

Topics in Drug Testing

Limitations of Point of Care Testing

2023 Podcast Series—Episode 3

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What is drug testing?

- Uses a biological sample (urine, saliva, sweat, or hair), to detect the presence or absence of a specific drug (or drugs) as well as drug metabolites, within a specific window of time
- Is frequently used in clinical, employment, educational, and legal settings¹
 - Screening and diagnosis
 - Treatment and recovery
 - Chronic care management
- Aids in clinical and pharmacological decision making²
- Complements self-report, collateral report, and provider assessment¹
- Urine is the most common specimen for drug testing due to its noninvasive route and ease of sample collection²
 - blood, hair, saliva, sweat, nails, and meconium have been used as well

Clinicians need a basic understanding of drug testing and interpretation²

1. ASAM Consensus Statement: [https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-\(7\).pdf?sfvrsn=2](https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-(7).pdf?sfvrsn=2) Clinical and Public Health Considerations in Urine Drug Testing to Identify and Treat Substance Use: <https://doi.org/10.3109/10826084.2015.1135953>
2. Moeller K, et al. Mayo Clin Proc..May 2017;92(5):774-796

Why is drug testing important?

Clinical Drug Testing is the only objective tool available to determine which substances patients are actually taking

Drug testing plays a critical role in combating the drug misuse epidemic. Drug monitoring using drug testing can help to:

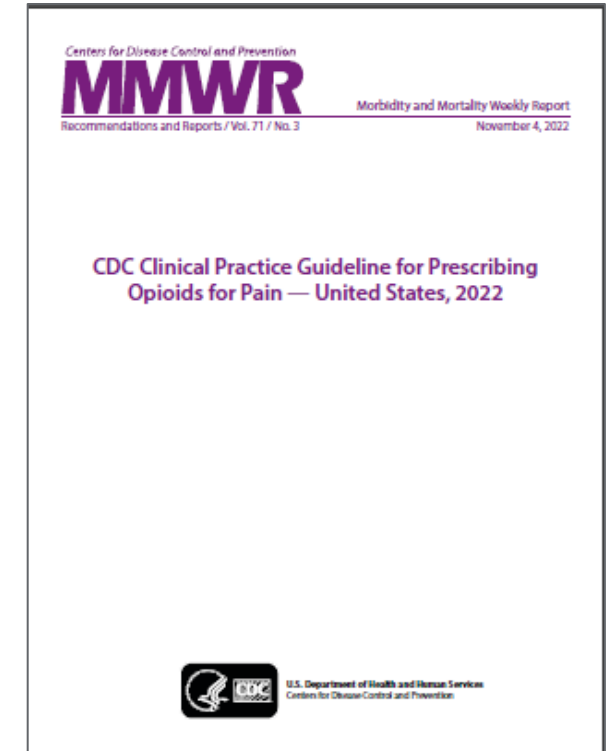
- Identify prescription drug use or non-use
- Detect use of illicit substances
- Identify polysubstance use and potential drug-drug interactions
- Complement Prescription Drug Monitoring Programs (PDMPs) to provide a fuller picture of patient status
- Aid risk mitigation: help keep patients safe, communities safe, and help protect clinician practices
- Maintain patient access to necessary prescription therapies
- Help uncover racial/ethnic disparities in prescription drug management and treatment

Provide insights to inform early detection of drug misuse leading to prevention, intervention, and treatment

Drug testing is supported by guidelines

—The CDC issues new clinical practice guidelines for prescribing opioids for pain in November 2022

- Before starting opioids and periodically (at least annually) during opioid therapy, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances
- Clinicians, practices, and health systems should aim to minimize bias in testing and should not apply this recommendation differentially
- Practice policies regarding testing and frequency can help minimize bias. For example, routine use of testing with standardized policies at the practice or clinic level might help destigmatize their use
- If unexpected results from toxicology screening are not explained, a confirmatory test on the same sample using a method selective enough to differentiate specific opioids and metabolites (eg, gas or liquid chromatography–mass spectrometry) might be warranted
- Limited toxicology screening can be performed with a relatively inexpensive presumptive immunoassay panel. Confirmatory testing should be used when toxicology results will inform decisions with major clinical or nonclinical implications for the patient
- Toxicology tests can provide information about drug use that is not reported by the patient



