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Urine Cup Complete

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Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

This Instruction Sheet is for testing of any combination of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine (Opiates) and Buprenorphine. Further you get information about the Alcohol Level and adulteration parameters as there are pH, Specific Gravity, Creatinine and Nitrite.

DRUGS (up to 12 parameters per cup)

INTENDED USE

The ulti med Urine Cup Complete is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of multiple drugs and drug metabolites in human urine. The ulti med Urine Cup Complete is a rapid urine screening test that utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine without the use of an instrument.

The ulti med Urine Cup Complete is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1000)	D-Amphetamine	1,000 ng/ml
Barbiturates (BAR 300)	Secobarbital	300 ng/ml
Benzodiazepines (BZD 300)	Oxazepam	300 ng/ml
Cocaine (COC 300)	Benzoylecgonine	300 ng/ml
Marijuana (THC 50)	11-nor-Δ^9-THC-9 COOH	50 ng/ml
Methadone (MTD 300)	Methadone	300 ng/ml
Methamphetamine (MET 1000)	D-Methamphetamine	1,000 ng/ml
Methylenedioxymethamphetamine (MDMA 500)	D,L Methylenedioxy-methamphetamine	500 ng/ml
Morphine (MOR 300)	Morphine	300 ng/ml
Opiates (OPI 2000)	Morphine	2,000 ng/ml
Oxycodone (OXY 100)	Oxycodone	100 ng/ml
Phencyclidine (PCP 25)	Phencyclidine	25 ng/ml
Propoxyphene (PPX 300)	Propoxyphene	300 ng/ml
Tricyclic Antidepressants (TCA 1000)	Nortriptyline	1,000 ng/ml
Buprenorphine (BUP 10)	Buprenorphine	10 ng/ml
Cotinine (COT 200)	Cotinine	200 ng/ml
EDDP (EDDP 100)	EDDP	100 ng/ml
Fentanyl (FYL 10)	Fentanyl	10 ng/ml

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Configurations of the the ulti med Urine Cup Complete can consist of any combination of the above listed drug analytes. This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. 1 Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF TEST

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dl) as the cut-off level at which an individual is considered positive for the presence of alcohol. I-III Determination of ethyl alcohol in blood and urine is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. The TM Urine Cup Complete is designed as the screen method to rapidly determine if the alcohol level in urine is higher than 0.04%.

PRINCIPLE OF THE PROCEDURE

Drugs: The ulti med Urine Cup Complete 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 coloured line will show up in the test line 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 coloured line will not form in the test line region.

Alcohol: The alcohol test is based on the high specificity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following: It should be pointed out that other alcohols such as methyl, propanol and allyl alcohol would develop the similar colour on the reactive pad. However, these alcohols are not normally present in urine.
Adulteration: A drug-positive urine specimen will not generate a coloured line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a coloured line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

DRUG TEST STRIPS:

AMPHETAMINE (AMP 1000): 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 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

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unchanged form, with the remainder as hydroxylated and deaminated derivatives.
The ulti med Urine Cup Complete yields a positive result when Amphetamines in urine exceed 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). [2]
* Substance Abuse and Mental Health Services Administration

BARBITURATES (BAR 300): Barbiturates produce a wide spectrum of central nervous system depression, from mild sedation to coma, and have been used as sedatives, hypnotics, anesthetics, and anticonvulsants. Barbiturates are classified as ultrashort, short, intermediate, and long-acting. These drugs are primarily used for insomnia and pre operative sedation daytime sedation and the treatment of seizure disorders. Veterinarians use pentobarbital, a long-acting barbiturate, for anesthesia and euthanasia.
Barbiturates are common drugs of abuse taken orally or intravenously. They produce symptoms similar to intoxication. Chronic use will develop tolerance, physical dependence and psychological dependence on barbiturates. Overdoses can cause profound shock, coma, or death.
Shorter acting barbiturates (Allobarbital, Alphenal, Amobarbital, Aprobarbital, Butabarbital, Butalbital, Butethal, Pentobarbital, Secobarbital) can be detected for only 1 to 4 days, while long-acting barbiturates (Barbital, Phenobarbital) can be detected for 2 to 3 weeks. Normally the suggested detection period for the Barbiturates in urine is 4 to 7 days.
The ulti med Urine Cup Complete yields a positive result when the Barbiturates (Secobarbital) in urine exceed 300 ng/ml.

BENZODIAZEPINES (BZD 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 the Benzodiazepines in the urine is 3-7 days.
The ulti med Urine Cup Complete yields a positive result when the Benzodiazepines in urine exceed 300 ng/ml.

COCAINE (COC 300): Cocaine is a potent central nervous system (CNS) 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.2.4 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]
The ulti med Urine Cup Complete yields a positive result when the cocaine metabolite 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). [2]

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MARIJUANA (THC 50): 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 (Δ^9-THC-COOH).
The ulti med Urine Cup Complete 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). [2]

METHADONE (MTD 300): 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. [13]
The ulti med Urine Cup Complete yields a positive result when the Methadone in urine exceeds 300 ng/ml.

