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IVD



See external label



2°C-30°C



$\Sigma=1$ tests

REF

Any Combination +Alcohol

DOA (Any Combination) + Alcohol RapiDip™ InstaTest

FOR THE QUALITATIVE ASSESSMENT OF DRUGS AND/OR THEIR METABOLITES IN
HUMAN URINE

For in vitro Diagnostic and Forensic Use

INTENDED USE

The Cortez Diagnostics, Inc. DOA/Alcohol RapiDip™ InstaTest is an immunochromatography based one step in vitro test. It is designed for qualitative determination of drug substances in human urine specimens. This assay may be used in the point of care setting. Below is a list of cut-off concentrations for each drug.

Amphetamine	1000 ng/ml of d-amphetamine
Barbiturate	300 ng/ml of secobarbital
Benzodiazepine	300 ng/ml of oxazepam
Buprenorphine	10 ng/ml of Buprenorphine-3-β-d-glucoronide
Cocaine	300 ng/ml of benzoylecgonine
EDDP	100 ng/ml of EDDP
Ketamine	1000 ng/ml of Ketamine

Methadone	300 ng/ml of methadone
Methamphetamine (includes Ecstasy)	1000 ng/ml of (+) methamphetamine
MDMA (Ecstasy specific)	500 ng/ml of MDMA
Opiate*	300 ng/ml of morphine
Opiate II*	2000 ng/ml of morphine
Oxycodone	100 ng/ml of oxycodone
Phencyclidine	25 ng/ml of phencyclidine
Cannabinoid (THC)	50 ng/ml of 11-nor- Δ^9 -THC-9-COOH
Propoxyphene	300 ng/ml of Norpropoxyphene
Tramadol	200 ng/ml of Tramadol
Tricyclic antidepressant (TCA)	1000 ng/ml of Nortriptyline
Alcohol	40 mg/dl (0.04% BAC) of Alcohol

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The optional built-in Adulteration Test is for validation of urine specimen's integrity and must not be used for In Vitro diagnostic use.

* **SAMHSA recommends a cut-off concentration of 2000 ng/ml for Opiates Test**

SUMMARY AND EXPLANATION

Drugs of Abuse

Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. The most common amphetamines are d-amphetamine and d,l-amphetamine. Amphetamines are central nervous stimulants that cause the neurotransmitters epinephrine, norepinephrine and dopamine to be released into the brain and body giving users feelings of euphoria, alertness, and increased energy. Chronic abuse of amphetamine leads to tolerance and drug reinforcement effect. Cardiovascular responses to amphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations and psychotic behavior. Amphetamine is metabolized by a number of pathways. In general, acid urine promotes excretion whereas alkaline urine retards it. In 24 hours, approximately 79% of the amphetamine dose is excreted in acid urine and about 45% in alkaline urine. Typically, about 20% is excreted as unchanged amphetamine. Unchanged amphetamine can be detected up to 1 –2 days after use.

Barbiturates are a group of prescription drugs that are frequently abused. They can depress the central nervous system. Acute higher dose induces exhilaration, sedation and respiratory depression. More acute responses produce respiratory collapse and coma. The effects of short-acting barbiturates, such as secobarbital last 3 to 6 hours. The effects of long-acting barbiturates such as phenobarbital last 10 to 20 hours. Short-acting barbiturates normally remain detectable in urine for 4 to 6 days, while long-acting barbiturates can be detected for up to 30 days. Barbiturates are excreted in the urine in unchanged forms, hydroxylated derivatives, carboxylated derivatives and glucuronide conjugates.

Benzodiazepines are a class of widely prescribed central nervous system depressants which have anxiolytic, hypnotic, anticonvulsant and muscle relaxant effects. Chronic abuse can result in addiction and tardive dyskinesia. Acute higher doses lead to drowsiness, dizziness, muscle relaxation, lethargy, coma and possible death. The effects of benzodiazepines use last 4 – 8 hours. Many of the benzodiazepines share a common metabolic route, and are excreted as oxazepam and its glucuronide in urine. Oxazepam is detectable in the urine for up to 7 days after drug use.