CDC Clinical Practice Guideline for Prescribing Opioids for Pain–United States, 2022¹

1. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. *MMWR Recomm Rep* 2022;71(No. RR-3):1–95. doi:10.15585/mmwr.rr7103a1

Physicians value drug testing

Medical best practice recognizes the value of presumptive screening and definitive testing to confirm a result on the same specimen (Results from Quest Diagnostics Health Trends physician survey)

Physicians value presumptive and definitive drug testing:

86% ●●●●●●●●●●

See definitive drug testing as essential to providing care to patients prescribed controlled substances

61% ●●●●●●●●●●

Believe that definitive drug testing is “worth it at any cost”

75% ●●●●●●●●●●

Say definitive drug testing is the only way they truly know what drugs their patient is taking

55% ●●●●●●●●●●

Agree that presumptive tests miss a lot of misuse that definitive drug tests identify

2 Methods of clinical drug testing: Presumptive and Definitive

What's the role of Presumptive testing? Definitive testing?

Presumptive testing methods include rapid point-of-care (POC) devices as well as more sensitive laboratory immunoassays. While POC testing devices (eg, cups), provide rapid and inexpensive qualitative results, POC testing:

- Often has lower sensitivity and specificity, which may lead to false-negative and false-positive results
- **May not be available for some commonly used and misused medications such as gabapentin, and emerging synthetic drugs**
- **Results are preliminary** and may require definitive laboratory confirmation, as per FDA labeling on some POC devices as well as medical guidelines

Definitive testing uses highly complex laboratory instruments to identify and quantify prescription medications, illicit substances, and specific parent drugs and their metabolites often missed by POC testing

- Definitive testing is recommended for certain situations, such as for a positive presumptive test for a patient showing signs of misuse
- Definitive testing provides greater sensitivity, can confirm or refute presumptive test results, and reduces the occurrence of false-positive/ false-negative results
- Definitive testing can take longer to produce a result and is typically more expensive than presumptive testing

Medical best practice recognizes the value of presumptive screening and definitive testing to confirm a result on the same specimen

Facts about POCT (point-of-care testing)

Are results on 2 different analyzers interchangeable?

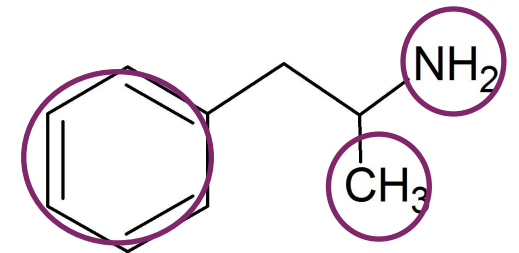
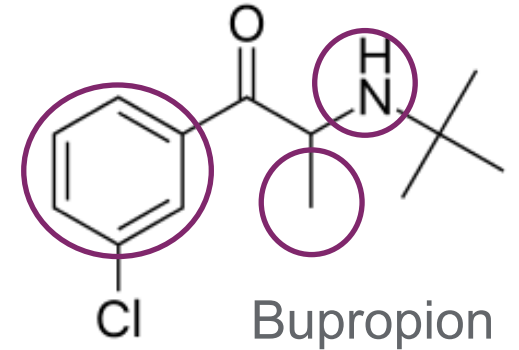
- Specimen analysis that is performed outside of the clinical laboratory setting. The testing is usually performed in close proximity (e.g., chairside or bedside) to the patient when rapid results are needed
- POCT is regulated by the Centers for Medicare and Medicaid Services through the Clinical Laboratory Improvement Amendments (CLIA)
- Some states require professional licensure of individuals who perform moderate complexity POCT that do not have a degree in clinical laboratory science
- The FDA determines complexity for all laboratory tests. Waived testing or CLIA-waived testing refers to testing that is simple to perform and demonstrates low risk of obtaining erroneous results
- Testing performed on different analyzers (e.g., POCT v clinical laboratory immunoassay) are not interchangeable

[Clinical Drug Testing in Primary Care \(samhsa.gov\)](http://samhsa.gov)

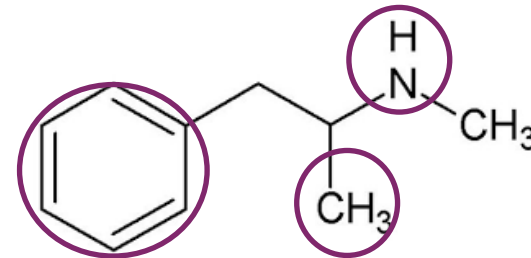
What is cross-reactivity?