METHAMPHETAMINE (MET 1000): 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 has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated 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.
The ulti med Urine Cup Complete yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/ml.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500): MDMA, ECSTASY; 3,4-METHYLENEDIOXY-N-METHYLAMPHETAMINE was first identified by a DEA Lab in 1972. MDMA is a Schedule 1 synthetic, psychoactive drug possessing stimulant and hallucinogenic properties. MDMA possesses chemical variations of the stimulant amphetamine or methamphetamine and a hallucinogen, most often mescaline.
Ecstasy is said to produce empathy, decreased anxiety, relaxation and heightened senses. MDMA also suppresses appetite, thirst and the need to sleep. Because of this in combination with dancing and increased activity can cause severe dehydration and exhaustion. Adverse effects may include nausea, cold sweats, chills, hallucinations, increased

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body temperature, tremors, teeth clenching, tremors, double vision and muscle cramps. Long term after-effects of MDMA include anxiety, paranoia and depression. This is most likely attributed to the decreased serotonin levels found in the brain for up to three weeks after their last dose. The National Institute of Mental Health conducted a study in 1998 to support this. It was found that the use of MDMA severely damaged the neurons in the brain that transmit serotonin. Serotonin is the chemical that is used in learning, sleep, and integration of emotion. The study concluded that even recreational users of the drug might be at risk of developing permanent damage that can manifest depression, anxiety, memory loss, and neuropsychotic disorders.
In addition to these troubling facts, recent research is pointing to the real cause of the long term effects of MDMA. The drug acts primarily on the serotonin receptor sites in the brain, enabling them to take in large quantities of serotonin. It also enables them to take in other chemicals in the brain. Namely, it takes in dopamine and as the serotonin receptor sites attempt to break the dopamine down, it produces hydrogen peroxide. Which many researches believe is the cause of long term damage to serotonin receptors.
The ulti med Urine Cup Complete yields a positive result when the Methylenedioxymethamphetamine in urine exceeds 500 ng/ml.

MORPHINE (MOR 300): Opiates 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 central nervous system. 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.
The ulti med Urine Cup Complete yields a positive result when the concentration of opiate exceeds the 300 ng/ml cut-off level.

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Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. 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.[4]
The ulti med Urine Cup Complete Test yields a positive result when the 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).

OXYCODONE (OXY): Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydro-hydroxycodeinone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR®, OxyFast®(immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral

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effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours).
The ulti med Urine Cup Complete Test yields a positive result when the Oxycodone in urine exceeds 100 ng/ml.

PHENCYCLIDINE (PCP 25): 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.
Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine 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 Phencyclidine.
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.5 Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[6]
The ulti med Urine Cup Complete Test yields a positive result when the phencyclidine level 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).
NOTE: Effexor Tablets (venlafaxine hydrochloride) a treatment for depressive, anxiety and social disorder have shown to cause false positive urine results for Phencyclidine (PCP). Positive urine screening should always be confirmed by GCMS.

PROPOXYPHENE (PPX 300): Propoxyphene (PPX) is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. 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 human, 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.
The ulti med Urine Cup Complete Test yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/ml.

TRICYCLIC ANTIDEPRESSANTS (TCA1000): TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system 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.
The ulti med Urine Cup Complete Test yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000 ng/ml.

BUPRENORPHINE (BUP 10): Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms.

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Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex®, and a Buprenorphine/Naloxone combination product, Suboxone®, are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.
The ulti med Urine Cup Complete Test yields a positive result when the concentration of Buprenorphine in urine exceeds 10 ng/ml.

COTININE (COT 200): Tobacco smoking results in the absorption of nicotine through the lung and buccal/ nasal epithelium, after which nicotine is metabolized into about 20 metabolites excreted in urine. Cotinine, a major metabolite accumulates in the body with regular smoking, it is reported that cotinine is stable in body fluids and has a relatively long half-life of approximately 17 hour. Therefore the detection of cotinine is less dependent on the time of sampling than that of nicotine and other metabolites. Cotinine has been widely used as a biomarker of tobacco exposure. Methods of analysis for cotinine in biological fluids in clued gas chromatography, gas chromatography, mass spectrometry, HPLC, HPLC-mass spectrometry, EIA and RIA. These methods usually require special equipment and complicated operation procedures.
The ulti med Urine Cup Complete Test is a one-step immunoassay that is used for the qualitative detection of cotinine in human urine. It is based on the principle of the highly specific immunochemical reactions of antigens and antibodies. It is a simple and convenient test for the rapid qualitative detection of cotinine in human urine at 200 ng/ml cut-off concentration.

EDDP (EDDP 100): (2-Ethylidin-1,5-Dimethyl -3,3-Diphenylpyrrolidine) is the most important metabolite of methadone. It is excreted into the bile and urine together with the other metabolite EMPD (2-Ethyl-5-methyl-3,3-diphenyl-pyrrolidine). EDDP is formed by N-demethylation and cyclisation of methadone in liver. The part of the unchanged excreted methadone is variable and depends on the urine's pH value, dose, and the patient's metabolism. Therefore, the detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.
The ulti med Urine Cup Complete Test is based on the principle of the highly specific immunochemical reactions of antigens and antibodies, which are used for the analysis of specific compounds in human urine. The EDDP Cassette and Dipstick Screen Tests are rapid, visual, competitive panel immunoassay that can be used for the simultaneous, qualitative detection of EDDP in urine. The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet. EDDP can be detected within 4 to 6 hours after use. It can be cleared by the body for 2 to 3 days after use.

FENTANYL (FYL 10): Fentanyl (N-(1-(2-phenylethyl)-4-piperidinyl)-N-phenyl-propanamide) is a synthetic opioid which is used as a potent analgesic in the anesthesia (at narcoses) as well as a transdermal therapeutic system for the therapy of chronic pain-conditions that can be treated sufficiently only with opiate analgesics. In Germany Fentanyl is regulated under the narcotics law, in Austria under the addiction law and in Switzerland under the narcotics law. Because of its strong analgesic effect, Fentanyl is frequently used in pre-surgery situations. It is used as a dermal band-aid analgesic on strong, chronic pains of cancer patients as well as analgesia of chronic non-tumor pains (like for example at muskoloskeletal pain conditions). At Emergency Rescue Services (EMS) Fentanyl can be administered

by the paramedic in case of acute-pain conditions. Fentanyl works predominantly strongly pain-relieving (analgetic) and soothing (sedative). It is about one hundred times as potent as Morphine (measured at the weight, only one hundredth of the quantity of Fentanyl is necessary in order to achieve the same effect), possesses a higher effectiveness (the effect-maximum is higher), while its drug effect duration is usually considerably shorter. With intravenous dispensation the drug effect duration is already reached after two to three minutes. Fentanyl is excreted mainly within at most 3 days by urine and mainly metabolized into Norfentanyl (4-N-(N-propionylanilino) piperidine. A maximum of 10% of the administered quantity reaches the urine unchanged.