Buprenorphine A derivative of thebaine, is an opioid that has been marketed in the United States as the

Schedule V parenteral analgesic Buprenex. In 2003, based on a reevaluation of available evidence regarding the potential for abuse, addiction, and side effect, DEA reclassified buprenorphine from a Schedule V to a Schedule III narcotic. Buprenorphine resembles morphine structurally but has a longer duration of action than morphine and can be administered sublingually as an analgesic. In October 2002, FDA approved the use of a buprenorphine monotherapy product, Subutex, and a buprenorphine/naloxone combination product, Suboxone, for the treatment of opioid addiction. Subutex and Suboxone are the first narcotic drugs available under the US Drug Act (DATA) of 2003 for the treatment of opiate dependence that can be prescribed in the US in a physician's work place. It has also been shown that buprenorphine has abuse potential and may itself cause dependency. In addition, a number of deaths have been recorded as a result of overdose with intravenously injected buprenorphine in conjunction with other psychotropic drugs such as benzodiazepines. Buprenorphine is metabolized primarily by n-dealkylation to form glucuronide-buprenorphine and glucuronide-norbuprenorphine.

Cocaine Derived from the leaves of cocoa plant, cocaine is a potent central nervous system stimulant as well as a local anesthetic. Some of the psychological effects induced by cocaine are: euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Continued ingestion of cocaine could induce tolerances and physiological dependency which leads to its abuse. Cocaine is used by smoking, intravenous, intranasal or oral administration and excreted in the urine primarily as benzoylecgonine in a short period. Benzoylecgonine has a biological half-life of 5 – 8 hours, which is much longer than that of cocaine (0.5 – 1.5 hours), and can be generally detected for 12 – 72 hours after cocaine use or exposure.

EDDP 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine, is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate dependant patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The detection of EDDP is more beneficial than traditional methadone screening, in that EDDP exists only in urine from individuals that ingested methadone. The tampering of specimens by spiking the urine with methadone can be prevented. Secondly, renal clearance of EDDP is not affected by urinary pH, therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone parent screen.

Methadone is a synthetic opioid, clinically available. It is used clinically for the treatment of severe pain and in maintenance programs for morphine and heroine addicts. Methadone acts on the central nervous and cardiovascular systems to produce respiratory and circulatory depression. Methadone also produces miosis and increases the tone of smooth muscle in the lower gastrointestinal tract while decreasing the amplitude of contractions. Acute higher doses induce analgesia, sedation, respiratory depression and coma. After methadone administration, the major urinary excretion products are methadone and its metabolites, EDDP and EMDP. Large individual variations in the urine excretion of methadone are output of methadone from 5-22%. Typically, following a 5 mg oral dose, methadone and EDDP account for 5% of the dose in the 24-hour urine. In those individuals on maintenance therapy, methadone may account for 5 to 50% of the dose in the 24-hour urine and EDDP may account for 3 to 25% of the dose.

Methamphetamine is the most popular synthetic derivative of the amphetamines. It is a potent sympathomimetic agent with therapeutic applications. Acute large doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. More acute response produces anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-40% of methamphetamine is excreted unchanged. Methamphetamine is generally detectable in the urine for 3 to 5 days after use.

MDMA Methylendioxyamphetamine (Ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. 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. The most pervasive effect of MDMA, occurring in almost all people who have taken a

reasonable dose of the drug, is to produce a clenching of the jaws. The MDMA Ecstasy Test Strip yields a positive result when Methylenedioxymethamphetamine in urine exceeds 500ng/ml.

Ketamine is a derivative of phencyclidine. It is used medically as a veterinary and human anaesthetic. Certain doses of ketamine can cause dream-like states and hallucinations. In high doses, ketamine can cause delirium, amnesia, impaired motor function, high blood pressure, depression, and potentially fatal respiratory problems. Ketamine is metabolized in the liver and excreted through the kidney. The half-life of ketamine in the body is around three hours.

Opiate Opioid analgesics comprised of a large group of substances that control pain by depressing the central nervous system. Acute high dose used by abusers or addicts can cause depressed coordination, disrupted decision, decreased respiration, hypothermia and coma. Morphine is excreted unmetabolized and is the marker metabolic product of opiates. Morphine and morphine glucuronide is detectable in urine for several days after opiates dose.

Oxycodone is known as Oxycontin, Roxicodone and is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiate derived from opium. Like other opiates, oxycodone is characterized by its analgesic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analgesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and respiratory arrest. Oxycodone is metabolized by N- and O-demethylation. One of the metabolites, oxycodone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% of a single dose of oxycodone is excreted in a 24 hour urine collection and consists of 13-19% free oxycodone, 7-29% glucuronide conjugated oxycodone, 13-14% glucuronide conjugated oxycodone and an unknown amount of noroxycodone. The detection time window of oxycodone is 1-3 days following use.

