



ACCU-TELL[®]
One Step Multi-Line Test Cassette
For in vitro diagnostic use only

for Urine Samples

This package insert is applied to the below products:

| Catalog No. | Product Name |
|--------------|-----------------------------------|
| ABT-DOA-B112 | Multi-2-line Drug Urine Cassette |
| ABT-DOA-B113 | Multi-3-line Drug Urine Cassette |
| ABT-DOA-B114 | Multi-4-line Drug Urine Cassette |
| ABT-DOA-B115 | Multi-5-line Drug Urine Cassette |
| ABT-DOA-B116 | Multi-6-line Drug Urine Cassette |
| ABT-DOA-B117 | Multi-7-line Drug Urine Cassette |
| ABT-DOA-B118 | Multi-8-line Drug Urine Cassette |
| ABT-DOA-B119 | Multi-9-line Drug Urine Cassette |
| ABT-DOA-B120 | Multi-10-line Drug Urine Cassette |

Instruction Sheet for testing of combination of the following drugs: **AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/MOP/M QL/OPI/PCP/PPX/TCA/TML/KET/OXY/COT/EDDP/FYL**

A rapid test for the simultaneous, qualitative detection of multi-line drugs and drug metabolites in human urine. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

INTENDED USE

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) is a rapid chromatographic immunoassay for the qualitative detection of multi-line drugs and drug metabolites in urine at the following cut-off concentrations:

| Test | Calibrator | Cut-off (ng/mL) |
|--------------------------------------|-----------------------------------|-----------------|
| Amphetamine (AMP 1000) | d-Amphetamine | 1,000 |
| Amphetamine (AMP 500) | d-Amphetamine | 500 |
| Amphetamine (AMP 300) | d-Amphetamine | 300 |
| Barbiturates (BAR) | Secobarbital | 300 |
| Benzodiazepines (BZO) | Oxazepam | 300 |
| Benzodiazepines (BZO) | Oxazepam | 200 |
| Benzodiazepines (BZO) | Oxazepam | 100 |
| Buprenorphine (BUP) | Buprenorphine | 10 |
| Cocaine (COC) | Benzoyllecgonine | 300 |
| Marijuana (THC) | 11-nor-Δ9-THC-9 COOH | 50 |
| Marijuana (THC) | 11-nor-Δ9-THC-9 COOH | 150 |
| Marijuana (THC) | 11-nor-Δ9-THC-9 COOH | 25 |
| Methadone (MTD) | Methadone | 300 |
| Methamphetamine (MET 1,000) | d-Methamphetamine | 1,000 |
| Methamphetamine (MET 500) | d-Methamphetamine | 500 |
| Methamphetamine (MET 300) | d-Methamphetamine | 300 |
| Methylenedioxymethamphetamine (MDMA) | d,l-Methylenedioxymethamphetamine | 500 |
| Morphine (MOP) | Morphine | 300 |
| Morphine (MOP) | Morphine | 100 |
| Methaqualone(MQL) | Methaqualone | 300 |
| Opiate (OPI) | Morphine | 2,000 |
| Phencyclidine (PCP) | Phencyclidine | 25 |
| Propoxyphene (PPX) | Propoxyphene | 300 |
| Tricyclic Antidepressants (TCA) | Nortriptyline | 1,000 |
| Tramadol (TML) | Tramadol | 100 |
| Ketamine (KET) | Ketamine | 1,000 |
| Oxycodone (OXY) | Oxycodone | 100 |
| Cotinine(COT) | Cotinine | 200 |
| 2-ethylidene-1,5-dimethyl- | 2-ethylidene-1,5-dimethyl- | 300 |

| | | |
|--|---|-----|
| 3,3-diphenylpyrrolidine (EDDP) | 3,3-diphenylpyrrolidine | |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 100 |
| Fentanyl(FYL20) | Norfentanyl | 20 |
| Fentanyl(FYL10) | Norfentanyl | 10 |

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

Amphetamine (AMP 1,000)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine[®]) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of amphetamines in urine exceeds 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).¹

Amphetamine (AMP 500)

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when amphetamines in urine exceed 500 ng/mL. See Amphetamine (AMP 1,000) for the summary.

