiate your business by choosing from a broad testing menu and customizing test panels to address patient needs
- Create additional revenue opportunities and expand your practice by testing more patients or offering your services to other clinicians
- Increase practice or facility efficiencies and reduce costs with the elimination of the more expensive send-outs

Start Your Testing Today

Ask your Thermo Fisher Scientific™ Sales Representative or your distribution partner how to start using the Thermo Scientific™ Complete Automated Drugs of Abuse Testing Solutions for CLIA moderate complexity lab testing today.

thermoscientific

References

1. Clinical Laboratory Improvement Amendments (CLIA). Mar. 2018, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm. (accessed June 13, 2018)
2. George S, Braithwaite RA. Use of On-Site Testing for Drugs of Abuse. Clinical Chemistry 48:10 1639-1646 (2002)
3. Center for Devices and Radiological Health. "IVD Regulatory Assistance - Clinical Laboratory Improvement Amendments (CLIA)." U S Food and Drug Administration Home Page, Center for Biologics Evaluation and Research, www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm (accessed June 13, 2018)
4. "What Are My Responsibilities As A Laboratory Director." Clinical Laboratory Improvement Amendments (CLIA). Brochure #7, Aug. 2006, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf (accessed June 13, 2018)
5. 2018 Clinical Diagnostic Laboratory Fee Schedule. Dec. 2017, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-FilesItems/18CLAB.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending (accessed June 13, 2018)
6. Director Survey and Certification Group. "Personnel Policies for Individuals Directing or Performing Non-waived Tests." Department of Health and Human Services, Center for Medicare and Medicaid Services, May 2016, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-18.pdf (accessed June 13, 2018)
7. "Proficiency Testing and PT Referral Dos and Don'ts." Clinical Laboratory Improvement
8. Data on file. U.S Food & Drug Administration, Medical Device Databases, Clinical Laboratory Improvement Amendment (CLIA), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm (accessed June 13, 2018)

In the United States:
For customer service, call 1-800-232-3342
To fax an order, use 1-800-829-8115
To order online: mgc.customerservice@thermofisher.com

Find out more at **thermofisher.com/SAMHSA**

SN-FR-0120-0MTL-Moderate-Complexity-SmartNotes-EN 2018 08

ThermoFisher SCIENTIFIC