Phencyclidine commonly known as PCP, is a hallucinogen which interacts with dopamine, cholinergic and adrenergic systems. It has dose dependent stimulant, depressant, hallucinogenic and psychological effects. PCP is mostly administered by oral or intravenously. Even moderate amount of PCP, from 5 to 100 ng/ml, can result in psychotic, violent and self-destruction. At high doses, from 100 to 500 ng/ml, PCP can cause convulsions, hypertension, prolonged coma, absent peripheral sensation, and even death. PCP is metabolized via hydroxylation, oxidation, and conjugation with glucuronic acid in the liver. About 10% of the dose is excreted in urine as unchanged drug. For chronic users, PCP can be detected in the urine for 7 to 8 days after drug administration.

Propoxyphene Propoxyphene is a prescription drug for the relief of pain. Although slightly less selective than morphine, Propoxyphene binds primarily to μ opioid receptors and produces analgesia and other CNS effects that are similar to those seen with morphine-like opioids. It is likely that at equianalgesic doses the incidence of side effects such as nausea, anorexia, constipation, abdominal pain, and drowsiness are similar to those of codeine. After oral administration, concentrations of Propoxyphene in plasma reach their highest values at 1 to 2 hours. There is great variability between subjects in the rate of clearance and the plasma concentrations that are achieved. The percentage of excreted unchanged Propoxyphene in urine is less than 1%. In humans, the major route of metabolism is N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent Propoxyphene (6 to 12 hours), and its accumulation with repeated doses may be responsible for some of the observed toxicity.

THC The agents of Marijuana that cause various biological effects in humans are called cannabinoid. Cannabinoid is a central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short term memory, and produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increased heart rate. Large doses of cannabinoid could cause the development of tolerances and physiological dependency and lead to abuse. A tolerance to the cardiac and psychotropic effects can occur and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. Δ^9 -THC is the primary active ingredient in cannabinoids. The main metabolite excreted in the urine is 11-nor- Δ^9 -THC-9-COOH, which are found within hours of exposure and remain detectable in the urine for 3-10 days after smoking.

Tramadol 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.

TCA Tricyclic antidepressants, commonly known as TCA, are a group of antidepressant drugs. TCA are mostly administered by oral or intramuscularly. The progressive symptomatology of TCA includes agitation, confusion, hallucinations, hypertonicity, seizures and EKG changes. Nortriptyline, Desipramine (Pertofran) and Imipramine (Tofranil) are the most often used TCA. TCA's half life varies from a few hours to a few days. TCA are excreted with less than 1% of the unchanged drug.

Alcohol Acute alcohol intoxication can lead to loss of alertness, coma, and even death. Long term effects include internal organ damage and birth defects. The blood alcohol concentration (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. Since urine alcohol concentration is normally higher than that in saliva and blood, the cutoff concentration for alcohol in urine is set at 0.04%.

UrineCheck: Adulteration Test(s)

UrineCheck adulteration tests are built-in firm plastic strips to which options of one (1) up to six (6) different reagent areas can be affixed. UrineCheck test(s) is/are read-to-use and disposable. No equipment is required for its use. Only fresh and uncentrifuged urine samples without preservatives are to be used. UrineCheck provides tests for Creatinine (C), Nitrite (N), pH (P), Specific Gravity (G), Glutaraldehyde (U), Bleach (B), and Pyridinium Chlorochromate (P) in urine. Test results may be useful for assessing the integrity of the urine sample while running Drugs-of-Abuse & Alcohol testing, for example, whether the sample is possibly diluted with water or other liquids as indicated by the Creatinine and specific gravity tests. UrineCheck detects whether the sample contains commercially available adulterants including nitrite, Glutaraldehyde, and other oxidizing agents. UrineCheck can also assess whether the sample is possibly contaminated by acidic (vinegar) or basic (ammonia solution) adulterants as indicated by the pH test.

PRINCIPLE

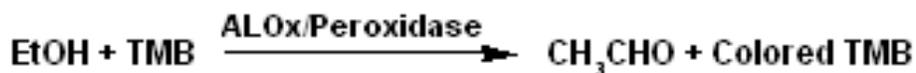
Drugs of Abuse

Each component strip of the DOA/Alcohol RapiDip™ InstaTest Device is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

Alcohol

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:



The distinct color on reactive pad could be observed in less than 20 seconds after the urine samples migrates over the reaction pad with the ethyl alcohol concentration greater than 0.04%. It should be pointed out that other alcohols such as methyl, propyl and allyl alcohol would develop the similar color on the

reactive pad. However, these alcohols are not normally present in urine.