FOR INTEGRATED TEST CUP:

Remove the test cup from the protective foil pouch. Issue the device to the individual to be tested. Have the donor void directly into the test cup. Ensure the specimen is above the minimum fill line on the test cup label. The cup must be returned immediately to the collector. Authorized personnel at the collection site should remove the tear-off label and read the results at 5 minutes post collection. DO NOT interpret results after more than 10 minutes . If adulteration test strips are included in the test, remove the tear off label and read the adulteration test results 1 minute post collection by comparing the adulteration test strips to the colour chart included. Do not interpret results after more than 2 minutes. Abnormal colours may indicate the specimen has been adulterated.
If alcohol test strips are included in the test, results after more than 2 minutes may not be accurate. In order to prevent an incorrect reading, do not read the test results after more than 5 minutes. After 5 minutes, the intensity of the coloured pad may change. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF DRUG RESULTS

Negative: Two lines appear.* One line visible in the control region (C), and another apparent line adjacent visible in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

***NOTE:** The shade of colour in the test line region (T) will vary, but it should be considered negative if a line is visible. There is no meaning attributed to the line colour intensity or width.

Positive: One line appears in the control region (C). No line whatsoever appears in the test region (T). The lack of a line in the test region (T) indicates a preliminary positive result for the corresponding drug of that specific test region. Send this urine specimen to a certified laboratory for a more specific confirmation by GC/MS.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, contact your supplier for technical support.

AFTER TESTING

Urine specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and dispose of all used test devices in an approved biohazard container. Residual urine should be disposed of in a medically approved manner after the completion of all testing, including the confirmatory assay.

LIMITATIONS OF PROCEDURE

The ulti med Urine Cup Complete is designed for in vitro detection use with human urine only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication. There is a possibility that technical or procedure error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to "Interference" section for list of substances that will interfere the test results.

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This diagnostic test provides a semi-quantitative screening for alcohol in urine. It is not to be used for quantitative determination of alcohol concentration in urine. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.

Adulterants, such as bleach or other strong oxidizing agents, may produce erroneous test results when added to urine specimens, regardless of the analysis method used. If an adulteration is suspected, a fresh urine specimen should be used.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, THC, Phencyclidine, Benzodiazepines, Methadone, Barbiturates, Propoxyphene, Oxycodone, Tricyclic Antidepressants, or Buprenorphine.

PRECAUTIONS

- For Professional Use Only.
- For In Vitro Diagnostic Use Only.
- Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- While urine is not classified by OSHA** or the CDC*** as a biological hazard unless visibly contaminated with blood, the use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test card and urine specimen should be discarded according to federal, state and local regulations.

** Occupational Safety and Health Administration
*** Center of Disease Control

STORAGE AND STABILITY

- Store as packaged in the sealed pouch at 2-30°C (36-86°F).
- The test is stable through the expiration date printed on the sealed pouch.
- The test device 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 must 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 allowed to settle to obtain a clear specimen for testing. Specimen Storage Urine specimens may be stored at 2-8°C (36-46°F) 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.

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MATERIALS PROVIDED

- Urine Cup Complete
- Desiccant
- Package insert
- Colour Procedure Card for tests with Adulterations strips

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Disposable gloves
- Timing device (i.e. timer, clock, watch, etc.)

DIRECTIONS FOR USE

Remove the test cup from the protective foil pouch. Issue the device to the individual to be tested. Have the donor void directly into the test cup. Ensure the specimen is above the minimum fill line on the test cup label. The cup must be returned immediately to the collector. Authorized personnel at the collection site should remove the tear-off label and read the results at 5 minutes post collection. DO NOT INTERPRET RESULT AFTER MORE THAN 10 MINUTES.

If adulteration test strips are included in the test, remove the tear off label and read the adulteration test results 1 minute post collection by comparing the adulteration test strips to the colour chart included. Do not interpret results after more than 2 minutes. Abnormal colours may indicate the specimen has been adulterated.

QUALITY CONTROL

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

(OPTIONAL TEST PARAMETER)

The Urine Cup Complete can be stocked with up to 12 drug test strips and expanded with (4) adulteration test strips and/or test strips for measuring the alcohol level.

ADULTERATION (optional)

PRINCIPLE OF THE PROCEDURE

A drug-positive urine specimen will not generate a coloured line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

INTENDED USE

The ulti med Adulteration Test 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. The ulti med Urine Cup Complete is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

INTERPRETATION OF ADULTERATION RESULTS (see colour charts at the end of the document)

Negative: Two lines appear.* One line visible in the control region (C), and another apparent line adjacent visible in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

***NOTE:** The shade of colour in the test line region (T) will vary, but it should be considered negative if a line is visible. There is no meaning attributed to the line colour intensity or width.

Positive: One line appears in the control region (C). No line whatsoever appears in the test region (T). The lack of a line in the test region (T) indicates a preliminary positive result for the corresponding drug of that specific test region. Send this urine specimen to a certified laboratory for a more specific confirmation by GC/MS.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, contact your supplier for technical support.