Presumptive tests (e.g., POCT) may experience varying rates of cross-reactivity between different drug classes and/or devices

- Cross-reactivity occurs when a test cannot distinguish between the substance being tested for and substances that are **chemically similar** to each other
- Substances other than the one being tested for may cross-react with the antibody in the presumptive test (e.g., POCT) to generate a 'false positive' result
- For example,
 - Bupropion, an antidepressant, may cause a positive for 'amphetamines' on a POCT
 - Phentermine, a weight loss medication, may cause a positive for 'amphetamines' on a POCT



Amphetamine



Methamphetamine

Why do 'false-negative' results occur?

Sensitivity – A drug test's ability to reliably detect the presence of a drug or metabolite at or above the 'cutoff'

- A 'cutoff' is a threshold at or above which a result is considered positive or below which a result is considered negative
- A 'false negative' result occurs when a test fails to detect the presence of the drug or metabolites
- This may occur due to low sensitivity demonstrated by the limitations of presumptive testing (i.e., POCT)
- 'False-negative' results may occur on definitive testing when cutoffs are set too high
- These occurrences can miss instances of potential drug relapse, low dosing of drugs, and drugs that store in the body for prolonged periods of time

Reliability of POCT results

A false sense of security?

Operator education/competency may impact reliability of a POCT result.

- The simplicity of CLIA-waived POCT may be deceptive and create a false sense of security
- Inexperienced personnel performing POCT may be not be privy to the limitations of POCT devices
 - Operators may be unfamiliar with appropriate test procedures, instrument maintenance, calibration, or quality control
 - Operators may not be familiar with the drug test menu the POCT provides and may assume a negative test means absence of substance when in actuality the POCT device did not test for the substance of interest
 - Operators may not be aware of the propensity for '**false negative**' results' in POCT and may incorrectly assume a patient is negative for an illicit drug or prescribed controlled substance
 - Operators may not be aware of the propensity for '**cross reactivity**' that can generate '**false positive**' POCT results and may lead to incorrect accusations of drug use
 - Operators may incorrectly assume that the depth of color or rapid result may correlate to the amount of drug consumed
- This may lead to incorrect interpretations of results and put clinicians at risk of damaging the provider-patient relationship

Possible limitations with point of care, presumptive drug testing

Results from Quest Diagnostics Health Trends physician survey and Population Health Management study

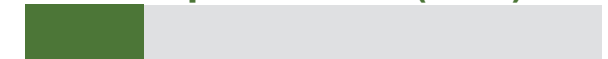
- Roughly half of all physicians who have prescribed controlled substances in the past 6 months do not order definitive testing for positive (51%) or inconclusive (47%) presumptive results
- While definitive testing is not always required, these survey findings take on new urgency amid increased fentanyl-drug combining and limitations in identifying fentanyl, a major source of overdose deaths
- Quest research shows that presumptive testing by point-of-care devices may miss true positive specimens (see graph)

If only presumptive tests at point of care are used, positive specimens may be missed for¹

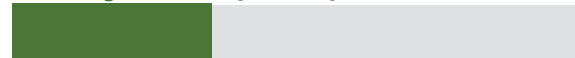
Fentanyl (74%)



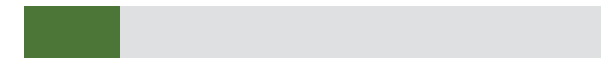
Methamphetamine (16%)



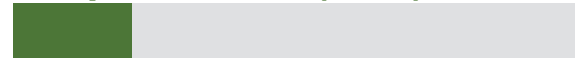
Marijuana (29%)



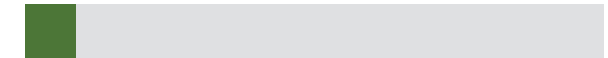
Oxycodone (11%)



Amphetamine (17%)



Cocaine (7%)



Quest Diagnostics Health Trends®, January 2020– December 2020

1. Niles JK, Gudín J, Radcliff J, Kaufman HW. The opioid epidemic within the COVID-19 pandemic: Drug testing in 2020. Population Health Management. 2021;24(S1). doi10.1089/pop.2020.0230.

