Summit DIAGNOSTICS

INFORMATIONAL AND BUYING GUIDE

POC Drug Testing Cups

CLIA VS NON CLIA

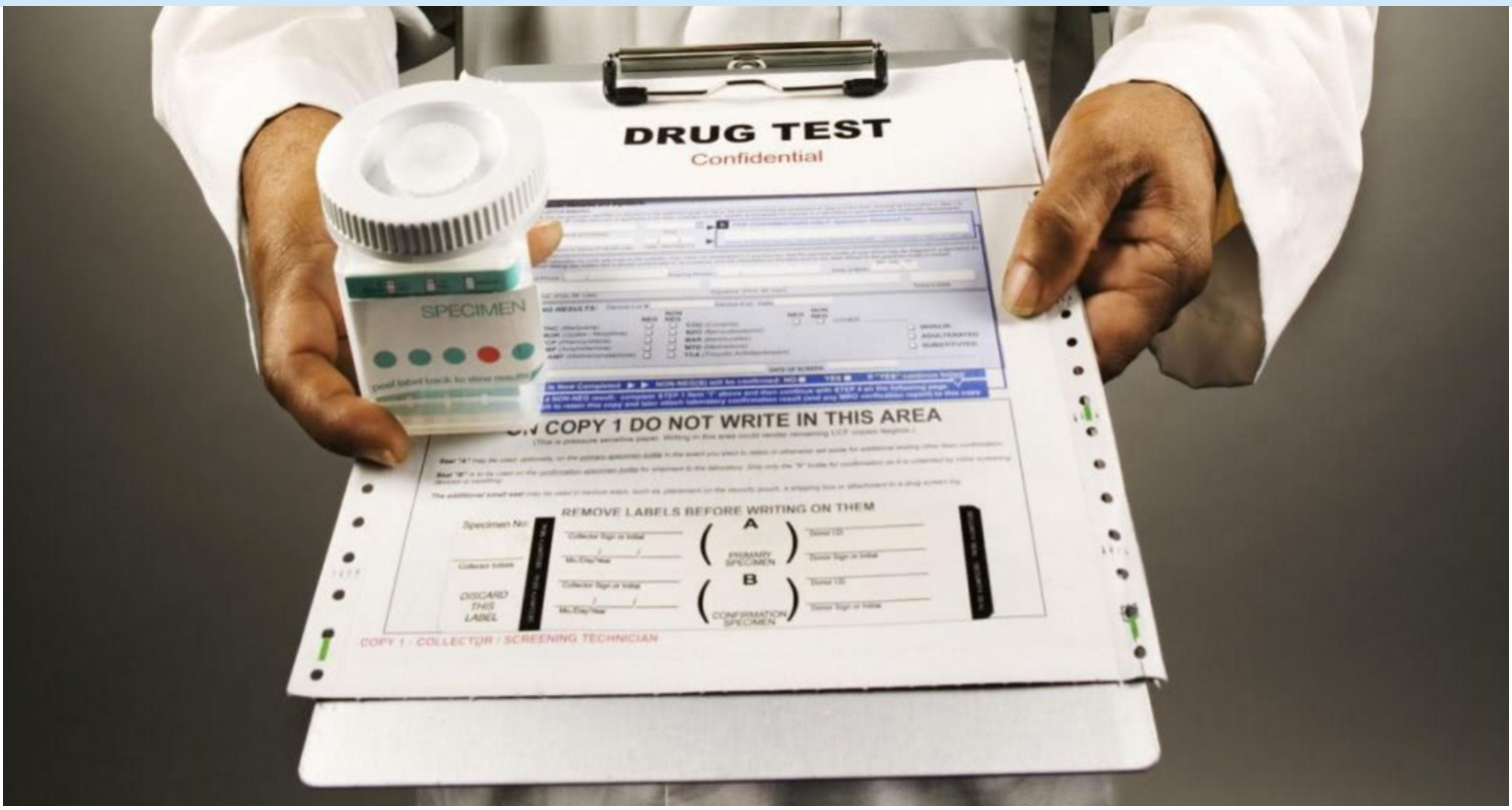
What does CLIA Mean?

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research.

In accord with the CLIA, the CLIA Program sets standards and issues certificates for clinical laboratory testing. CLIA defines a clinical laboratory as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for:

- diagnosis, prevention, or treatment of disease or impairment
- health assessments

An objective of the CLIA is to ensure the accuracy, reliability and timeliness of test results regardless of where the test was performed. Most Laboratory Developed Tests have been regulated under this program. In 2014 the FDA started a public discussion about regulating some LDTs.



