



Drug Testing to Support Pain Management

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INTRODUCTION

Pain is the number one reason people seek medical care in the United States, and the prevalence of chronic, non-cancer pain (i.e., pain that persists for several months after an injury or disease has been treated) is estimated at 20 to 60 percent over the course of a person's lifetime, affecting as many as one in 10 Americans (more than 25 million people).

Chronic pain disables more people than cancer or heart disease and costs as much as \$635 billion per year in medical costs, disability payments, and productivity. Chronic pain is also the leading cause of health-related absenteeism and is associated with an increased risk of depressive and anxiety disorders.

TREATING PAIN

By treating chronic pain and restoring function, pain management promotes a better quality of life. Pain can be managed in several ways: non-invasive, non-drug pain management (e.g., exercise, massage), traditional pain management (e.g., pain medications), and invasive pain management (e.g., injections, surgery). An effective treatment approach is multi-disciplinary.

Commonly used medications for traditional pain management include opioids, benzodiazepines, antidepressants, anticonvulsants, medical marijuana, and muscle relaxants.

MISUSE OF PAIN RELIEVERS

Pain relievers are the most often used illicit drugs in the United States. The National Survey on Drug Use in Health reports that 13 percent of 12th graders reported nonmedical use of hydrocodone or oxycodone, and 60 percent of people who use pain relievers for nonmedical reasons obtain the drugs from a relative or friend.

One motivation for drug diversion may be financial. The retail price of oxycodone, for example, is approximately \$6 per pill. The street price, on the other hand, may be as high as \$40, so a person selling his/her prescription of oxycodone could make a profit of up to \$34 per pill.

Unfortunately, drug diversion and misuse of prescription medication is also deadly. In 2007, deaths associated with opioid analgesics topped 10,000 (more than five times the number of deaths associated with heroin use).

The FDA now requires drug sponsors and manufacturers of select opiate and opioid formulations, including morphine, methadone, oxycodone, oxymorphone, fentanyl, and hydromorphone, to participate in REMS, or Risk Evaluation and Mitigation Strategies, which are designed to protect patients from harm, by providing educational programs and materials for prescribers and patients.

DRUG TEST OBJECTIVES

Drug testing in the pain management setting is a tool intended to supplement self-reporting and clinical monitoring. Drug testing can detect drug use by verifying adherence to prescribed medications and identifying use of undisclosed drugs; as such, drug testing can discourage drug misuse and abuse.

Urine remains the biologic specimen of choice to determine the presence or absence of various drugs. Urine drug testing is superior to blood testing because there is an increased window of detection (one to three days); it also costs less and is less invasive than blood drug testing.

Urine drug testing in clinical practice should be a consensual diagnostic process, designed to benefit patient care and management. Urine drug testing can provide objective documentation showing compliance or noncompliance with the agreed-upon treatment plan and can assist in the diagnosis and treatment of addiction or drug abuse.

DRUG TESTING APPROACHES

Drug testing for pain management purposes should not mirror traditional drugs of abuse testing. Pain management drug testing is used pre-therapeutically for selected prescription and illicit drugs to help qualify a patient for drug therapy, and periodically (at random) during therapy to verify adherence to the treatment plan. Drug testing is commonly performed using drug screens and confirmation tests.

A drug screen is a qualitative (either positive or negative) test that is usually designed to detect various drugs or drug classes; a screen is generally based on an immunoassay and may be accomplished with point-of-care testing devices.

A confirmation test may be qualitative or quantitative (i.e., report the amount of drug that is present) and is commonly based on methods that are much more specific and sensitive than drug screens. The most common techniques employ a combination of chromatography and mass spectrometry.

The most likely approach for routine pain management testing is to collect a random urine sample and perform a multi-drug qualitative screen. In-office testing provides the most rapid turnaround times and allows discussion of results with the patient in real time. When confirmation testing is indicated, targeted testing for drugs of interest should be utilized.

Confirmation testing is indicated when:

- Screening tests available are not sensitive or specific for the drug(s) of interest.
- Results are inconsistent with clinical expectations.
- Quantitative results are needed to interpret results.
- Pharmacokinetic evaluations are performed.

DRUG TESTING INTERPRETATION	
A negative drug testing result could indicate that:	A positive drug testing result could indicate that:
Drug was not taken or administered.	Appropriate drug was taken.
Drug was taken incorrectly (less than prescribed or less frequently than prescribed).	The drug detected is a metabolite of a prescribed drug.
Drug was not absorbed as expected.	The drug detected represents a process impurity.
Drug was eliminated faster than expected.	Appropriate drug was added directly to the urine.
Drug delivery was variable.	Patient engaged in inappropriate use of unprescribed drug(s).
Specimen was collected too late after use.	Past prescription and time since drug discontinuation were insufficient for elimination.
Specimen was diluted or adulterated.	A prescription was obtained from another clinic.
There was a clinic or lab mix-up.	Incorrect prescription was filled.
The test performed is not designed to detect the drug(s) of interest.	There was a clinic or lab mix-up.
	The test performed has poor specificity, resulting in a false positive.
Failure to detect an expected drug should stimulate investigation of the test, the drug, the patient, and the sample.	Detection of an unexpected drug should stimulate investigation of the test, the drug, the patient, and the sample

Since dose delivery may vary with formulation and pharmacokinetics may vary by patient, a urine drug test cannot reliably evaluate dosing. Urine also varies based on hydration status, renal function, pH, etc. A urine drug test is based primarily on measurement of drug metabolites, which can arise from more than one drug; routine administration of a drug affects the amount of drug and drug metabolites in the urine.

CONCLUSION

Urine drug testing offers many useful opportunities to identify and evaluate patient drug use if testing technologies and frequency of testing are aligned with clinical expectations. Results should be interpreted in the context of the test, drug(s), patient, and sample(s) tested, and unexpected positive or negative results should be discussed with the patient and confirmed as necessary. Dose and dosing of a drug cannot be reliably determined by urine drug testing; testing alternative specimens may be appropriate.

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