UrineCheck: Adulteration Test(s)

In general, all UrineCheck Tests are based on the chemical reactions of the indicator reagents on the pads with components in the urine sample effecting color changes. Results are obtained by comparing the color on each of the test pads with the corresponding pad on the color chart provided.

Creatinine: Testing for sample dilution. In this assay, Creatinine reacts with a Creatinine indicator in an alkaline condition to form a purplish- brown color complex. The concentration of Creatinine is directly proportional to the color intensity of the test pad.

Specific Gravity: Testing for sample dilution. This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow in urine of higher ionic concentration.

pH: Testing for the presence of acidic or alkaline adulterant. This test is based on the well-known double pH indicator method that gives distinguishable colors over wide pH range. The colors range from orange (low pH) to yellow and green to blue (high pH).

Nitrite: Testing for the presence of exogenous nitrite. Nitrite. Nitrite reacts with an aromatic amine to form a diazonium compound in an acid medium. The diazonium compound in turn couples with an indicator to produce a pink-red/purple color.

Glutaraldehyde: Testing for the presence of exogenous aldehyde. In this assay, the aldehyde group on the Glutaraldehyde reacts with an indicator to form a pink/purple color complex.

Bleach: Testing for the presence of bleach in urine. In this test, the presence of bleach forms a blue-green, brown, or orange color complex.

Pyridinium Chlorochromate: Testing for the presence of Pyridinium Chlorochromate in urine. In this test, the presence of chromate forms a blue-green color complex.

MATERIALS PROVIDED

- 1. Instructions for use**
- 2. One Drugs of DOA/Alcohol RapiDip™ InstaTest Device (with optional Alcohol and /or Adulteration Test)**

Drugs Of Abuse

The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.

Test zone: contains drug bovine protein antigen conjugates

Control zone: contains Goat anti-mouse IgG antibody

Conjugate pad: contains mice monoclonal anti-drug antibody.

Alcohol (optional)

Each Alcohol test contains these materials:

Tetramethylbenzidine (TMB)	0.12 mg
Alcohol oxidase (EC)	0.5 IU
Peroxidase (EC)9	35 IU
Proteins	0.15mg

Adulteration Test (optional)

3. **Alcohol/Adulteration Test Color Chart** (When order Alcohol and/or Adulteration Tests)

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection container.
2. Timer or clock.

STORAGE AND STABILITY

The DOA/Alcohol RapiDip™ InstaTest Device should be stored at 4 to 30°C and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

PRECAUTIONS

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Humidity sensitive product. Do not open foil pouch until it is ready to be tested.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine does not require any special handling or pretreatment. Specimen should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8 °C or frozen up to 7 days. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 50% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which are not provided with this test kit are commercially available.

Drugs of Abuse

The DOA/Alcohol RapiDip™ InstaTest Device provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not ppear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

Alcohol

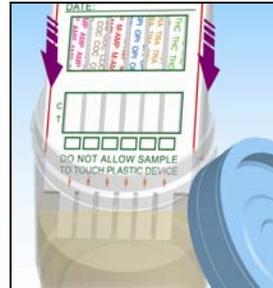
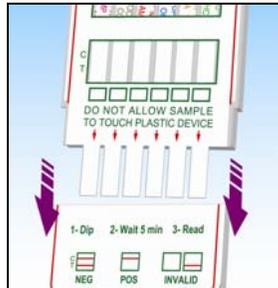
Alcohol test may be qualitatively verified by using a test solution prepared by adding 0.75 ml of ethanol alcohol into 240 ml of distilled water or negative urine control. This solution should show a distinct positive result.

UrineCheck: Adulteration Test(s)

For best results, performance of UrineCheck test should be confirmed by testing known negative and positive specimens.

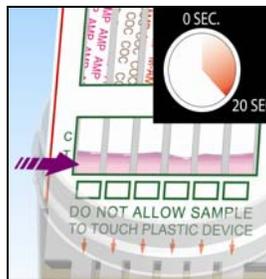
PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the DOA/Alcohol RapiDip™ InstaTest Device from sealed foil pouch.
3. Place the sample pad end into the urine specimen. Use care to hold each pad in the urine without touching the plastic card.