References

- CLIA related Federal Register and Code of Federal Regulation Announcements, and the FDA's Clinical Laboratory Improvement Amendments (CLIA). Accessed Nov. 14, 2015.
- CLIA Program homepage
- CLIA Overview. CMS. 11 April 2018.
- Laboratory Developed Tests. FDA. 26 March 2018.
- CLIA Categorization Criteria (December 2012)
- CLIA Waived Testing booklet" (PDF). December 2012.
- CLIA Waived IVD Regulatory Assistance". November 2007. Archived from the original on 2012-12-05. Retrieved 2012-12-10.
- Gabler, Ellen (2015-10-31). "Hidden Errors – A Watchdog Report – Common medical tests escape scrutiny but often fall short". Milwaukee Journal Sentinel. Retrieved 2017-10-10.

Per CLIA, each specific laboratory system, assay, examination is graded for level of complexity by assigning scores of 1, 2, or 3 for each of the following seven criteria. A score 1 is the lowest level of complexity and a score of 3 indicates the highest level. Score 2 is assigned when the characteristics for a particular test are intermediate between the descriptions listed for scores of 1 and 3.

Criteria for categorization:
1. Knowledge
2. Training and experience
3. Reagents and materials preparation
4. Characteristics of operational steps
5. Calibration, quality control, and proficiency testing materials
6. Test system troubleshooting and equipment maintenance
7. Interpretation and judgment

Centers for Medicare and Medicaid Services (CMS) has the primary responsibility for the operation of the CLIA Program. Within CMS, the program is implemented by the Center for Medicaid and State Operations, Survey and Certification Group, and the Division of Laboratory Services.

The CLIA Program is funded by user fees collected from approximately 200,000 laboratories, most located in the United States.

WHAT DOES "FORENSIC USE ONLY" REALLY MEAN?

"Forensic use only" is a category of drug tests which may only be sold to companies or agencies within the criminal justice system for a purpose relevant to legal proceedings. In guidance published on September 5, 2008 from CMS – Department of Health & Human Services, Survey and Certification Group, CMS states, "In the forensic testing context, laboratory results are generated purely for the purpose of detecting illegal substances or illegal amounts of certain substances in the body that may be relevant to legal proceedings." These tests are not regulated, or approved, by the FDA or CLIA, "there is no concern in such testing for developing accurate and reliable data for use by health care professionals for the purpose of diagnosis or treatment." Because these tests have not gone through the FDA's 510(k) premarket notification process, they cannot be sold to entities or individuals not related to the criminal justice system.

CLIA is specific for testing which is done "with respect to its applicability to facilities that conduct testing for the medical diagnosis and treatment of individuals." Forensic testing" is excluded under CLIA since forensic testing is conducted to determine if there has been a violation of the law and is not done for the purpose of providing remedial treatment." 57 FR 7014.

Additional information :
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123682.htm#1
http://www.captodayonline.com/forensic-use-urine-drug- screening-reagents/

