

NYS OASAS Provider Q&A
On-Site Laboratory Testing Registration Requirements

1. Question: What is CLIA?

Response:

The federal government passed a series of laws and standards known as the Clinical Laboratory Amendments (CLIA) beginning in 1988 to ensure that all samples taken of materials from the human body met certain criteria that assured accuracy, reliability and timeliness. States are required to implement these laws and standards.

2. Question: As an OASAS provider, am I a laboratory?

Response:

Any provider, practitioner or other person that collects a sample and performs testing of that material from the human body “for the diagnosis, prevention, or treatment of any disease or impairment of the health of, human beings” is a laboratory. If you collect and test even one sample of blood, urine, or saliva at your program, you are a laboratory.

3. Question: As an OASAS provider, do I need NYS Department of Health’s authorization to conduct on-site laboratory testing (e.g. fingerstick glucose, urine pregnancy, drugs of abuse, dipstick urinalysis, breath alcohol)?

Response:

Yes. OASAS providers interested in performing on-site laboratory testing must obtain approval from the Department of Health’s Clinical Laboratory Evaluation Program.

4. Question: What type of laboratory approval should I apply for? How long is approval good for, and how much does it cost?

Response:

Providers interested in performing on-site laboratory testing must register as either a **Limited Service Laboratory** or a **NYS Clinical Laboratory** depending on the testing performed, and the devices used to do that testing.

Limited Service Laboratory

Providers interested in performing on-site laboratory testing using test devices categorized by the Food and Drug Administration (FDA) as Waived must apply for a Limited Service Laboratory Registration Certificate. A certificate is good for two years. The initial application and reapplication fees are \$200.00:

Application materials to obtain a Limited Service Laboratory Registration certificate are available at: <https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs>

NYS Clinical Laboratory

Providers interested in performing on-site laboratory testing using test devices categorized by the FDA as Non-Waived (Moderate or High complexity) must apply for a NYS Clinical Laboratory Permit. A permit is good for one year. The initial application fee is \$1,100.00:

Application materials to obtain a NYS clinical laboratory permit are available at:
<https://www.wadsworth.org/regulatory/clip/clinical-labs/obtain-permit>

5. Question: What are the most common tests performed by OASAS providers?

Response

According to a recent survey, breath alcohol, drugs of abuse, glucose, pregnancy test (urine) & saliva alcohol were the most common tests reported. Providers should understand what they are testing for and how they are using test results. For example, testing urine for the presence of drugs (or other substances) is drugs of abuse testing, not urinalysis.

6. Question: How do I know if the test device that I am using for drugs of abuse, glucose, pregnancy, etc. testing is an FDA Approved CLIA Waived test device for use under a Limited Service Laboratory Registration Certification?

Response:

To determine if your test device is an FDA Approved CLIA Waived test device:

- a) Check the manufacturer's package insert. It may state that the device is *CLIA Waived*. Otherwise, contact the manufacturer via the 800 number found in the package insert.
- b) Contact the distributor where the test device was purchased.
- c) Search the FDA database of approved test devices:

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

If the test device that you wish to use is not categorized as "Waived," then you may not use it under a Limited Service Laboratory Registration and you must apply for a NYS Clinical Laboratory permit.

7. Question: How do I search the FDA database for approved Waived test devices at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>

Response:

While you may search by Test System/Manufacturer Name if known, it may be easier to search by *Analyte Specialty* (ex: *Toxicology/TDM*), and Complexity (ex: *Waived*)

Select Analyte Specialty (ex: Toxicology/TDM)

FDA U.S. FOOD & DRUG ADMINISTRATION SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

CLIA - Clinical Laboratory Improvement Amendments

FDA Home | Medical Devices | Databases

Enter any combination of fields and select Search. You can use the Analyte Drop Down box to select a specific Analyte. For Test System Name/Manufacturer: enter a single word (e.g., Analyzer) or an exact phrase (e.g., Acme Analyzer). [Learn More...](#)

Search Database Help Download Files

Test System / Manufacturer:

Analyte Name: Show Text Input:

Document Number: Complexity:

Analyte Specialty 510(k) Exempt?

Effective Date: to

Sort by:

[Clear Form](#)

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

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Specify Complexity (ex: Waived)

FDA U.S. FOOD & DRUG ADMINISTRATION A to Z Index | Follow FDA | En Español SEARCH

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Search Database Help Download Files

Test System / Manufacturer:

Analyte Name: Show Text Input:

Document Number: Complexity:

Analyte Specialty: 510(k) Exempt?

Effective Date: to

Sort by:

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Other Databases

- 510(k)s
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Once an *Analyte Specialty* and *Complexity* have been selected, hit *Search* button

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

CLIA - Clinical Laboratory Improvement Amendments

FDA Home | Medical Devices | Databases

Enter any combination of fields and select Search. You can use the Analyte Drop Down box to select a specific Analyte. For Test System Name/Manufacturer: enter a single word (e.g., Analyzer) or an exact phrase (e.g., Acme Analyzer). [Learn More...](#)

Search Database Help | Download Files

Test System / Manufacturer:

Analyte Name: Show Text Input

Document Number: Complexity: **Waived**

Analyte Specialty: **Toxicology / TDM** 510(k) Exempt?