Amphetamine (AMP 300)

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when amphetamines in urine exceed 300 ng/mL. See Amphetamine (AMP 1,000) for the summary.

Barbiturates (BAR 300)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.

The approximate detection time limits for barbiturates are:

| | | |
|----------------------------------|------------------|---------------------|
| Short acting (e.g. Secobarbital) | 100 mg PO (oral) | 4.5 days |
| Long acting (e.g. Phenobarbital) | 400 mg PO (oral) | 7 days ² |

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of barbiturates in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Barbiturate positive specimens.



Benzodiazepines (BZO 300)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3-7 days.

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of benzodiazepines in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for benzodiazepine positive specimens.

Benzodiazepines (BZO 200)

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of Benzodiazepines in urine exceeds 200ng/mL. See Benzodiazepines (BZO 300) for the summary.

Benzodiazepines (BZO 100)

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of Benzodiazepines in urine exceeds 100ng/mL. See Benzodiazepines (BZO 300) for the summary.

Buprenorphine (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations.¹⁰ The plasma half life of Buprenorphine is 2-4 hours.¹⁰ While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the Buprenorphine in urine exceeds 10 ng/mL.

Cocaine (COC 300)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine. 3,4 Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8

hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.⁴

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of benzoylecgonine in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).¹

Marijuana (THC50)

THC (Δ^9 -tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).¹

Marijuana (THC150)

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of THC-COOH in urine exceeds 150ng/mL. See Marijuana (THC 50) for the summary.

Marijuana (THC25)

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of THC-COOH in urine exceeds 25ng/mL. See Marijuana (THC 50) for the summary.

Methadone

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.⁷

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of methadone in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for methadone positive specimens.

Methamphetamine (MET 1,000)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic



behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug have a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the Methamphetamine in urine exceeds 1,000ng/mL

Methamphetamine (MET 500)

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of Methamphetamine in urine exceeds 500 ng/mL. See Methamphetamine (MET1000) for the summary.

Methamphetamine (MET 300)

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of Methamphetamine in urine exceeds 300 ng/mL. See Methamphetamine (MET1000) for the summary.

Methylenedioxy-methamphetamine

Methylenedioxy-methamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.⁵ Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of Methylenedioxy-methamphetamine in urine exceeds 500 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for Methylenedioxy- methamphetamine positive specimens.

Morphine/Opiate (MOP 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.²

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of morphine in urine exceeds 300 ng/mL.

Morphine/Opiate (MOP 100)

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of morphine in urine exceeds 100ng/mL. See Morphine/Opiate (MOP 300) for the summary.

Morphine/Opiate (OPI 2,000)

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for

positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).¹ See morphine (MOP 300) for summary

Methaqualone (MQL)

Methaqualone (Quaalude, Sopor) is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956.² It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form, and is also available in European countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule. At least 12 metabolites have been identified in the urine.

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of Methaqualone in urine exceeds 300 ng/mL.

Phencyclidine (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.⁶ PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).⁶

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of phencyclidine in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).¹

Propoxyphene (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet[™], one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for propoxyphene positive specimens.

Tricyclic Antidepressants (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

ACCU-TELL[®] One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of tricyclic antidepressants in urine exceeds 1,000 ng/mL. At present, the Substance Abuse



and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

Tramadol (TML)

Tramadol(TML) is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O-demethylation, glucuronidation or sulfation in the liver.

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Tramadol in urine. The ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when Tramadol in urine exceed 100 ng/mL.