Conclusion

Why should you drug test?

- Manage prescription drug use
 - Positive for prescribed drug(s) of interest
 - Negative for illicit drugs and other prescribed drugs
- Objectively analyze adherence to the plan
- Help diagnosis substance misuse, abuse, and addiction
- Identify patients who may be diverting medications
- Meet expectations of medical boards and regulatory agencies
- Advocate for patients
- **PROTECT YOURSELF**

Quest Best Practices

We provide and support (advocate for) **responsible drug testing**

- **At Quest, our best practices include presumptive testing with definitive testing for confirmation of positives or when clinically appropriate.** This helps minimize over-testing while providing the right level of information needed to make informed decisions. We understand every situation is different and partner with customers to provide flexible solutions that meet their patients' needs and the needs of their practice
- **We provide only clinically relevant panels and are up-front about costs,** offering financial assistance programs and transparency about prior authorization
- **We are committed to reducing health disparities.** Our Quest for Health Equity initiative aims to address key social determinants of health in underserved communities, providing equitable care to everyone, no matter where they are or what their condition is

Close

Thank You for your time today

Backup

Results from Quest Diagnostics Health Trends physician survey —Clinical drug testing is deemed the standard of care

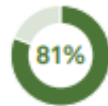
Key Finding: Clinical drug testing is considered critical by physicians to preventing drug misuse and overdose, but clearer guidelines would help optimize this tool

- The larger majority of physicians agree that clinical drug testing is critical to preventing drug misuse (88%) and overdose deaths (81%), and is increasingly becoming the standard of care when prescribing controlled substances (86%)

Clinical drug testing is deemed the standard of care



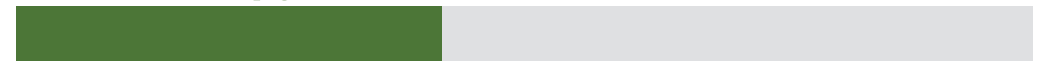
88% agree that clinical drug testing is critical to preventing drug misuse



81% agree that clinical drug testing is critical to preventing overdose deaths

- The most common practice of physicians is to use a combination of presumptive and definitive tests on the same specimen
- Specifically, 39% of physicians who use clinical drug testing perform a presumptive test first and, if the result is positive or inconclusive, perform a definitive test on the sample collected on the same day as the presumptive test

39%

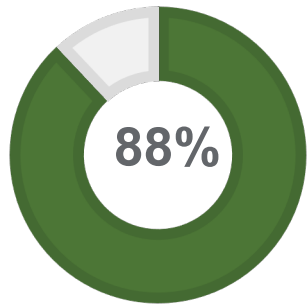


Physicians who order presumptive and definitive tests (to confirm a positive or inconclusive presumptive test) on the same sample

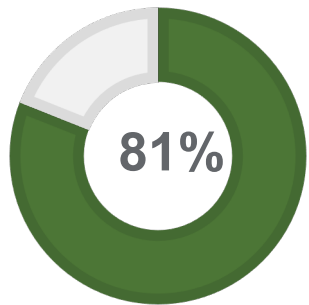
- By comparison, 16% order only presumptive tests and 19% order definitive tests for all patients