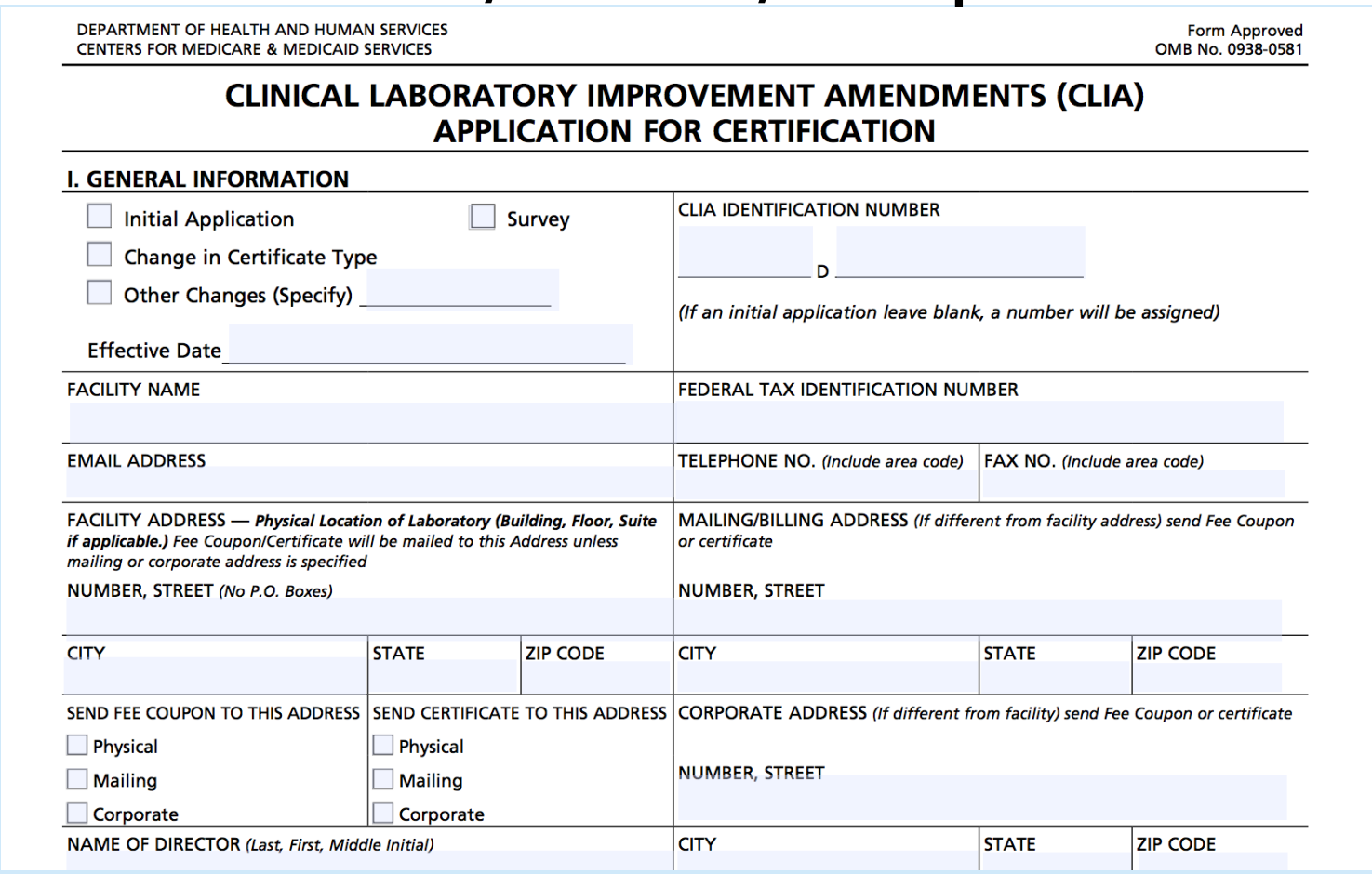
HOW TO OBTAIN A CERTIFICATE OF WAIVER APPLICATION

To find more information on FDA Actions on CLIA Waiver by Application Submission, User Fee For a CLIA Waiver by Application, and CLIA Waiver by Application Decision Summaries visit:

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393233.htm

and fill out a form at:

https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☐ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____
Effective Date _____

CLIA IDENTIFICATION NUMBER
_____ D _____
(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS

TELEPHONE NO. *(Include area code)*

FAX NO. *(Include area code)*

FACILITY ADDRESS — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified*
NUMBER, STREET *(No P.O. Boxes)*

CITY | STATE | ZIP CODE

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*
NUMBER, STREET

CITY | STATE | ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
☐ Physical
☐ Mailing
☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
☐ Physical
☐ Mailing
☐ Corporate

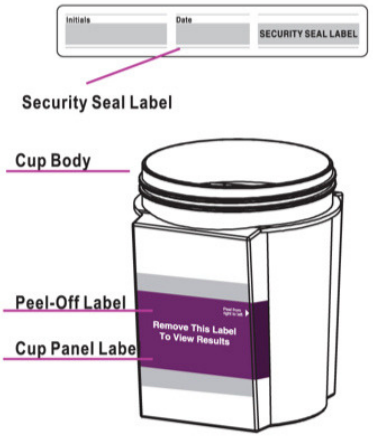
CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*
NUMBER, STREET

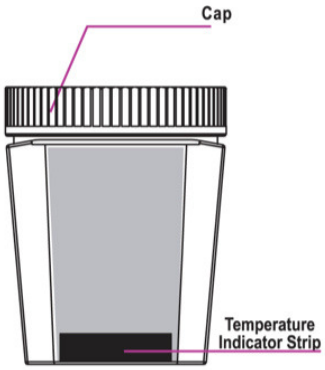
NAME OF DIRECTOR *(Last, First, Middle Initial)*

