Alliance Toxicology LLC provides clinical drug testing services for physicians. Our company provides a comprehensive drug testing panel which includes over 40 commonly prescribed prescription drugs. The following pages provide information on our company and the reasons for implementing a urine drug testing program. The following pages include:

1.) An overview of why urine drug testing for clinical purpose makes sense for physicians in order to provide better care for their patients, to monitor their patients’ drug treatment regimens, as well as protect their practice.
2.) ACOEM Guidelines recommendation for urine drug screening for patients prescribed opioids for chronic pain.
3.) A sample letter to insurance carriers explaining the medical necessity for clinical urine drug testing.
4.) A sample Alliance Toxicology LLC urine drug testing results Form showing the drugs included in the comprehensive panel.

If you have any questions regarding the information provided in this binder, please do not hesitate to contact me.

Regards,

Kim Hansen
Director of Operations
Alliance Toxicology LLC

Cell: 714-496-6164
Email: kim@alliancetox.com
Kim Hansen – Director of Operations
   kim@alliancetox.com
   714.496.6164

Tanya Moreland – Director of Sales and Marketing
   tanya@alliancetox.com
   949.375.7128

Diego Encinas - Operations/Tech Manager
   Diego@alliancetox.com
   714.280.7759

Jodi Little - Office/Scheduling Manager
   Jodi@alliancetox.com
   714.542.2153

Jason Hansen - Technical Consultant
   jason@alliancetox.com
   619.838.7908

Jason Shorb - Arizona Sales & Marketing
   jshorb@alliancetox.com
   602.750.3468

Brittani Summers - Administration/Results
   admin@alliancetox.com
   858.222.6137

Martin Pieretti - Medical Review Officer
   mpieretti@vzw.blackberry.net
   877-340-6101 office
   267.549.6488 cell

Corporate Address
   PO Box 5000, PMB 190
   Rancho Santa Fe, CA 92067

   Administrative Offices
   540 N. Golden Circle #202
   Santa Ana, CA 92705
Why Clinical Urine Drug Testing?
Why Utilize Urine Drug Testing In Your Clinical Practice?...

- To provide better care for your patients:
  - Patient advocacy
    - UDT can be used to advocate for patients in family, workplace, and contested situations as documentation of adherence to an agreed-upon treatment plan
    - When a patient agrees to a UDT program it reduces the risk of an undiagnosed drug misuse problem
  - Identifying abuse of prescribed drugs
    - A UDT program can be used to ensure compliance of the directed treatment plan and to identify whether a patient is taking other drugs in addition to those prescribed by the physician, which can be fatal

- To protect your practice:
  - Physicians can be held liable for patients misusing or abusing prescription drugs
    - A UDT program can be valuable in an investigation or law suit to show that your practice is taking all possible efforts to protect patients from prescription drug misuse and abuse
  - The Drug Enforcement Agency (DEA) investigates medical practices and meticulously examines records
    - If the DEA feels a physician is not properly managing the distribution of controlled substances, they can shut down a physician’s practice, take away a physicians license, or even prosecute in extreme circumstances
    - A UDT program will show that the practice is actively helping to control illegal distribution of controlled substances by patients
  - Uncovering diversion or prescription drug trafficking
    - A UDT program can be used to investigate possible diversion or drug trafficking by analyzing inconsistencies in the drug prescription amount versus the actual quantities shown from the lab results

www.alliancetox.com
ACOEM Guidelines
Recommendation:
Urine Drug Screening for Patients Prescribed Opioids for Chronic Pain
6. Recommendation: Urine Drug Screening for Patients Prescribed Opioids for Chronic Pain

Routine use of urine drug screening for patients on chronic opioids is recommended as there is evidence that urine drug screens can identify aberrant opioid use and other substance use that otherwise is not apparent to the treating physician. \(^\text{614,615}\)

**Indications** – All patients on chronic opioids for chronic pain.

**Frequency** – Screening is recommended at baseline, randomly at least twice and up to 4 times a year and at termination. Screening should also be performed “for cause” (e.g., provider suspicion of substance misuse including over-sedating, drug intoxication, motor vehicle crash, other accidents and injuries, driving while intoxicated, premature prescription renewals, self-directed dose changes, lost or stolen prescriptions, using more than one provider for prescriptions, non-pain use of medication, using alcohol for pain treatment or excessive alcohol use, missed appointments, hoarding of medications and selling medications). Standard urine drug/toxicology screening processes should be followed (consult a qualified medical review officer).\(^\text{616}\)