Key Finding 5: Clinical drug testing is critical to prevent drug misuse

Clinical drug testing is deemed standard of care

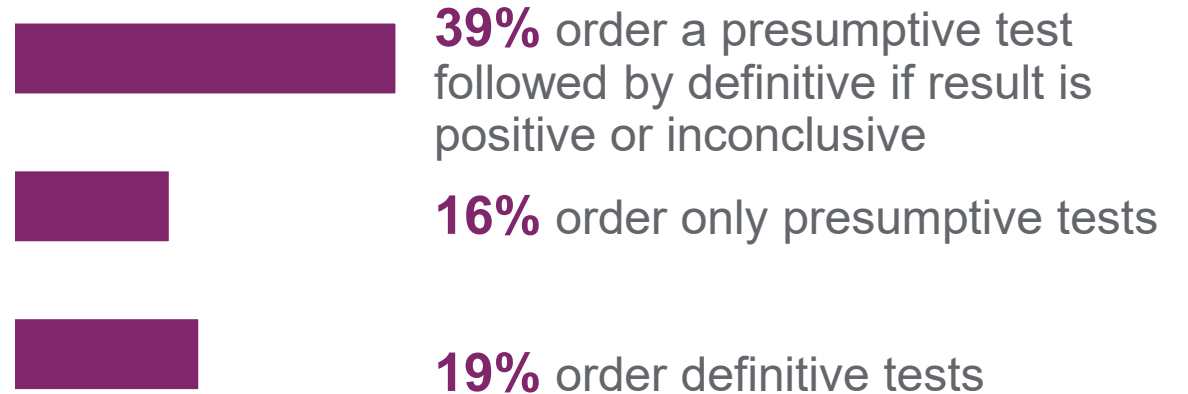


88% agree that clinical drug testing is critical to preventing drug misuse



81% agree that clinical drug testing is critical to preventing overdose deaths

Physicians commonly use a combination of presumptive and definitive tests



What insights can drug testing surveillance data provide?

- Which drugs are being misused in the country, the state, the community?
- Which patient groups represent the largest risk for drug misuse?
- How do different treatment programs compare within a local community, state, region, etc?
- Are providers adequately informed to identify potentially dangerous polysubstance use?
- Are the patients enrolled in treatment programs adhering to their MAT regimen?
- Are providers testing for the right drugs and substances?
- **Have treatment programs successfully impacted the drug misuse epidemic in their local communities?**

How do clinicians decide which test to choose?

Presumptive Test

Chemistry Instrumentation or Mass Spectrometry

- Testing is performed at the drug class level
- Qualitative results are produced
- If result is negative, testing ends
- If result is presumptive positive, further testing is needed to identify the drugs/metabolites

Presumptive Positives confirmed by Definitive Test (if ordered)

Presumptive positive tests are followed by confirmation testing, if ordered

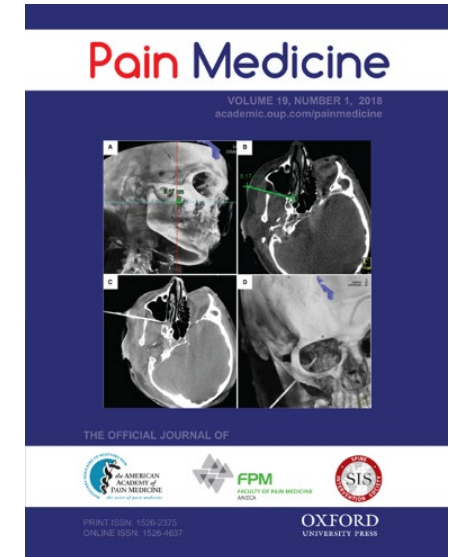
Mass Spectrometry Definitive Test

Definitive test is performed using Mass Spectrometry

- Drug(s) and metabolite(s) are identified
- Qualitative or quantitative results are reported
- Confirmations and Direct-to-Definitive

Rational urine drug monitoring in patients receiving opioids for chronic pain: consensus recommendations (AAPM)

- To develop consensus recommendations on urine drug monitoring (UDM) in patients with chronic pain who are prescribed opioids
- Definitive testing is recommended as most clinically appropriate for UDM because of its accuracy; however, institutional or payer policies may require initial use of presumptive testing (ie, immunoassay)
- The rational choice of substances to analyze for UDM involves considerations that are specific to each patient and related to illicit drug availability
- Appropriate opioid risk stratification is based on patient history (especially psychiatric conditions or history of opioid or substance use disorder), prescription drug monitoring program data, results from validated risk assessment tools, and previous UDM
- Urine drug monitoring is suggested to be performed at baseline for most patients prescribed opioids for chronic pain and at least annually for those at low risk, 2 or more times per year for those at moderate risk, and 3 or more times per year for those at high risk. Additional UDM should be performed as needed on the basis of clinical judgment



Conclusions

- Clinicians who prescribe controlled substances must develop risk management strategies including skill sets in drug testing as well as mitigation of drug misuse and abuse
- **Drug monitoring is standard of care when managing patients on controlled substances**
- Communicate with your laboratories and toxicologists to ensure proper interpretation of test results
 - 1.877.40.RX.TOX (1.877.407.9869)
- More structured therapy with comprehensive monitoring plans can help patients adhere to opioid-based treatment regimens, especially those who are higher risk or display aberrant behaviors
- Better guidelines for drug monitoring are needed from regulatory agencies and medical societies