

CLIA information

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.

Source: www.cms.hhs.gov/CLIA

Drugs of abuse screen CPT® code: 80101QW

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 manufacturers' 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.

CPT® codes and reimbursement

Drugs of abuse screens are typically billed as 80101 multiplied by the number of drug classes. For billing purposes, drug classes include:

Amphetamines (AMP, MET, XTC)
Barbiturates (BAR)
Benzodiazepines (BZD)
Cocaine (COC)
Methadone (MTD)
Opiates (BUP, MOR/OPI, OXY, PPX)
Phencyclidine (PCP)
Tricyclic/Nortriptyline (TCA)
Marijuana (THC)

Example billing:

A 6-panel cup with PCP/AMP, COC/THC, MET/OPI would be coded as 80101 x 5 because AMP and MET are in the same drug class. CLIA-waived drug tests include a QW modifier next to their CPT® code (80101QW).

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