**Strength of Evidence** – Recommended, Evidence (C)

**Rationale for Recommendations**

While there are many quality studies of opioids for treatment of chronic, non-malignant pain, there is a dearth of quality evidence regarding long-term efficacy or adverse effects. Thus, there are no large-scale studies with robust data to definitively address these important questions. Most of the available evidence from studies of non-malignant pain addresses nociceptive pain, with a few studies including a minority of patients with neuropathic pain. Evidence to support treatment of neuropathic pain with opioids is weak. There is evidence that tramadol is effective for treatment of neuropathic pain,\(^\text{617}\) and that oxycodone is effective despite adverse effects.\(^\text{618}\) However, carbamazepine is more effective than morphine.\(^\text{619}\) There is evidence that opioids are not particularly effective for treating radicular pain syndromes.\(^\text{620}\) There is no quality evidence evaluating opioids for the treatment of trigger points/myofascial pain. The conclusions derived from a direct review of the RCTs regarding opioid use for chronic, non-visceral pain conditions are consequently consistent with those reached by the systematic reviews and meta-analyses described both previously and in Appendix 5. While many, although not all, of the studies suggest that the use of short- and medium-term opioids may lead to a decrease in pain when compared to placebo, they do not allow one to conclude that the use of opioids is consistently accompanied by evidence of functional benefit or increased quality of life. They also do not allow for conclusions to be drawn regarding the efficacy of chronic opioid therapy. It is unknown whether this reflects the failure of studies assessing the impact of long-term opioids to have been performed, or whether the absence of such studies reflects investigative biases (studies were not performed) or publication biases (studies demonstrating lack of long-term efficacy were performed and not published). Nonetheless, the absence of evidence is not evidence of absence, and it is possible that the data with regards to the benefits accrued from chronic opioid use in the “general” chronic pain population may not be uniformly applicable to discreet patient subsets. In other words, it is possible that appropriate patient selection and follow-up, coupled with discontinuation of opioid therapy in those who fail to show benefit, may facilitate identification of a subgroup of the pain population that would demonstrate increased functionality on opioids.

There is quality evidence that other medications and treatments are superior to opioids for both patients with nociceptive pain and those with CRPS; however, a select number of patients are believed to do better with opioids than without them. If a patient can not tolerate or has failed other therapies for nociceptive pain or CRPS, a trial of opioids may be warranted and continued if use is associated with documented functional gains. Even so, the goal should be to employ other rehabilitative interventions with reduction or eventual elimination of opioids as a treatment goal. The decision to treat a patient with opioids, both short- and long-term should be undertaken with care. Since this decision typically has long-term impacts, if the practitioner does not have specialized knowledge and/or experience regarding the appropriate use of opioids it is generally recommended that a second opinion from a physician with experience in chronic pain management and/or a
Medical Necessity For Urine Drug Testing
TO: Bill Review Examiner

RE: Medical Necessity of Clinical Urine Drug Testing

Please see the attached urine drug test results for the patient indicated on the form. If you are unfamiliar with Urine Drug Testing (UDT) for clinical practice, please see the following bullet point list describing the benefits and necessity for clinical UDT. UDT has become very common in pain management clinics as well as industrial clinics throughout the country. The number of doctors who are adamantly requesting this service be performed on their patients is consistently growing for the following reasons:

A.) To better monitor their patients:
   a. A urine drug test can provide extremely valuable information to the doctor as to whether patients are in compliance with their agreed-upon drug treatment regimen.
      i. Patients with negative results can signal that the patient is not taking the prescribed drugs and possibly trafficking them
      ii. Patients with positive results for drugs that are not being prescribed by the primary treating physician can indicate a potential drug abuse problem. This information can be valuable in preventing a potential fatal drug interaction or overdose.
      iii. Patients who may be adulterating their specimen can be identified by the pH and creatinine level information in the urinalysis portion of the urine drug test, which can be an indication of aberrant behavior

B.) To protect their practice
   a. Physicians can be held liable for patients misusing or abusing prescription drugs
      i. A UDT program can be valuable in an investigation or law suit to show that their practice is taking all possible efforts to protect patients from prescription drug misuse and abuse
   b. The Drug Enforcement Agency (DEA) investigates medical practices and meticulously examines records
      i. If the DEA feels a physician is not properly managing the distribution of controlled substances, they can shut down a physician's practice, take away a physicians license, or even prosecute in extreme circumstances
      ii. A UDT program demonstrates to the DEA that the practice is actively helping to control illegal distribution of controlled substances by patients by analyzing inconsistencies in the drug prescription amount versus the actual quantities shown on the laboratory results

In summary, physicians deem clinical urine drug testing medically necessary for the important reasons listed above. From an insurance carrier’s perspective, the implementation of a urine drug testing program ensures that the medications being prescribed by the primary treating physician are controlled and patient behavior in regards to his/her prescribed medications is being monitored.