Ketamine

Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained. The effects of Ketamine generally last 4-6 hours following use. Ketamine is excreted in the urine as unchanged drug (2.3%) and metabolites (96.8%).¹

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Ketamine in urine. ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when Ketamine in urine exceeds 1,000ng/mL.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%). The window of detection for Oxycodone in urine is expected to be similar to that of other opioids such as morphine.

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Oxycodone in urine. ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when Oxycodone in urine exceeds 100ng/mL.

Cotinine (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as

nicotine gum, transdermal patches and nasal sprays. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.¹ While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. 2 Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

The Multi-lineRapid Test Cassette yields a positive result when the concentration of Cotinine in urine exceeds 200 ng/ml

2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 300)

Methadone is an unusual drug in that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure, making them very difficult to detect using immunoassays targeted to the native compound.¹ Exacerbating this problem, there is a subsection of the population classified as "extensive metabolizers" of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance. EDDP represents a better urine marker for methadone maintenance than unmetabolized methadone.

The Multi-Drug Rapid Test Cassette yields a positive result when the concentration of EDDP in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for EDDP positive specimens.

2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 100)

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of EDDP in urine exceeds 100ng/mL. See 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP300)forthe summary.

Fentanyl (FYL20)

Fentanyl, belongs to powerful narcotics analgesics, and is a µ special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain¹. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc^{2,3}, which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose ⁴.

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of FYL in urine. The FYL Rapid Test Strip (Urine) yields a positive result when FYL in urine exceeds 20 ng/mL.

Fentanyl (FYL10)

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) yields a positive result when the concentration of Norfentanyl in urine exceeds 10 ng/mL. See FLY20 for the summary.

PRINCIPLE

ACCU-TELL® One Step Multi-Line Test Cassette(Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein



conjugate and a visible colored line will show up in the test region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region. A drug-positive urine specimen will not generate a colored line in the specific test region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
• Immunoassay for in vitro diagnostic use only. The test card should remain in the sealed pouch until use.
• All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
• The used test panel should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test panels must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

Test Cassettes Package insert Droppers

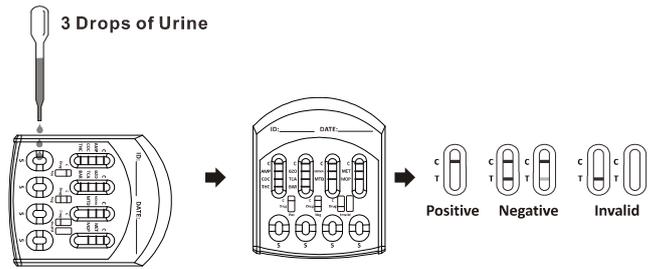
Materials Required But Not Provided

- Specimen collection container timer

TEST PROCEDURE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

- 1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A colored line appears in the Control region (C) and colored lines appears in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

*NOTE: The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- 1. ACCU-TELL® One Step Multi-Line Test Cassette(Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

EXPECTED VALUES

This negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

PERFORMANCE CHARACTERISTICS

Accuracy



A side-by-side comparison was conducted using ACCU-TELL® One Step Multi-Line Test Cassette(Urine) and commercially available drug rapid tests. Testing was performed on approximately 250 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated from these clinical studies:

| Method | GC/MS | | % Agreement with GC/MS | Overall agreement |
|--|----------|------|------------------------|-------------------|
| | Pos. | Neg. | | |
| Multi-Drug Rapid Test Cassette | Positive | 92 | 8 | 97.9% |
| | Negative | 2 | 148 | 94.9% |
| Methamphetamine (MET 1,000ng/ml) | Positive | 103 | 7 | 97.2% |
| | Negative | 3 | 137 | 95.1% |
| Methamphetamine (MET 500ng/ml) | Positive | 107 | 5 | 98.2% |
| | Negative | 2 | 136 | 96.5% |
| Methamphetamine (MET 300ng/ml) | Positive | 103 | 5 | 97.1% |
| | Negative | 3 | 139 | 96.5% |
| Cocaine (COC 300ng/ml) | Positive | 115 | 3 | >99.9% |
| | Negative | 0 | 132 | 97.8% |
| Marijuana (THC50ng/ml) | Positive | 127 | 5 | 97.6% |
| | Negative | 3 | 185 | 97.3% |
| Marijuana (THC150ng/ml) | Positive | 117 | 9 | 99.2% |
| | Negative | 1 | 193 | 95.5% |
| Marijuana (THC25ng/ml) | Positive | 95 | 9 | 97.9% |
| | Negative | 2 | 144 | 94.1% |
| Amphetamine (AMP 1,000ng/ml) | Positive | 101 | 11 | 99.0% |
| | Negative | 1 | 137 | 92.6% |
| Amphetamine (AMP 500ng/ml) | Positive | 105 | 7 | 98.1% |
| | Negative | 2 | 136 | 95.1% |
| Amphetamine (AMP 300ng/ml) | Positive | 118 | 4 | 97.5% |
| | Negative | 3 | 125 | 96.9% |
| Benzodiazepines (BZO 300ng/ml) | Positive | 137 | 2 | 97.2% |
| | Negative | 4 | 157 | 98.7% |
| Benzodiazepines (BZO 200ng/ml) | Positive | 138 | 2 | 97.9% |
| | Negative | 3 | 157 | 98.7% |
| Benzodiazepines (BZO 100ng/ml) | Positive | 107 | 5 | 96.4% |
| | Negative | 4 | 134 | 96.4% |
| Methadone (MTD 300ng/ml) | Positive | 111 | 7 | 95.7% |
| | Negative | 5 | 127 | 94.8% |
| Barbiturates (BAR 300ng/ml) | Positive | 109 | 11 | 94.0% |
| | Negative | 7 | 123 | 91.8% |
| Tricyclic Antidepressants (TCA 1000ng/ml) | Positive | 125 | 5 | 96.9% |
| | Negative | 4 | 116 | 95.9% |
| Methylenedioxy methamphetamine (MDMA 500ng/ml) | Positive | 103 | 11 | 95.4% |
| | Negative | 5 | 119 | 91.5% |
| Morphine (MOP 300ng/ml) | Positive | 142 | 5 | >99.9% |
| | Negative | 0 | 163 | 97.0% |
| Morphine (MOP 100ng/ml) | Positive | 108 | 4 | 95.6% |
| | Negative | 5 | 133 | 97.1% |
| Phencyclidine (PCP 25ng/ml) | Positive | 115 | 11 | 96.6% |
| | Negative | 4 | 120 | 91.6% |
| Propoxyphene (PPX 300ng/ml) | Positive | 116 | 11 | 94.3% |
| | Negative | 7 | 116 | 91.3% |
| Opiate (OPI 2000ng/ml) | Positive | 107 | 11 | 91.5% |
| | Negative | 10 | 122 | 91.7% |
| Methaqualone (MQL 300ng/ml) | Positive | 120 | 8 | 97.6% |
| | Negative | 3 | 119 | 93.7% |
| Tramadol (TML 100ng/ml) | Positive | 123 | 1 | 98.4% |
| | Negative | 2 | 124 | 99.2% |
| Buprenorphine (BUP 10ng/ml) | Positive | 100 | 8 | 95.2% |
| | Negative | 5 | 137 | 94.5% |
| Ketamine (KET 1000ng/ml) | Positive | 104 | 2 | 98.1% |
| | Negative | 2 | 142 | 98.6% |
| Oxycodone (OXY 100ng/ml) | Positive | 87 | 4 | 94.6% |
| | Negative | 5 | 154 | 97.4% |
| COT 200 | Positive | 82 | 5 | 98.8% |
| | Negative | 1 | 112 | 95.7% |
| EDDP 300 | Positive | 87 | 6 | 96.7% |
| | Negative | 3 | 104 | 94.5% |
| EDDP 100 | Positive | 108 | 10 | 99.1% |
| | Negative | 1 | 131 | 92.9% |
| FYL 20 | Positive | 110 | 13 | 99.1% |
| | Negative | 1 | 126 | 90.6% |

* Clinical samples for each drug were run using each of ACCU-TELL® One Step Multi-Line Test Cassette(Urine) by an untrained operator at a professional point of care site. Based on GC/MS data, the operator obtained statistically similar positive agreement, negative agreement and overall agreement rates as trained laboratory personnel.