CITY | STATE | ZIP CODE

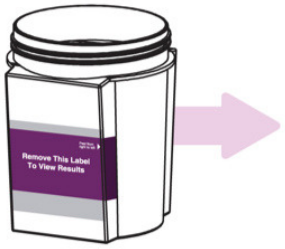
HOW TO READ A TEST

MULTI-DRUG SCREEN TEST CUP | PROCEDURE CARD



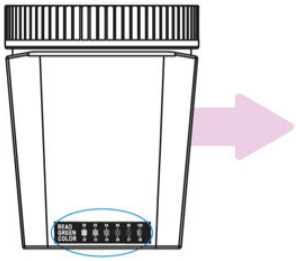


1 Donor provides urine specimen in cup. If desired, cap can be held by operator to initiate the test at a later time.



2 Once urine sample has been collected, screw cap **firmly** until you heard a click.

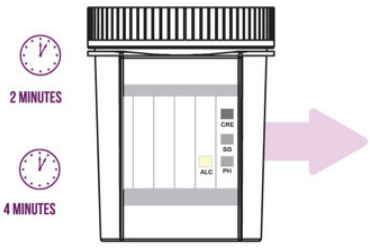
3 Check urine temperature at 2-4 minutes by reading green color on temperature indicator strip.



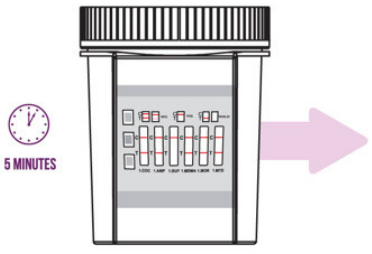
4 Donor dates and initials security seal. Operator checks cap for tightness and attaches security seal label over cap as shown (Optional).

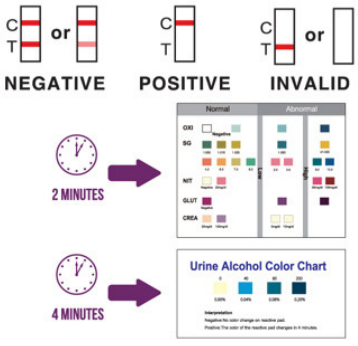
5 Remove peel-off label.

6 Read adulteration strip pads or urine alcohol pads at 2 minutes or at 4 minutes if applicable.

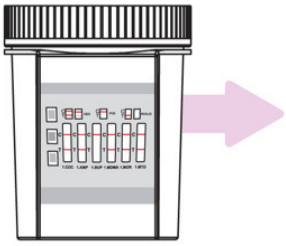


7 Read test results at 5 minutes. Refer to diagram below for result interpretation.





8 Positive test results must be confirmed by another test method. Send cup and urine specimen with security seal label intact to a toxicology laboratory for confirmation.



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CUP PRICING

3 Panel Drug Test Cup: $2.22
4 Panel Drug Test Cup: $2.35
5 Panel Drug Test Cup: $2.47
6 Panel Drug Test Cup: $2.54
7 Panel Drug Test Cup: $2.82
8 Panel Drug Test Cup: $2.89
9 Panel Drug Test Cup: $2.98
10 Panel Drug Test Cup: $2.40
11 Panel Drug Test Cup: $3.20
12 Panel Drug Test Cup: $2.50
13 Panel Drug Test Cup: $3.45
14 Panel Drug Test Cup: $3.55

POC CUPS TEST FOR A RANGE OF DRUGS INCLUDING:

AMP: Amphetamine
BAR: Barbiturates
BZO: Benzodiazepines
COC: Cocaine
THC: Cannabinoids
MTD: Methadone
MET/mAMP: Methamphetamine
MDMA: methylenedioxymethamphetamine
MOP: Morphine
OPI: Opiate
OXY: Oxycodone
PCP: Phencyclidine
PPX: Propoxyphene
TCA: Tricyclic Antidepressants
K2: Synthetic Cannabinoids FEN: Fentanyl

CONFIRMATION SERVICES

Confirmation testing is considered the gold standard for drug testing. The only way to truly know what medications a person is taking is to perform a drug test and obtain full confirmation results from a quality laboratory. It is a useful tool to help identify and address issues involving Prescription Drug Abuse, Diversion and Addiction. Confirmation testing also helps to protect physicians and their practice. It allows for overall patient safety and this compliance minimizes the physicians/organizations liability.

With early detection of drug problems, physicians are afforded the opportunity to take measures to address the effects of diversion, abuse, and addiction. Some additional benefits of confirmation testing is:

- Prevents potential drug to drug interactions by identifying the specific drug and levels in the patient at the time of testing
- There are several drugs and subtypes that cannot be tested on POC devices, they can only be detected through confirmation testing
- The accuracy of our labs' confirmation testing is nearly 100% accurate
- Confirmation reports provide a permanent record of the physician's efforts to minimize the potential for abuse and diversion within the practice
- Up to 10% of prescribed opioids are missed by POC testing