ADULTERATION TEST STRIPS (SEE COLOUR CHARTS AT THE END OF THE DOCUMENT)

Adulteration results are obtained by direct comparison of the reacted strips with the colour blocks on the enclosed cards. Adulterated urine will show result colours under the "Abnormal" block colours of the colour chart enclosed. Unadulterated samples will show strip colours similar to the "Normal" block colours of the colours chart enclosed.

pH: Normal pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

Specific gravity: Random urine may vary in specific gravity from 1.003-1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016-1.022. Elevated urine specific gravity values may be obtained in the presence of moderate quantities of protein. A urine specimen with a specific gravity level of less that 1.003 can be an indication of substitution. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is substituted.

Creatinine: Daily creatinine excretion, related to muscle mass of the human body, is usually constant. A urine specimen with creatinine levels of less than 5 mg/dl is an indication of substitution. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution, samples with creatnine level of lower than 20mg/dl should be considered diluted.

Nitrite: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. In the test cup with adulteration nitrite levels above 15 mg/dl are considered abnormal.

Specific gravity: Random urine may vary in specific gravity from 1.003-1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016-1.022. Elevated urine specific gravity values may be obtained in the presence of moderate quantities of protein. A urine specimen with a specific gravity level of less that 1.003 can be an indication of substitution. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is substituted.

PROCESS AND QUALITY CONTROL

Good laboratory Practice recommends the daily use of control material to validate the reliability of device. Commercially available controls that contain sodium azide or other preservatives that will inhibit the enzyme activity cannot be used with this test. The TM Urine Cup Complete may be qualitatively verified by using a test solution prepared by adding 10 drops of ethanol alcohol into 8 oz of distill water. This solution should show a distinct positive result.

LIMITATIONS

- The ulti med Adulteration Test 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. [3,4,7]

- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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 and a new test device.
- A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

ALCOHOL (optional)

PRINCIPLE OF THE PROCEDURE

Alcohol: The alcohol test is based on the high specificity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following: It should be pointed out that other alcohols such as methyl, propanol and allyl alcohol would develop the similar colour on the reactive pad. However, these alcohols are not normally present in urine.

INTENDED USE

The ulti med Urine Cup Complete is intended for the rapid semi-quantitative determination of ethyl alcohol level in human urine. The test is a rapid enzymatic method to detect the presence of alcohol in urine greater than 0.04%. The tests are designed to obtain a visual, semi-quantitative result and are intended for professional use only. They are not intended for quantitative results, not for over-the-counter sale. The Urine Cup Complete provides only preliminary analytical data. A more specific, alternative method is required to obtain a confirmed analytical result. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used. Clinical considerations and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.

INTERPRETATION OF ALCOHOL RESULTS (see colour charts at the end of the document)

Negative: Almost no colour change on test pad by comparing with the background of the provided coloured chart. The negative result indicates that the concentration of ethyl alcohol in urine is less than 0.04%.

Positive: A distinct colour developed all over the pad. The positive result indicates that the concentration of ethyl alcohol in urine is 0.04% or higher.

Invalid: The test should be considered invalid if only the edge of the reactive pad turned colour that might be ascribed to insufficient sampling. The subject should be re-tested.

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TEST PERFORMANCE CHARACTERISTICS

Sensitivity: The ulti med Urine Cup Complete have been designed for detection of alcohol in urine at the detection sensitivity of 20mg/dl (0.02g/dl). In sensitivity studies performed, samples with concentrations of alcohol equal to or higher than 20mg/dl were identified as positive results for all samples. Thus, the cut-off level of the ulti med Urine Cup Complete was determined to be 20mg/dl. Tests, within-lot and inter-lot reproducibility studies were performed. Results of the within-lot reproducibility studies clearly showed excellent repeatability for all positive and negative urine samples using one lot of ulti med Urine Cup Complete. The results of inter-lot reproducibility studies clearly demonstrated that there was no appreciable inter-lot variation when testing both positive and negative samples across three different lots of ulti med Urine Cup Complete.

INTERFERENCE

The following substances were added to the sample, which had alcohol levels of 0 and 0.08%.
None of the substances at concentration tested interfered in the ulti med Urine Cup Complete Test.

Acetaminophen	20 mg/dl
Caffeine	20 mg/dl
Glucose	2,000 mg/dl
Hemoglobin	1 mg/dl
Human Serum Protein	2,000 mg/dl

The following substances may interfere with the test:

Strong oxidizers	Ascorbic acid
Tannic acid	Polyphenolic Compounds
Mercaptans	Uric acid
Bilirubin	Oxalic acid

These compounds are not normally present in sufficient amount in urine to interfere with the test.

QUALITY CONTROL

A procedural control is included in the test. A red 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.

ASSAY COMPARISONS & EQUIVALENCY

Accuracy and equivalency comparisons of ulti med Urine Cup Complete was evaluated as well as against 86 individual external SAMHSA**-certified clinical laboratory samples. The results have been tabulated below:

Alcohol Strip	GC (+)	GC (-)	Row Totals
(+)	41	2	43
(+)	3	40	43
Col. Totals	44	42	86

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When compared to the GC data, the relative sensitivity or percent agreement of ulti med Alcohol Test positive samples with the external clinical study was 41/44 or 93.2%. Negative samples recovered a relative specificity of agreement of 40/42 or 95.2%. The overall relative accuracy obtained was 81/86 or 94.2%.