Precision

A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The correlation with expected results was >99% across all lots and sites (with a 95% confidence interval).

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to various concentrations. >99% agreement with expected results was found at ± 50% cut-off for each drug tested (with a 95% confidence interval).

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by ACCU-TELL® One Step Multi-Line Test Cassette(Urine) at 5 minutes.

| Analytes | Concentration (ng/mL) | Analytes | Concentration (ng/mL) |
|------------------------------------|-----------------------|---------------------|-----------------------|
| AMPHETAMINE (AMP 1,000) | | | |
| D,L-Amphetamine sulfate | 200 | Phentermine | 800 |
| L-Amphetamine | 25,000 | Maprotiline | 50,000 |
| (±) 3,4-Methylenedioxy amphetamine | 400 | Methoxyphenamine | 6,000 |
| | | D-Amphetamine | 1,000 |
| AMPHETAMINE (AMP 500) | | | |
| D,L-Amphetamine sulfate | 100 | Phentermine | 400 |
| L-Amphetamine | 12,500 | Maprotiline | 25,000 |
| (±) 3,4-Methylenedioxy amphetamine | 200 | Methoxyphenamine | 3,000 |
| | | D-Amphetamine | 500 |
| AMPHETAMINE (AMP 300) | | | |
| D,L-Amphetamine sulfate | 70 | Phentermine | 300 |
| L-Amphetamine | 10,000 | Maprotiline | 12,500 |
| (±) 3,4-Methylenedioxy amphetamine | 150 | Methoxyphenamine | 2,000 |
| | | D-Amphetamine | 300 |
| BARBITURATES (BAR 300) | | | |
| Amobarbital | 3,000 | Alphenol | 300 |
| 5,5-Diphenylhydantoin | 6,000 | Aprobarbital | 450 |
| Allobarbital | 450 | Butobarbital | 150 |
| Barbital | 6,000 | Butalbital | 6,000 |
| Talbutal | 30 | Butethal | 450 |
| Cyclopentobarbital | 25,000 | Phenobarbital | 300 |
| Pentobarbital | 6,000 | Secobarbital | 300 |
| BENZODIAZEPINES (BZO 300) | | | |
| Alprazolam | 100 | Bromazepam | 780 |
| a-hydroxyalprazolam | 1,500 | Chlordiazepoxide | 780 |
| Clobazam | 200 | Nitrazepam | 200 |
| Clonazepam | 390 | Norchlordiazepoxide | 100 |
| Clorazepate dipotassium | 390 | Nordiazepam | 780 |
| Delorazepam | 780 | Oxazepam | 300 |
| Desalkylflurazepam | 200 | Temazepam | 100 |
| Flunitrazepam | 200 | Diazepam | 1,500 |
| (±) Lorazepam | 3,100 | Estazolam | 6,250 |
| RS-Lorazepam glucuronide | 200 | Triazolam | 3,100 |
| Midazolam | 6,250 | | |
| BENZODIAZEPINES (BZO 200) | | | |
| Alprazolam | 70 | Bromazepam | 520 |
| a-hydroxyalprazolam | 1,000 | Chlordiazepoxide | 520 |
| Clobazam | 120 | Nitrazepam | 120 |
| Clonazepam | 260 | Norchlordiazepoxide | 70 |
| Clorazepate dipotassium | 260 | Nordiazepam | 520 |
| Delorazepam | 520 | Oxazepam | 200 |
| Desalkylflurazepam | 120 | Temazepam | 70 |
| Flunitrazepam | 120 | Diazepam | 1,000 |
| (±) Lorazepam | 2,000 | Estazolam | 4,200 |
| RS-Lorazepam glucuronide | 120 | Triazolam | 2,000 |
| Midazolam | 4,200 | | |
| BENZODIAZEPINES (BZO 100) | | | |
| Alprazolam | 40 | Bromazepam | 260 |
| a-hydroxyalprazolam | 500 | Chlordiazepoxide | 260 |
| Clobazam | 60 | Nitrazepam | 60 |
| Clonazepam | 130 | Norchlordiazepoxide | 40 |
| Clorazepate dipotassium | 130 | Nordiazepam | 260 |
| Delorazepam | 260 | Oxazepam | 100 |
| Desalkylflurazepam | 60 | Temazepam | 400 |
| Flunitrazepam | 60 | Diazepam | 500 |
| (±) Lorazepam | 1,000 | Estazolam | 2,100 |
| RS-Lorazepam glucuronide | 60 | Triazolam | 1,000 |
| Midazolam | 2,100 | | |
| BUPRENORPHINE (BUP) | | | |
| Buprenorphine | 10 | Norbuprenorphine | 50 |
| Buprenorphine | 50 | Norbuprenorphine | 100 |



