Med-Lake Laboratory

QUARTERLY NEWSLETTER

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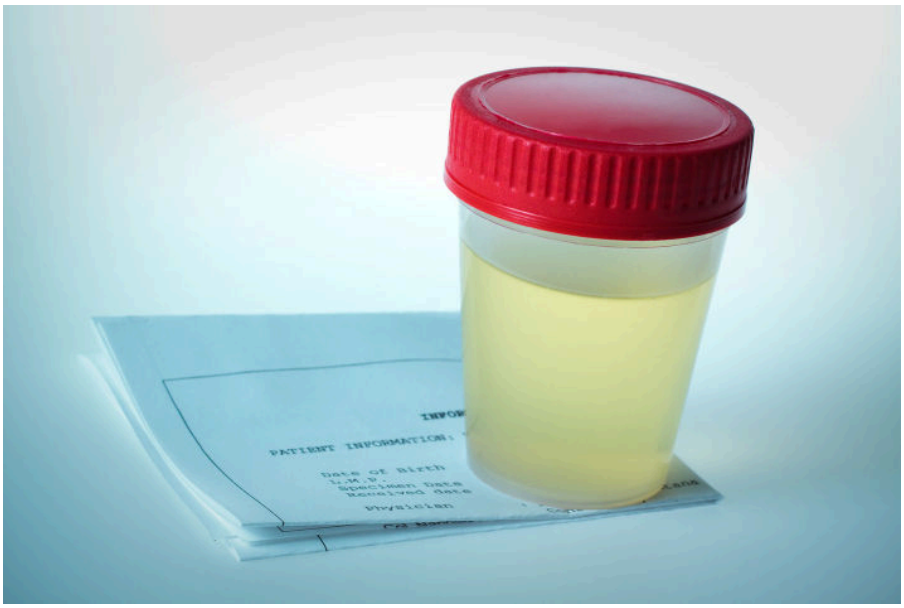

Urine Drug Testing

Urine drug testing (UDT) provides timely, objective, and actionable information to clinicians by identifying the presence or absence of drugs of potential abuse in the body to assist the clinician in making treatment decisions. Patients are put into one of three groups based on their specific needs: Group A, Group B, or Group C.

Group A - Symptomatic patients, Multiple drug ingestion, and/or Patients with unreliable history

A patient who presents in a variety of medical settings with signs or symptoms of substance use toxicity will be treated presumptively to stabilize the patient while awaiting presumptive, then definitive testing to determine the cause(s) of the presentation. The need for definitive UDT is based upon presumptive test findings, responses to medical interventions, and treatment plan. A presumptive UDT should be performed as part of the evaluation and management of a patient who presents in an emergency room or urgent care setting with any 1 of the following:

- Coma;
- Altered mental status in the absence of a clinically defined toxic syndrome or toxidrome;
- Severe or unexplained cardiovascular instability (cardiotoxicity);
- Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome;
- Seizures with an undetermined history;
- To provide antagonist to specific drug.

The presumptive findings, definitive drug tests ordered, and reasons for the testing must be documented in the patient's medical record.

Group B - Diagnosis and treatment for substance abuse or dependence

A patient in active treatment for a SUD or monitoring across different phases of recovery may undergo medical management for a variety of medical conditions. A physician who is writing prescriptions for medications to treat either the SUD or other conditions may need to know if the patient is taking substances which can interact with prescribed medications or taking prescribed medications as expected. The risk of drug-drug interactions is inherent to the patient and may be compounded by prescribed medications. UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment. The UDT result influences treatment and level of care decisions. Ordered tests and testing methods (presumptive and/or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM V) diagnosis. For patients with no known indicators of risk for SUD, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT. For patients with known indicators of risk for SUD, the clinician may screen for a broad range of commonly abused drugs using definitive UDT. For patients with a diagnosed SUD, the clinician should perform random UDT at random intervals to properly monitor the patient. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:

- Patient history, physical examination, and previous laboratory findings;
- Stage of treatment or recovery;
- Suspected abused substance;
- Substances that may present high risk for additive or synergistic interactions with prescribed medication (e.g., benzodiazepines, alcohol).

The patient's medical record must include an appropriate number of UDTs billed over time based on the stage of screening, treatment, or recovery; and the rationale for the drugs/drug classes ordered; the results must be documented in the medical record and used to direct care.

Group C - Treatment for patients on chronic opioid/opiate therapy (COT).

A physician who is writing prescriptions for medications to treat chronic pain can manage a patient better if the physician knows whether the patient is consuming another medication or substance, which could suggest the possibility of SUD or lead to drug-drug interactions.

Additionally, UDT may help the physician monitor for medication adherence, diversion, efficacy, side effects, and patient safety in general. A broad cross section of the general population will develop either cancer pain syndrome or non-cancer pain which will require prolonged or chronic opioid therapy for management with normal risk of addiction inherent to the substance(s) exposed.

