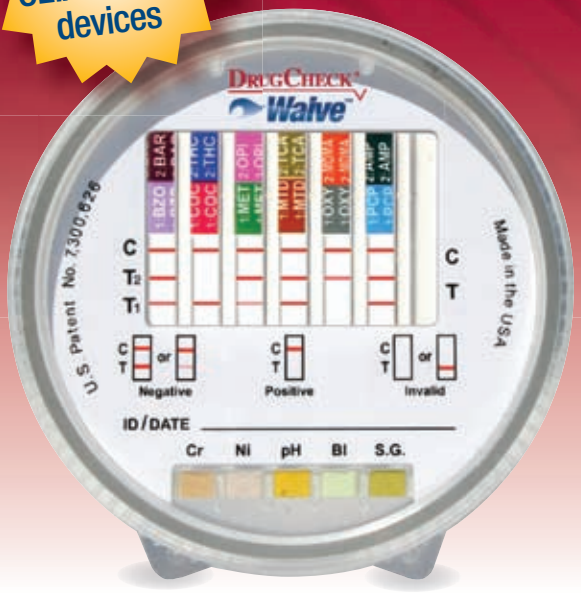
Ride the Waive™

✓ **CLIA-waived cups and dip** ✓ Waived for up to 12 drugs ✓ Lab accuracy
✓ Results in 5 minutes ✓ FDA 510K cleared ✓ Consistent with SAMHSA cut-offs

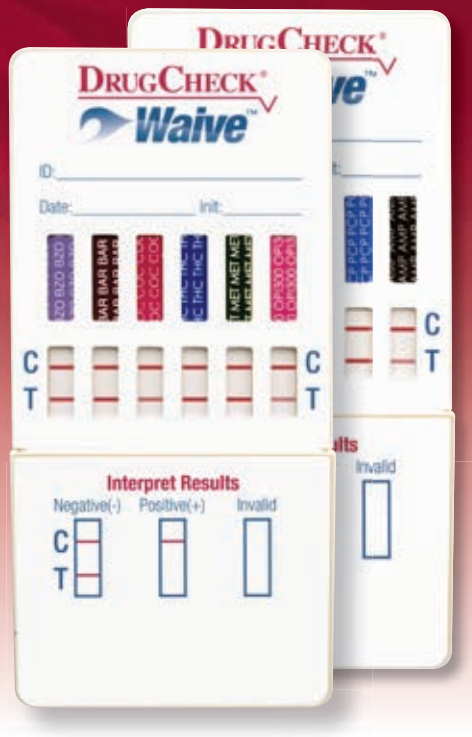
These CLIA-waived screens are some of the simplest, most cost effective drugs of abuse tests on the market. DrugCheck® Waive™ devices provide fast, accurate, easy-to-read results in minutes.

NEW CLIA-waived devices



 # DCC-81205-5
Example shows positive results for THC and OXY

 # DC Waive FP 21200-4
Cup example shows positive results for COC



 # DC Waive-1124
12-panel dip (two sided)

1 *Secure test lid* 2 *Lay cup down* 3 *Interpret results*

Waive™ Test Cup

- Two drugs per test strip
- Operator activated – activate when ready
- Leak-proof urine collection/testing system
- No donor access to test
- Neat, clean, easy – No urine exposure
- OPI 2000 cut-off
- Detects 12 drugs and 5 adulterants (OX, SG, CR, pH, NI)

Waive™ FP Test Cup

- Flat panel for easy copying/scanning & permanent record
- No tipping to activate
- One-way valve prevents urine back-flow
- Gasket/screw top prevents leakage
- Neat, clean, easy – No urine exposure
- OPI 300 cut-off
- Detects 12 drugs and 4 adulterants (OX, SG, CR, pH)

TEST FOR: Amphetamines, Barbiturates, Benzodiazepine, Cocaine, Marijuana, Methadone, Methamphetamines, Methylenedioxymethamphetamine (Ecstasy), Opiates, Oxycodone, Phencyclidine, Tricyclic Antidepressants

CLIA information

Source: http://www.cms.hhs.gov/CLIA/05_CLIA_Brochures.asp

In the wake of reports of inaccurate results from Pap smears intended to detect cervical cancer, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to ensure the accuracy and reliability of all laboratory testing. This legislation, for the first time, extended Federal regulation to all laboratories – hospital, independent, and physician office laboratories, etc. – that perform testing on human specimens for the purpose of diagnosing or treating a disease, illness, or assessment of the health of human beings.

Current regulation

CLIA established three categories of tests:

- Waived tests
- Moderate-complexity tests
- High-complexity tests

Waived tests – simple tests with small chance of error or risk – are exempt from virtually all CLIA rules, as long as testing is performed in strict compliance with the manufacturers' instructions. To follow the manufacturer's instructions for performing the test means to follow all of the instructions in the product insert from "intended use" to "limitations of the procedure." The manufacturer's instructions can be found in the product insert for each test. It is good laboratory practice and important to read the entire product insert before you begin testing.

Does my organization need a certificate?

Under CLIA, if an organization performs a test, including a waived test, on "materials derived from the human body for the purpose of providing information for diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" it is considered to be a laboratory and must register with the CLIA program.

How do I enroll in the CLIA program?

You can enroll your laboratory in the CLIA program by completing an application (Form CMS-116) available online at www.cms.hhs.gov/clia or from your local State Agency. You will need a CLIA certificate for each site where you perform testing unless you qualify for certain exceptions.

For waived testing, CLIA requires that you:

- Enroll in the CLIA program by obtaining a certificate;
- Pay certificate fee every two years;
- Follow the manufacturer's instructions;
- Notify your State Agency of any changes in ownership, name, address or director within 30 days, or if you wish to add tests that are more complex; and
- Permit inspections by a CMS agent, such as a surveyor from the State Agency. However, your laboratory is not subject to a routine survey or inspection.

NOTE: The above is for informational purposes only. Refer to www.cms.hhs.gov for the most current regulations.