Effective Date: to

Sort by: **Effective Date (descending)**

[Clear Form](#) **Search**

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- Device Classification
- FDA Guidance Documents
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The results of your query will be displayed based on the search criteria entered (*Analyte Specialty Toxicology/TDM* that have a test *Complexity Waived*). For easier viewing, you may wish to change the Results per Page from the default number 10 to 500 Results per Page:

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

CLIA - Clinical Laboratory Improvement Amendments

FDA Home | Medical Devices | Databases

1 to 10 of 500 Results *
 Analyte Specialty *Toxicology / TDM* Complexity *Waived*
 Effective Date To 05/30/2018

1 2 3 4 5 6 7 8 9 10 >

Results per Page 10

[New Search](#) Export to Excel | Help

Document	Parent	Analyte	Analyte Specialty	Complexity	Effective Date
Innovative Laboratory Solutions, EZ Test Cup					
CR180300	K180349	Amphetamines	Toxicology / TDM	WAIVED	05/25/2018
Innovative Laboratory Solutions, EZ Test Cup					
CR180300	K180349	Cannabinoids (THC)	Toxicology / TDM	WAIVED	05/25/2018
Innovative Laboratory Solutions, EZ Test Cup					
CR180300	K180349	Phencyclidine (PCP)	Toxicology / TDM	WAIVED	05/25/2018
Innovative Laboratory Solutions, EZ Test Cup					
CR180300	K180349	Cocaine metabolites	Toxicology / TDM	WAIVED	05/25/2018
Innovative Laboratory Solutions, EZ Test Cup					
CR180300	K180349	Methadone	Toxicology / TDM	WAIVED	05/25/2018
Innovative Laboratory Solutions, EZ Test Cup					
CR180300	K180349	Propoxyphene	Toxicology / TDM	WAIVED	05/25/2018
Innovative Laboratory Solutions, EZ Test Cup					
CR180300	K180349	Methamphetamines	Toxicology / TDM	WAIVED	05/25/2018
Innovative Laboratory Solutions, EZ Test Cup					
CR180300	K180349	Benzodiazepines	Toxicology / TDM	WAIVED	05/25/2018
Innovative Laboratory Solutions, EZ Test Cup					
CR180300	K180349	Barbiturates	Toxicology / TDM	WAIVED	05/25/2018
Innovative Laboratory Solutions, EZ Test Cup					

9. Question: How do I know if my breath alcohol device is an acceptable FDA Over-The-Counter Device for use under a Limited Service Laboratory Registration Certification?

Response:

Search the FDA Database for IVD Over-The-Counter Lab Test Devices at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm>

If the breath alcohol test device that you wish to use does not appear on the list under **Test Type: Alcohol, Breath**; it may not be used under a Limited Service Laboratory Registration and you must apply for a NYS Clinical Laboratory permit.

10. Question: How do I search the FDA Database for IVD Over-The-Counter breath alcohol test devices at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm>?

Response:

Select **Test Type** (ex: *Alcohol, breath*) and hit **Search** button

The screenshot shows the FDA's 'OTC - Over the Counter' search page. The 'Test Type' dropdown menu is open, displaying a list of test types including 'Alcohol, breath', 'Alcohol, saliva', 'Allergen specific IgE and/or mixed allergen panel', 'Amphetamines', 'Apolipoprotein E (APOE) gene', 'Barbiturates', 'Benzodiazepines', 'Beta-glucocerebrosidase (GBA)', 'Bilirubin, urine', 'BRCA mutations', 'Buprenorphine', 'Cannabinoids (THC)', 'Carbon Monoxide', 'Chloride', 'Cholesterol', 'Cocaine metabolites', 'Creatinine', 'EDDP (methadone metabolite)', and 'Estrone-3 glucuronide'. The 'Alcohol, breath' option is highlighted. Below the dropdown, the search form includes fields for 'Test Name', 'Manufacturer Name', 'Document Number', and 'Effective Date'. The 'Effective Date' field has a date range selector. The 'Sort by' dropdown is set to 'Effective Date (descending)'. At the bottom of the form, there is a 'Search' button, a 'Clear' button, a '10' dropdown for 'Records per Report Page', and a 'Records per Report Page' label. The page footer indicates 'Page Last Updated: 09/10/2018' and provides a note about accessing information in different file formats.

The results of your query will be displayed based on the search criteria entered (Analyte ID: Alcohol, breath). For easier viewing, you may wish to change the Results per Page from the default number 10 to 100 Results per Page:

U.S. Department of Health & Human Services

U.S. FOOD & DRUG ADMINISTRATION

OTC - Over the Counter

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

51 records meeting your search criteria returned - Analyte_ID: Alcohol, breath

Test Name	Document	Test Type	Effective Date
Think Twice, LLC, Think Twice Breath Alcohol Detector	K093143	Alcohol, breath	12/11/2017
Express Diagnostics International AlcoCheck Breath Alcohol Screen Test (0.02, 0.04, 0.05, and 0.08 % BAC)	K102225	Alcohol, breath	08/14/2013
Breathalyzer Equalizer LLC Breathalyzer Equalizer Breath Alcohol Detector 0.05%	K093143	Alcohol, breath	08/01/2013
PAS Alcovisor Mars Breath Alcohol Analyzer	K123470	Alcohol, breath	05/01/2013
PAS Alcovisor Satellite Breath Alcohol Analyzer	K123470	Alcohol, breath	05/01/2013
Express Diagnostics Alcocheck Breath Alcohol Screen (0.02, 0.04, 0.05, and 0.08, % BAC)	K093143	Alcohol, breath	01/02/2013

11. Question: Are there any special staff requirements to provide waived tests?

Response

Yes, testing staff must be trained by a qualified individual with knowledge of the testing procedure. Staff must perform the test as directed by the manufacturer, and in accordance established policies and procedures. Staff must be assessed for competency at least once per year thereafter.

12. Question: What happens if I submit an incomplete or illegible application?

Response:

Applications must be completed as required with no exceptions. The submission of incomplete and/or illegible applications will result in delayed processing.

For questions regarding this document please email: Legal@OASAS.ny.gov