THE FOLLOWING RESULTS ARE TABULATED FROM THESE CLINICAL STUDIES:

[Note abbreviations: "Pos." for "Positive" and "Neg." for "Negative"]

%Agreement with Commercial Kit															
	AMP 1000	BAR 300	BZD 300	COC 300	THC 50	MTD 300	MET 1000	MDMA 500	MOR 300	OPI 2000	OXY 100	PCP 25	PPX 300	TCA 1000	BUP 10
Pos. Agreement	98%	100%	100%	98%	98%	100%	98%	100%	98%	98%	100%	98%	98%	98.5%	95%
Neg. Agreement	100%	100%	98%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	>99%
Total Results	99%	100%	99%	99%	99%	100%	99%	100%	99%	99%	100%	99%	99%	99%	97.5%

%Agreement with GC / MS												
	AMP 1000	BAR 300	BZD 300	COC 300	THC 50	MTD 300	MET 1000	MDMA 500	MOR 300	OPI 2000	PCP 25	TCA 1000
Pos. Agreement	95%	98.5%	95.7%	95%	95%	98.5%	95%	97.1%	95%	95%	95%	95.7%
Neg. Agreement	100%	98%	98%	100%	100%	96%	100%	98%	100%	100%	100%	98%
Total Results	97.5%	98.2%	96.8%	97.5%	97.5%	97%	97.5%	97.5%	97.5%	97.5%	97.5%	96.8%

40 clinical samples for each drug were run using each strip contained within the ulti med Urine Cup Complete Test by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the untrained operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained laboratory personnel. *Note: TCA was based on HPLC data.

	AMP 1000	BAR 300	BZD 300	COC 300	THC 50	MTD 300	MET 1000	MDMA 500	MOR 300	OPI 2000	OXY 100	PCP 25	PPX 300	TCA 1000
Pos. Agreement	95%	97.4%	95.7%	96%	96%	93.7%	96%	92.5%	96%	100%	95%	95%	95%	95.7%
Neg. Agreement	100%	97.6%	100%	100%	100%	97.9%	100%	100%	100%	96%	100%	100%	100%	100%
Total Results	97.5%	97.5%	97.5%	98%	98%	96.2%	98%	96.2%	98%	98%	97.5%	97.5%	97.5%	98.7%

EDDP – Positive Agreement: 96.5% and Negative Agreement: 100%

	(-)		(+)		
drug screen	**GC/MS neg.**	**75% cutoff-cutoff**	**cutoff-125% cutoff**	**>125% cutoff**	**% Agreement with GC/MS**
(+)	0	0	8	47	96.5%
(-)	53	9	2	0	100%
total	53	9	10	47	98.3%

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

ACCURACY

Accuracy of the EDDP cup and dip tests was established by running urine sample against GC/MS specification (GC/MS specifications are the value of EDDP). In this study, one hundred nineteen (119) negative and positive urine samples (0 to 56700 ng/ml) were tested and compared with GC/MS. The concentrations of both discrepant specimens were confirmed with GC/MS to be close to the cutoff value (103.4 and 104.0 ng/ml).
The results are summarized below:
Positive Agreement: 96.5 % and Negative Agreement: 100%

	(-)		(+)		
drug screen	**GC/MS neg.**	**75% cutoff-cutoff**	**cutoff-125% cutoff**	**>125% cutoff**	**% Agreement with GC/MS**
(+)	0	0	8	47	96.5%
(-)	53	9	2	0	100%
total	53	9	10	47	98.3%

ANALYTICAL SENSITIVITY

The sensitivity of EDDP Cassette and Dipstick Screen Tests was determined by tested GC/MS confirmed controls to the concentration at negative, 50% cutoff, 75% cutoff, cutoff, 125% cutoff, 150% cutoff and 3 times of cutoff (3°—Cutoff). The results are summarized below:

Drug Conc.	**No. tested**	**Result**	
(Cutoff-Range)		-	+
Negative	50	50	
50% cutoff	50	50	
150% cutoff	50		50
3°-cutoff	50		50

PRECISION

The precision study (POC) was conducted at three physician's office sites by untrained operators using 3 different lots of product to demonstrate the within run, between run and between operator precision. Each product lot was tested by using GC/MS confirmed controls at concentration levels of negative, 50%, 75%, 125%, and 150% of the cutoff. Each concentration level was tested 5 times a day for 3 days continuously.

Drug Conc.	**No. tested**	**Site 1**		**Site 2**		**Site 3**		**Total**	
EDDP		+	-	+	-	+	-	+	-
Negative	45	0	15	0	15	0	15	0	45
50% of cutoff	45	0	15	0	15	0	15	0	45
75% of cutoff	45	0	15	0	15	0	15	0	45
125% of cutoff	45	15	0	15	0	15	0	45	0
150% of cutoff	45	15	0	15	0	15	0	45	0

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

REPRODUCIBILITY

Reproducibility studies were carried out using commercially available standards. Each standard was diluted in normal, drug-free urine to give the appropriate concentration. Each specimen, at each concentration of analyte, was tested four times daily, in duplicate, for five consecutive days. A total of 40 determinations were made at each concentration. The results are given below:

	AMPHETAMINE (AMP 1000)					BARBITURATES (BAR 300)				
Drug Conc. (ng/ml)	no drug present	500	750	1,000	1,500	no drug present	150	225	300	450
Total No. of Determination	40	40	40	40	40	40	40	40	40	40
Result	40 negative	40 negative	40 negative	40 positive	40 positive	40 negative	40 negative	40 negative	40 positive	40 positive
Precision	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%

	BENZODIAZEPINES (BZD 300)					COCAINE (COC 300)				
Drug Conc. (ng/ml)	no drug present	150	225	300	450	no drug present	500	750	1,000	1,500
Total No. of Determination	40	40	40	40	40	40	40	40	40	40
Result	40 negative	40 negative	40 negative	40 positive	40 positive	40 negative	40 negative	40 negative	40 positive	40 positive
Precision	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%