| | | | |
|--|---------|--|---------|
| 3-D-Glucuronide | | 3-D-Glucuronide | |
| COCAINE (COC 300) | | | |
| Benzoyllecgonine | 300 | Cocaehtylene | 12,500 |
| Cocaine HCl | 200 | Ecgonine | 30,000 |
| MARIJUANA (THC50) | | | |
| Cannabinol | 20,000 | Δ8-THC | 15,000 |
| 11-nor-Δ8-THC-9 COOH | 30 | Δ9-THC | 15,000 |
| 11-nor-Δ9-THC-9 COOH | 50 | | |
| MARIJUANA (THC150) | | | |
| Cannabinol | 60,000 | Δ8-THC | 45,000 |
| 11-nor-Δ8-THC-9 COOH | 180 | Δ9-THC | 45,000 |
| 11-nor-Δ9-THC-9 COOH | 150 | | |
| MARIJUANA (THC25) | | | |
| Cannabinol | 10,000 | Δ8-THC | 7,500 |
| 11-nor-Δ8-THC-9 COOH | 15 | Δ9-THC | 7,500 |
| 11-nor-Δ9-THC-9 COOH | 25 | | |
| METHADONE (MTD300) | | | |
| Methadone | 300 | Doxylamine | 100,000 |
| METHAMPHETAMINE (MET1, 000) | | | |
| p-Hydroxymethamphetamine | 25,000 | (±)-3,4-Methylenedioxy-methamphetamine | 6,250 |
| D-Methamphetamine | 1,000 | | |
| L-Methamphetamine | 12,500 | Mephentermine | 50,000 |
| METHAMPHETAMINE (MET500) | | | |
| p-Hydroxymethamphetamine | 12,500 | (±)-3,4-Methylenedioxy-methamphetamine | 3,000 |
| D-Methamphetamine | 500 | | |
| L-Methamphetamine | 9,000 | Mephentermine | 25,000 |
| METHAMPHETAMINE (MET300) | | | |
| p-Hydroxymethamphetamine | 7,500 | (±)-3,4-Methylenedioxy-methamphetamine | 1,800 |
| D-Methamphetamine | 300 | | |
| L-Methamphetamine | 3,750 | Mephentermine | 15,000 |
| METHYLENEDIOXYMETHAMPHETAMINE (MDMA500) Ecstasy | | | |
| (±) 3,4-Methylenedioxy methamphetamine HCl | 500 | 3,4-Methylenedioxyethyl-amphetamine | 300 |
| (±) 3,4-Methylenedioxyamphetamine HCl | 3,000 | | |
| MORPHINE (MOP 300) | | | |
| Codeine | 200 | Norcodeine | 6,000 |
| Levorphanol | 1,500 | Normorphone | 50,000 |
| Morphine-3-β-D-Glucuronide | 800 | Oxycodone | 30,000 |
| Ethylmorphine | 6,000 | Oxymorphone | 50,000 |
| Hydrocodone | 50,000 | Procaine | 15,000 |
| Hydromorphone | 3,000 | Thebaine | 6,000 |
| 6-Monoacetylmorphine | 400 | Morphine | 300 |
| MORPHINE (MOP 100) | | | |
| Codeine | 80 | Norcodeine | 2,000 |
| Levorphanol | 500 | Normorphone | 20,000 |
| Morphine-3-β-D-Glucuronide | 300 | Oxycodone | 10,000 |
| Ethylmorphine | 2,000 | Oxymorphone | 20,000 |
| Hydrocodone | 20,000 | Procaine | 5,000 |
| Hydromorphone | 1,000 | Thebaine | 2,000 |
| 6-Monoacetylmorphine | 100 | Morphine | 100 |
| Methaqualone (MQL 300) | | | |
| Methaqualone | 300 | | |
| OPIATE (OPI 2,000) | | | |
| Codeine | 2,000 | Morphine | 2,000 |
| Ethylmorphine | 3,000 | Norcodeine | 25,000 |
| Hydrocodone | 50,000 | Normorphone | 50,000 |
| Hydromorphone | 12,500 | Oxycodone | 25,000 |
| Levorphanol | 25,000 | Oxymorphone | 25,000 |
| 6-Monoacetylmorphine | 3,000 | Procaine | 50,000 |
| Morphine 3-β-D-glucuronide | 2,000 | Thebaine | 25,000 |
| PHENCYCLIDINE (PCP) | | | |
| Phencyclidine | 25 | 4-Hydroxyphencyclidine | 6,250 |
| PROPOXYPHENE (PPX) | | | |
| D-Propoxyphene | 300 | D-Norpropoxyphene | 300 |
| TRICYCLIC ANTIDEPRESSANTS (TCA) | | | |
| Nortriptyline | 1,000 | Imipramine | 400 |
| Nordoxepine | 400 | Clomipramine | 50,000 |
| Trimipramine | 3,000 | Doxepine | 1,500 |
| Amitriptyline | 1,500 | Maprotiline | 1,500 |
| Promazine | 3,000 | Promethazine | 25,000 |
| Desipramine | 200 | Perphenazine | 25,000 |
| Cyclobenzaprine | 1,500 | | |
| TRAMADOL (TML) | | | |
| n-Desmethyl-cis-tramadol | 200 | o-Desmethyl-cis-tramadol | 7,000 |
| Cis-tramadol | 100 | Phencyclidine | 100,000 |
| Procyclidine | 100,000 | d,l-O-Desmethyl venlafaxine | 50,000 |
| KETAMINE (KET1, 000) | | | |
| Ketamine | 1,000 | Benzphetamine | 25,000 |
| Dextromethorphan | 1,500 | (+) Chlorpheniramine | 25,000 |
| Methoxyphenamine | 12,500 | Clonidine | 100,000 |
| d-Norpropoxyphene | 12,500 | EDDP | 50,000 |
| Promazine | 25,000 | 4-Hydroxyphencyclidine | 50,000 |
| Promethazine | 25,000 | Levorphanol | 50,000 |