1. COT UDT Testing Objectives:

a. Identifies absence of prescribed medication and potential for abuse, misuse, and diversion;
b. Identifies undisclosed substances, unsanctioned prescription medication, or illicit substances;
c. Identifies substances that contribute to adverse events or drug-drug interactions;
d. Provides objectivity to the treatment plan;
e. Reinforces therapeutic compliance with the patient;
f. Provides additional documentation demonstrating compliance with patient evaluation and monitoring;
g. Provides diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

2. Medical Necessity Guidance:

Criteria to establish medical necessity for UDT must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements:[12]

a. Patient history, physical examination, and previous laboratory findings;
b. Current treatment plan;
c. Prescribed medication(s);
d. Risk assessment plan.

National pain organizations, physician societies, and the Federation of State Medical Boards[13] recommend a practical management approach to definitive UDT for COT. The number of UDTs billed over time beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record. Recommendations for the ordering of presumptive and definitive UDT for patients on COT are as follows:

3. COT Baseline Testing:

Depending on the patient's specific circumstances, initial presumptive and/or definitive COT patient testing may include amphetamine/ methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, tetrahydrocannabinol, opioids, opiates, heroin, and synthetic/analog or "designer" drugs.

4. COT Monitoring Testing:

a. Ongoing testing may be medically reasonable and necessary based on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern. As part of the clinical evaluation of the patient, the provider should inquire about prescription compliance and potential issues of abuse or diversion such as lost prescriptions, early refill requests, or requests for escalating dose of medication. The number of UDTs billed over time must be based on the individual's risk potential. Appropriate number of UDTs billed over time based on risk is listed in the table below.
b. The clinician should perform random UDT at random intervals to properly monitor a patient. UDT testing does not have to be associated with an office visit.
c. Patients with specific symptoms of medication aberrant behavior or misuse may be tested in accordance with this document's guidance for monitoring patient adherence and compliance during active treatment (<90 days) for substance use or dependence.

Other Covered Services

1. Reflex Testing by Reference Laboratories – since reference laboratories do not have access to patient-specific data, reflex testing under the following circumstances is reasonable and necessary:
   a. To verify a presumptive positive UDT using definitive methods that include but are not limited to GC-MS or LC-MS/MS before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or
   b. To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician.
2. When medical record documentation that is individualized for a particular patient satisfies medical necessity requirements found elsewhere in this LCD (e.g., risk assessment, frequency), direct to definitive UDT without a presumptive UDT may be reasonable and necessary.
3. Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:
   a. The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
   b. Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or
   c. When there is an unexpected negative presumptive UDT result, and it is clinically imperative to know if it is truly positive or negative; the medical record should state such.
4. Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan.

Testing must be based on clinician's documented medical necessity and reviewed by the clinician in the management of prescribing/renewing a controlled substance for every risk group outlined below.

Risk Group	Baseline	Frequency of Testing
Low Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 2 times each in a rolling 365 days for prescribed medications, non- prescribed medications that may pose a safety risk if taken with prescribed medications, and illicit substances based on patient history, clinical presentation, and/or community usage.
Moderate Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 2 times each in a rolling 180 days for prescription medications, non- prescribed medication that may pose a safety risk if taken with prescribed medications, and illicit substances, based on patient history, clinical presentation, and/or community usage.
High Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 3 times each in a rolling 90 days for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed and illicit substances based on patient history, clinical presentation and/or community usage.

*Note: Any additional definitive UDT beyond recommendations above must be justified by the clinician in the medical situations in which changes in prescribed medications may be needed, such as:

- Patient response to prescribed medication suddenly changes;
- Patient side effect profile changes;

- To assess for possible drug-drug interactions;
- Change in patient's medical condition;
- Patient admits to use of illicit or non-prescribed controlled substance.

Reference: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34645

A Message From Management

At Med-Lake Laboratory, we recognize that our laboratory services are only as strong as the partnerships we build—with both our clinical clients and our incredible sales team. Every test we perform supports a patient, a physician, and a promise of accuracy, speed, and reliability.

As our laboratory continues to grow, we strive to invest in expanding our testing capabilities across blood, molecular, and toxicology. From high-sensitivity PCR to advanced LC-MS workflows, our teams are committed to ensuring the highest quality results, backed by rigorous QC protocols and CAP-compliant standards.

Our turnaround times remain a priority, and we continually implement new process improvements that allow for faster reporting without compromising precision. We also maintain detailed documentation for all lab processes, and routinely audit internal procedures to identify opportunities for continuous improvement. These practices ensure that our clients can trust the results they receive—whether it's a routine CBC, a complex PCR panel, or a detailed toxicology confirmation.

You can feel confident knowing that behind every sample is a dedicated technical team ready to deliver results that reflect the high standards that are promised by our laboratory. We're here to support you with accurate data and ongoing improvements.

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