For additional information and medical opinions regarding UDT, please see the following appendix which contains excerpts taken from recognized industry periodicals, reports, and government agencies describing the purpose of and medical treatment benefits of UDT.
Appendix I:
Excerpts from Industry Periodicals

If you are unfamiliar with Urine Drug Testing (UDT) for clinical practice, please see the following excerpts below taken from recognized industry periodicals, reports, and government agencies describing the purpose of and medical treatment benefits of UDT:

Although only a minority of patients either misuse or become addicted to their prescribed medications, those who do generally have a current or past history of substance misuse or addiction.¹ There is no evidence in the literature that rational pharmacotherapy for the treatment of any medical condition leads to iatrogenic addiction; however, there is no evidence to the contrary either. Therefore, routine screening for a history of misuse or addiction in all patients is appropriate before prescribing any medication, especially a controlled substance.¹ This may include a UDT to determine whether the patient is taking or has recently taken illicit and/or licit non-prescribed substances.¹

“The Federation of State Medical Boards (FSMB) adopted a policy for prescribing controlled substances stressing the critical importance in documenting, evaluating, and monitoring controlled substances in the management of pain patients. This is consistent with the guidelines set forth by federal agencies including the Drug Enforcement Agency (DEA). Part of this policy — dealing with the implementation of monitoring drug compliance — is the regular use of UDT.”²

Urine Drug Testing can be used to provide objective documentation showing adherence to the agreed-upon treatment plan, to aid in the diagnosis and treatment of the disease of addiction or drug misuse, if present, and to advocate for the patient in family and social issues.³

The Center for Disease Control (CDC) recommends tightening regulatory measures, improving physician awareness, supporting treatment for drug dependence and possibly modifying drugs themselves to reduce the potential for abuse. The CDC attributes the 62.5% rise in drug overdose deaths from 1991-2004 to a higher use of prescription painkillers.⁴

“Monitoring the behavior alone of patients on chronic opioid treatment will fail to detect potential problems revealed by urine toxicology testing.”⁵

“Rule out drug diversion by documenting that you are able to recover the prescribed medications with a urine drug screen.”⁶

“Urine drug testing can improve a physician’s professional ability to manage therapeutic prescription drugs with controlled substances, and to diagnose substance abuse or appropriate intake of drugs, thereby leading to proper treatment”.⁷

Drug Overdose is the second leading cause of accidental death in the United States and the leading cause of death for California’s opioid-using population.⁸

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² "Urinary Drug Testing in Pain Management", *Practical Pain Management*. Florete, Orlando G. Jr., MD, April 2005
³ *Urinary Drug Testing in a Clinical Practice: Dispelling the Myths and Designing Strategies*. Heit, Howard MD et al 2006 (CME Accredited)
⁸ California SB 767 Hearing April, 2007
Sample Urine Drug Test Results Form
**Patient Information**
- **Specimen ID:** 123456789
- **Last Name:** DOE
- **First Name:** JOHN
- **SS#:** 555-44-3333
- **DOB:** 1/2/1970
- **Sex:** MALE
- **Address:** 1234 EASY STREET
- **City:** LOS ANGELES
- **State:** CA
- **Date of Injury:** 1/1/2009
- **Insurance:** ABC INSURANCE
- **Claim #:** 987654321
- **Diag Code:** 840

**Physician Information**
- **Clinic Name:** ABC MEDICAL
- **Prescriber Name:** DR. JANE DOE
- **State License #:** A1234567
- **DEA #:** BD1234567
- **Office Address:** 555 FIRST AVE
- **City:** LOS ANGELES
- **State:** CA
- **DOB:** 1/2/1970

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**Specimen Test Result:** POSITIVE

### Drugs Tested

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<th>Cutoff (ng/ml)</th>
<th>Result</th>
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**Drugs Tested**

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**Urinalysis Report**

- **Creatinine Urine (mg/dL):** 333.0 Normal
- **pH Urine:** 6.8 Normal

**General Information**

- **Lab Address:** 8433 Quivira Road; Lenexa, KS 66215
- **Date of Report:** 6/3/2010
- **MRO Notes:** Test Cancelled