| | | | |
|--|---------|------------------------------------|---------|
| Pentazocine | 25,000 | MDE | 50,000 |
| Phencyclidine | 12,500 | Meperidine | 25,000 |
| Tetrahydrozoline | 400 | d-Methamphetamine | 25,000 |
| Mephentermine | 25,000 | l-Methamphetamine | 50,000 |
| (1R, 2S) - (-)-Ephedrine | 100,000 | 3,4-Methylenedioxy-methamphetamine | 100,000 |
| Disopyramide | 12,500 | Thioridazine | 50,000 |
| OXYCODONE (OXY100) | | | |
| Oxycodone | 100 | Hydromorphone | 50,000 |
| Oxymorphone | 200 | Naloxone | 25,000 |
| Levorphanol | 50,000 | Naltrexone | 25,000 |
| Hydrocodone | 6,250 | | |
| COTININE (COT) | | | |
| (-)-Cotinine | 200 | (-)-Nicotine | 3,000 |
| 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP300) | | | |
| 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | | | 300 |
| 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP100) | | | |
| 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | | | 100 |
| FENTANYL (FYL20) | | | |
| Alfentanyl | 600,000 | Buspirone | 15,000 |
| Fenfluramine | 40,000 | Fentanyl | 100 |
| Norfentanyl | 20 | Sufentanyl | 60,000 |
| FENTANYL (FYL10) | | | |
| Alfentanyl | 300,000 | Buspirone | 8,000 |
| Fenfluramine | 20,000 | Fentanyl | 50 |
| Norfentanyl | 10 | Sufentanyl | 30,000 |