	MARIJUANA (THC 50)					METHADONE (MTD 300)				
Drug Conc. (ng/ml)	no drug present	25	37,5	50	75	no drug present	150	225	300	450
Total No. of Determination	40	40	40	40	40	40	40	40	40	40
Result	40 negative	40 negative	40 negative	40 positive	40 positive	40 negative	40 negative	40 negative	40 positive	40 positive
Precision	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%

	METHAMPHETAMINE (MET 1000)					METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500)				
Drug Conc. (ng/ml)	no drug present	500	750	1,000	1,500	no drug present	250	375	500	750
Total No. of Determination	40	40	40	40	40	40	40	40	40	40
Result	40 negative	40 negative	40 negative	40 positive	40 positive	40 negative	40 negative	40 negative	40 positive	40 positive
Precision	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%

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	MORPHINE (MOR 300)					OPIATES (OPI 2000)				
Drug Conc. (ng/ml)	no drug present	150	225	300	450	no drug present	1,000	1,500	2,000	3,000
Total No. of Determination	40	40	40	40	40	40	40	40	40	40
Result	40 negative	40 negative	40 negative	40 positive	40 positive	40 negative	40 negative	40 negative	40 positive	40 positive
Precision	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%

	OXYCODONE (OXY 100)					PHENCYCLIDINE (PCP 25)				
Drug Conc. (ng/ml)	no drug present	50	75	100	150	no drug present	12.5	19	25	37.5
Total No. of Determination	40	40	40	40	40	40	40	40	40	40
Result	40 negative	40 negative	40 negative	40 positive	40 positive	40 negative	40 negative	40 negative	40 positive	40 positive
Precision	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%

	PROPOXYPHENE (PPX 300)					TRICYCLIC ANTIDEPRESSANTS (TCA 1000)				
Drug Conc. (ng/ml)	no drug present	150	225	300	400	no drug present	500	750	1,000	1,500
Total No. of Determination	40	40	40	40	40	40	40	40	40	40
Result	40 negative	40 negative	40 negative	40 positive	40 positive	40 negative	40 negative	40 negative	40 positive	40 positive
Precision	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%

	BUPRENORPHINE (BUP 10)					COTININE (COT 200)				
Drug Conc. (ng/ml)	no drug present	5	7.5	10	15	no drug present	100	400	-	-
Total No. of Determination	40	40	40	40	40	40	40	40	-	-
Result	40 negative	40 negative	40 negative	40 positive	40 positive	40 negative	40 negative	40 positive	-	-
Precision	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	-	-

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

ANALYTICAL SENSITIVITY

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

		AMP 1000		BAR 300		BZD 300		COC 300		THC 50		MTD 300		MET 1000		MDMA 500		MOR 300		OPI 2000		OXY 100		PCP 25	
Drug conc. Cut-off-Range	**n**	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	**10**	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	**10**	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	**10**	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
Cut-off	**10**	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+25% Cut-off	**10**	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+50% Cut-off	**10**	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10

Samples	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Buprenorphine Concentration (ng/ml)										
0	-	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-	-
7.5	-	-	-	-	-	-	-	-	-	-
10	+	+	+	+	+	+	+	+	+	+
12.5	+	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+	+

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

ANALYTICAL SPECIFICITY

The following table lists the concentration of compounds (ng/ml) that were detected positive in urine by the ulti med Urine Cup Complete Test at a read time of 5 minutes.

Drug	Conc. (ng/ml)	Drug	Conc. (ng/ml)	Drug	Conc. (ng/ml)
AMPHETAMINE (AMP 1000)		**BENZODIAZEPINES (BZD 300)**, cont.		**MARIJUANA (THC 50)**, continuation	
d-amphetamine	1,000	Delorazepam	1,562	Δ^8-Tetrahydrocannabinol	20,000
D,l-amphetamine	1,000	Desalkylflurazepam	390	Δ^9-Tetrahydrocannabinol	20,000
l-amphetamine	20,000	Diazepam	195	**METHADONE (MTD 300)**	
Phentermine	1,250	Estazolam	2,500	Methadone	300
(+/-)- Methylenedioxy-amphetamine (MDA)	1,500	Flunitrazepam	390	Doxylamine	50,000
		(±) Lorazepam	1,562	**METHAMPHETAMINE (MET 1000)**	
BARBITURATES (BAR 300)		RS-Lorazepam glucuronide	156	(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Secobarbital	300	Midazolam	12,500		
Amobarbital	300	Nitrazepam	98	Procaine (Novocaine)	60,000
Alphenol	15	Norchlordiazepoxide	195	Trimethobenzamide	20,000
Aprobarbital	200	Nordiazepam	390	+/-methamphetamine	1,000
Butabarbital	75	Temazepam	98	+methamphetamine	1,000
Butalbital	2,500	Triazolam	2,500	Ranitidine (Zantac)	500,000
Butethal	100	**COCAINE (COC 300)**		(+/-) 3,4-Methylenedioxy-methamphetamine (MDMA)	2,500
Cyclopentobarbital	600	Benzoylecogonine	300		
Pentobarbital	300	Cocaethylene	300	MDA	100,000
Phenobarbital	100	Cocaine	300	**METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500)**	
BENZODIAZEPINES (BZD 300)		**MARIJUANA (THC 50)**			
Oxazepam	300	11-Hydroxy-Δ^9-Tetrahydrocannabinol	5,000	D,L-3,4-Methylenedioxymethamphetamine HCII (MDMA)	500
Alprazolam	196				
_-Hydroxyalprazolam	1,262	11-Nor-Δ^8-Tetrahydrocannabinol	50	3,4-Methylenedioxy-amphetamine HCl (MDA)	3,000
Bromazepam	1,562				
Chlordiazepoxide	1,562	11-Nor-Δ^9-Tetrahydrocannabinol	50	3,4-Methylenedioxyethylamphetamine (MDEA)	300
Chlordiazepoxide HCl	781				
Clobazam	98	11-Nor-Δ^9-Tetrahydrocannabinol-9 Carboxylic Glucuronide	2,500	**MORPHINE (MOR 300)**	
Clonazepam	781			6-acetylmorphine	500
Clorazepate dipotassium	195			Codeine	300