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. ACCU-TELL® One Step Multi-Line Test Cassette(Urine) was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with ACCU-TELL® One Step Multi-Line Test Cassette(Urine). The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing, Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxy-methamphetamine, Morphine, Tramadol, Methaqualone, Ketamine, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with ACCU-TELL® One Step Multi-Line Test Cassette(Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

| | | | |
|----------------------|-----------------------|-------------------|--------------------------------|
| Acetophenetidin | Cortisone | Zomepirac | d-Pseudoephedrine |
| N-Acetylprocainamide | Creatinine | Ketoprofen | Quinidine |
| Acetylsalicylic acid | Deoxycorticosterone | Labetalol | Quinine |
| Aminopyrine | Dextromethorphan | Loperamide | Salicylic acid |
| Amoxicillin | Diclofenac | Meprobamate | Serotonin |
| Ampicillin | Diflunisal | d,l-Propranolol | Sulfamethazine |
| l-Ascorbic acid | Digoxin | Methylphenidate | Sulindac |
| Apomorphine | Diphenhydramine | Nalidixic acid | Tetracycline |
| Aspartame | Ethyl-p-aminobenzoate | Naproxen | Tetrahydrocortisone, 3-acetate |
| Atropine | β-Estradiol | Niacinamide | Tetrahydrocortisone |
| Benzilic acid | Estrone-3-sulfate | Nifedipine | Tetrahydrozoline |
| Benzoic acid | Erythromycin | Norethindrone | Thiamine |
| Bilirubin | Fenoprofen | Noscapine | Thioridazine |
| d,l-Brompheniramine | Furosemide | d,l-Octopamine | Oxalic acid |
| Caffeine | Gentisic acid | Oxolinic acid | Tolbutamide |
| Cannabidiol | Hemoglobin | Oxymetazoline | Triamterene |
| Chloral hydrate | Hydralazine | Papaverine | Trifluoperazine |
| Chloramphenicol | Hydrochlorothiazide | Penicillin-G | Trimethoprim |
| Chlorothiazide | Hydrocortisone | o-Hydroxyhippuric | d,l-Tryptophan |
| d,l-Chlorpheniramine | Isosuprine | Phenelzine | Uric acid |
| Chlorpromazine | 3-Hydroxytyramine | Prednisone | Verapamil |
| Cholesterol | d,l-Isoproterenol | | |
| Clonidine | | | |

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GLOSSARY OF SYMBOLS

| | | | |
|--|------------------------------------|--|------------------------|
| | Catalog number | | Temperature limitation |
| | Consult instructions for use | | Batch code |
| | In vitro diagnostic medical device | | Use by |
| | Manufacturer | | Do not reuse |



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