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

Drug	Conc. (ng/ml)	Drug	Conc. (ng/ml)	Drug	Conc. (ng/ml)
MORPHINE (MOR 300), cont.		**OXYCODONE (OXY 100)**		**TRICYCLIC ANTIDEPRESSANTS (TCA 1000)**, continuation	
Ethylmorphine	1,500	Oxycodone	100		
Heroin	300	Codeine	50,000	Doxepin	2,000
Hydromorphone	2,000	Dihydrocodeine	12,500	Maprotiline	2,000
Hydrocodone	1,250	Ethylmorphine	25,000	Promethazine	25,000
Meperidine	300,000	Hydrocodone	1,580	**BUPRENORPHINE (BUP 10)**	
Morphine	300	Hydromorphone	12,500	Buprenorphine	10
Morphine-3-glucuronide	300	Oxymorphone	1,580	Norbuprenorphine	10
Oxycodone	negative at 100,000	Thebaine	50,000	Codeine	no reaction at 10 ug/ml
		PHENCYCLIDINE (PCP 25)			
OPIATES (OPI 2000)		Phencyclidine	25	Morphine	no reaction at 10 ug/ml
Codeine	2,000	Phencyclidine-d5	10,000		
Hydrmorphone	5,000	**PROPOXYPHENE (PPX 300)**		**COTININE (COT)**	
Oxycodone	negative at 100,000	D-Propoxyphene	300	Cotinine	200
		D-Norpropoxyphene	300	(-)-Nicotine	>235,000
Morphine Sulfate	2,000	**TRICYCLIC ANTIDEPRESSANTS (TCA 1000)**		**EDDP (EDDP 100)**	
Morphine-3-b-D-glucuronide	2,000			EDDP	100
Morphine-6-b-D-glucuronide	2,000	Notriptyline	1,000	Doxylamine	>1,000,000
Methadone	negative at 100,000	Nordoxepine	1,000	Methadone	>10,000
		Trimipramine	3,000	Methadol	>10,000
Nalorphine	negative at 100,000	Amitriptyline	1,500	**FENTANYL (FYL)**	
		Promazine	1,500	Fentanyl	50
Heroin	2,000	Desipramine	200	Norfentanyl	10
Ethylmorphine	5,000	Imipramine	400	Sufentanyl	200
Meperidine	5,000,000	Clomipramine	12,500	Alfentanyl	200

FENTANYL

Accuracy: The accuracy of the ulti med Urine Cup Complete test was quantitatively evaluated through the measurement with fentanyl specimen at an independent laboratory. The results were 100% in agreement.

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

Reproducibility: The reproducibility precision of the test was determined by blind tests with control solutions. Control solutions with a FYL- concentration <5 ng/mls should yield a negative result; control solutions with a FYL-concentration of 15 ng/mls should yield a positive result.

Specificity: The specificity of the ulti med Urine Cup Complete Test was tested with the substances, drug metabolites and compounds listed below, all of which can be found in a normal urine specimen. They were added to normal drug-free urine. The compounds listed in the table above with a similar chemical structure produced a positive result when tested at levels equal or greater than the concentrations.

EFFECT OF URINARY SPECIFIC GRAVITY

15 urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.03) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The ulti med Urine Cup Complete Test was tested in duplicate using ten 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 THE URINARY PH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the ulti med Urine Cup Complete Test. 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 Cocaine, Barbiturates, Benzodiazepines, Amphetamine, Methamphetamine, Marijuana, Methadone, Methylenedioxymethamphetamine, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with The ulti med Urine Cup Complete Test at concentrations of 100 ng/ml. Positive urine screening should always be confirmed by GCMS.

THE FOLLOWING DRUGS ARE NOT DETECTED BY ULTI MED URINE CUP COMPLETE TEST FOR BUPRENORPHINE AT CONCENTRATIONS LESS THAN 100,000 NG/ML.

Acetaminophen
Aspirin
Biotin
Boron
Caffeine
Calcium
Calcium Carbonate
Chloride
Chlorpheniramine Maleate
Chromium
Citric Acid
Copper
Dimenhydrinate
Diphenhydramine HCl
Dextromethorphan Hydrobromide
Doxylamine Succinate
Famotidine
Folic Acid
Guaifenesin
Ibuprofen
Iodine
Iron
L-Lysine
Loperamide HCl
Loratadine
Lutein
Lycopene
Magnesium
Magnesium Hydroxide
Manganese
Meclizine HCl
Molybdenum
Naproxen Sodium
Niacin
Nikel
Oxymetazoline HCl
Pantothenic Acid
Pantothenic Acid
Phenylephrine HCl
Potassium
Pseudoephedrine HCl
Selenium
Silicon
Simethicone
Sodium Bicarbonate
Thiamin
Tin
Vanadium
Vitamin A
Vitamin B12
Vitamin B6
Vitamin C
Vitamin D
Vitamin E
Vitamin K
Zinc

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

NON CROSS-REACTING COMPOUNDS

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
L-Ascorbic acid
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzphetamine*
Bilirubin
D/L-Brompheniramine
Caffeine
Cannabidol
Chloralhydrate
Chloramphenicol
Chlorothiazide
D/L-Chloropheniramine
Chlorpromazine
Chloroquine
Cholesterol
Clonidine
Cortisone
L-Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Ecgonine methyl ester
L -Δ-Ephedrine
b-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
[1R,2S] (-) Ephedrine
L(–)-Epinephrine
Erythromycin
Fenoprofen
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxyamphetamine
p-Hydroxytyramine
Ibuprofen
Iproniazid
D/L-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Loperamide
Meperidine
Meprobamate
Methoxyphenamine
Methylphenidate
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norethindrone
D-Norpropoxyphene
Noscapine
D/L-Octopamine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine hydrochloride
Perphenazine
Phenelzine
Trans-2-phenylcyclo-propylamine-hydrochloride
L-Phenylephrine
Δ-Phenylethylamine
Phenylpropanolamin
Prednisolone
Prednisone
D-Propoxyphene
D-Pseudoephedrine
Quinacrine
Quinine
Quindine
Ranitidine
Salicylic acid
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone 3-acetate
Tetrahydrocortisone 3 (b-D-glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
D/L-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Tryptamine
D/L-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

*Parent compound only; metabolizes into amphetamine and methamphetaminein the body.

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

Furosemide
D/L-Propranolol

COTININE

The following compounds were found not to cross-react when tested at concentrations at 100 µg/ml.

Acetaminophen
Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame
Aspirin
Benzocaine
Bilirubin
Caffeine
Chloroquine
Chlorpheniramine
Creatine
Dextrorphan tartrate
4-Dimethylaminoantipyrine
Dopamine
(+/-)-Ephedrine
(-)-Ephedrine
Ethanol Erythromycin
Furosemide
Guaiacol Glyceryl Ether
Hemoglobin
Ibuprofen
Imipramine
(+/-)-Isoproterenol
LidocaineAtropine
N-Methyl-Ephedrine
(+)-Naproxen
Oxalic Acid
Penicillin-G
Pheniramine
Phenothiazine
L-Phenylephrine
b-Phenylethylamine
Procaine
Quinidine
Ranitidine
Sulindac
Tyramine
Vitamin C

EDDP

The following compounds were found not to cross-react when tested at concentrations at 100 µg/ml.

Acetaminophen
Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame
Aspirin
Atropine
Benzocaine
Bilirubin
Caffeine
Chloroquine
Chlorpheniramine
Creatine
Dextrorphan tartrate
4-Dimethylaminoantipyrine
Dopamine
(+/-)-Ephedrine
(-)-Ephedrine
Furosemide
Guaiacol Glyceryl Ether
Hemoglobin
Ibuprofen
Imipramine
(+/-)-Isoproterenol
Lidocaine
N-Methyl-Ephedrine
(+)-Naproxen
Oxalic Acid
Penicillin-G
Pheniramine
Phenothiazine
L-Phenylephrine
b-Phenylethylamine
Procaine
Quinidine
Ranitidine
Sulindac
Tyramine
Vitamin C

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

FENTANYL

The following compounds were found not to cross-react when tested at concentrations at 100 µg/ml.

Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame
Aspirin
Atropine
(+/-)Isoproterenol
Coffeine
Creatine
Lidocaine
(+)-Naproxen
Oxalic Acid
Paracetamol
Benzocaine
Bilirubin
Chinidine
Chloroquin
(+/-)-Chlorpheniramin
Dexbrompheniramine
Dextromethorphan
Penicillin-G
Pheniramine
Phenothiazine
Phenylethylamine
Procaine
Ranitidine
Riboflavin
4-Dimethylaminoantipyrine
Erythromycin
Ethanol
Glucose
Guaiacol-Glyceryl-Ether
Hemoglobin
Imipramin
Sodium Chloride
Sulindac
Thioridazine
Trifluorperazine
Trimethobenzamide
Tyramine
Vitamin C

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

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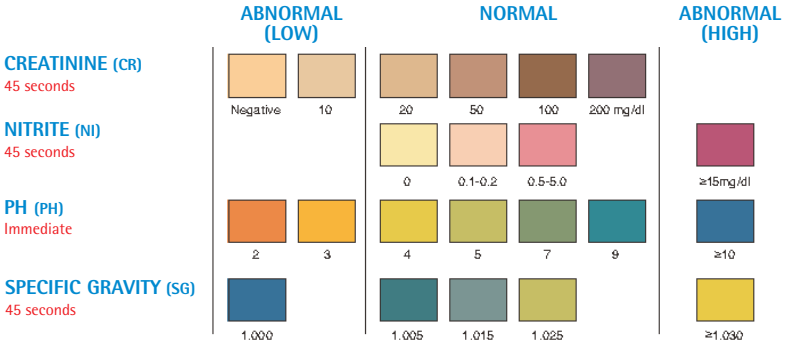
CE

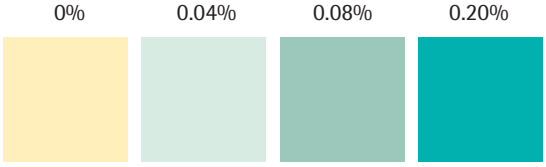
	Manufacturer	$\sum_n$	Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
2	For single use only		Expiry date
	Read instructions for use		Store at

Urine Cup Complete – for the rapid semi-quantitative determination of drugs of abuse plus adulterations and alcohol in human urine

ADULTERATION Colour Comparison Chart



ALCOHOL Colour Comparison Chart



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Urine Cup Complete

– proudly made in the USA –

ulti med Products (Deutschland) GmbH
Reeshoop 1 · 22926 Ahrensburg · Germany
Phone: +49 (0)4102-80090 · Fax: +49 (0)4102-50082
E-mail: info@ultimed.de · Internet: www.ultimed.org

Distributor
ulti med Products (Belgium) BVBA
Honzebroekstraat 137 · 8800 Roeselare · Belgium
Phone: +32 (0)51-200425 · Fax: +32 (0)51-200449
E-Mail: belgium@ultimed.org · Internet: www.ultimed.org

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