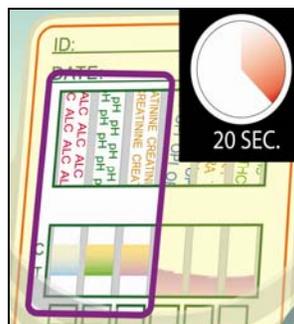
4. DOA/Alcohol RapiDip™ InstaTest with no Alcohol nor Audlteration Tests

Hold the device in the urine until a reddish color appears at the test area (approximately 20 seconds)*.

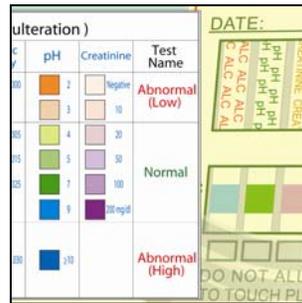


DOA/Alcohol RapiDip™ InstaTest with Alcohol or Audlteration Tests

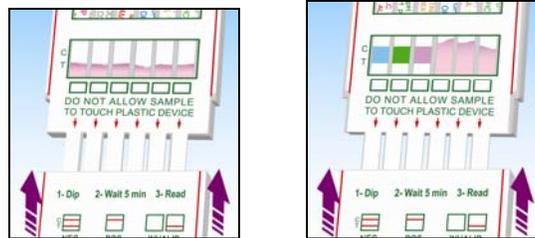
Hold the device in the urine until a reddish color appears at the test area and urine flow over Alcohol pad or Adulteration pad (approximately 20 seconds)*.



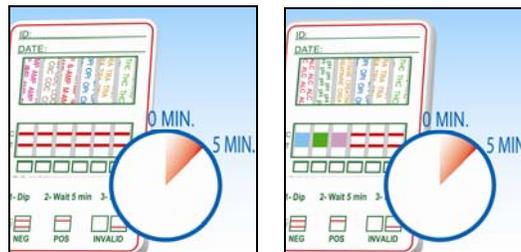
Read Reaction Pads against Color chart provided.



Recap the device



5. Read the Drugs of Abuse Test results at 5 minutes after adding the sample.



*** Note:** If urine Alcohol strip is integrated in the DOA/Alcohol RapiDip™ InstaTest Device, the device should be held until the whole alcohol detection pad is wet, which takes about 20 to 30 seconds.

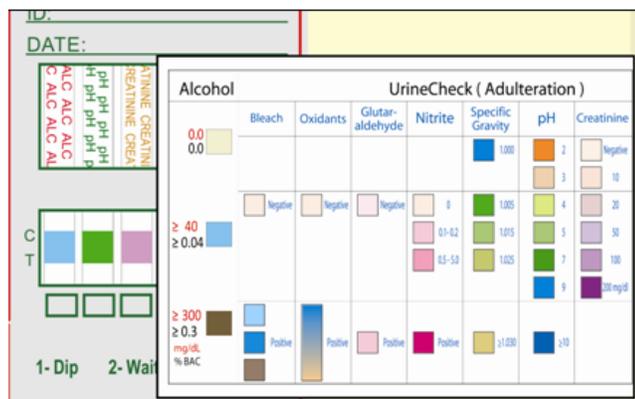
Caution: Results after 10 minutes may not be accurate.

INTERPRETATION OF RESULTS

Names of drugs on the test could be different depending on the various combination of drugs selected.

If there is no colored band in control line zone (C) of any strip, the test result is invalid. Retest the sample with a new device.

Alcohol & Adulteration



1. Read Reaction Pads against the Alcohol /Adulteration Test Color Chart provided.
2. Refer to supplied color chart for the level of each index to be tested and check if it is in the normal range.

Note: A borderline(+/-) in test line zone should be considered negative result.

LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer "SPECIFICITY" section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED RESULTS

The DOA/Alcohol RapiDip™ InstaTest Device is a qualitative assay. It identifies the drug(s) in human urine at its cut-off concentration or higher. The concentration of the drug(s) can not be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the DOA/Alcohol RapiDip™ InstaTest Device was evaluated in each component strip and in comparison to GC/MS method at the following concentration: d-amphetamine 1000ng/ml (AMP), secobarbital 300 ng/m (BAR), oxazepam, 300 ng/ml (BZO), buprenorphine-3-β-d-glucoronide 10ng/ml (BUP), benzoylecgonine 300ng/ml (COC), EDDP 100ng/ml (EDDP), Ketamine 1000ng/ml (KET), methadone 300 ng/ml (MTD), MDMA 500ng/ml (MDMA), (+)methamphetamine 1000 ng/ml (MET), phencyclidine 25 ng/ml (PCP), morphine 300 ng/ml (OPI), morphine 2000 ng/ml (OPI II), oxycodone 100ng/ml (OXY), nor-propoxyphene 300 ng/ml (PPX), 11-nor-Δ⁹-THC-9-COOH 50ng/ml (THC), Tramadol 200 ng/ml (TRA) and Nortriptyline 1000 ng/ml (TCA). The results of each component strip are listed below:

1. **Amphetamine** The accuracy of the amphetamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml. Three hundred and forty five (345) urine specimens which composed of one hundred thirty three (133) d-amphetamine positive samples and two hundred twelve (212) negative samples were evaluated in this study. The results are summarized and presented below:
Positive % agreement:98.5, Negative % agreement: 100
2. **Barbiturate** The accuracy of the barbiturate test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of secobarbital. One hundred thirteen (113)urine specimens which composed of sixty four (64) barbiturate positive samples and forty nice (49) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 100, Negative % agreement: 100.
3. **Benzodiazepine** The accuracy of the benzodiazepine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of oxazepam. Three hundred and forty four (344) urine specimens which composed of one hundred eleven (111) benzodiazepine positive samples and two hundred thirty three (233) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 98, Negative % agreement: 100
4. **Buprenorphine** The accuracy of the buprenorphine test was evaluated in comparison to GC/MS at a cut-off of 10 ng/ml of buprenorphine-3-β-d-glucuronide. One hundred and one (101) urine specimens which composed of forty nine (49) buprenorphine-3-β-d-glucuronide positive samples and fifty two (52) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 96, Negative % agreement: 100.
5. **Cocaine** The accuracy of the cocaine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of benzoylecgonine. Three hundred and forty four (344) urine specimens which composed of one hundred twenty one (121) benzoylecgonine positive samples and two hundred twenty three (223) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 99, Negative % agreement: 99
6. **EDDP** The accuracy of the methadone metabolite (EDDP) test was evaluated in comparison to GC/MS method at a cut-off of 100 ng/mL EDDP. Ninety (99) specimens which composed of forty four (44) positive samples and forty five (45) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 98, Negative % agreement:100
7. **Ketamine** The accuracy of the ketamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml of ketamine. Three hundred and forty four (344) urine specimens which composed of one hundred twenty seven (127) ketamine positive samples and two hundred seventeen (217) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 99, Negative % agreement: 100
8. **MDMA** The accuracy of the MDMA test was evaluated in comparison to GC/MS at a cut-off of 500 ng/ml of (+)methylenedioxymethamphetamine. Eighty (111) urine specimens with GC/MS confirmed MDMA concentration were evaluated in this study. The results are summarized and presented below:
Positive % agreement: 96, Negative % agreement: 95
9. **Methadone** The accuracy of the methadone test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of methadone. Three hundred and forty four (344) urine specimens which composed of one hundred eighty seven (187) methadone positive samples and one hundred fifty seven (157) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 100, Negative % agreement: 100.
10. **Methamphetamine** The accuracy of the methamphetamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml of (+)methamphetamine. Three hundred and forty four (344) urine specimens which composed of one hundred twenty eight (128) methamphetamine positive samples and two hundred sixteen (216) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 98, Negative % agreement: 100

11. **Opiate** The accuracy of the opiate test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of morphine. Three hundred and forty four (344) urine specimens which composed of one hundred fifty nine (159) opiate positive samples and one hundred eighty five (185) negative samples were evaluated in this study. The results are summarized as below:

Positive % agreement:99, Negative % agreement: 99

12. **Opiate II** The accuracy of the opiate II test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of morphine. One hundred and eight (108) urine specimens which composed of fifty three nine (53) opiate positive samples and fifty five (55) negative samples were evaluated in this study. The results are summarized as below: Positive %13. **Oxycodone** The accuracy of the oxycodone test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 100 ng/ml of oxycodone. One hundred and forty four (140) urine specimens which composed of fifty eight (58) opiate positive samples and eighty two (82) negative samples were evaluated in this study. The results are summarized as below: Positive % agreement: 100, Negative % agreement: 95

14. **Phencyclidine** The accuracy of the PCP test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 25 ng/ml of phencyclidine. Eighty (80) urine specimens which composed of thirty five (35) phencyclidine positive samples and forty five (45) negative samples were evaluated in this study. The results are summarized as below:

Positive % agreement: 98, Negative % agreement:95

15. **Propoxyphene** The accuracy of the propoxyphene test was evaluated in comparison to GC/MS method at a cut-off of 300 ng/ml of nor-propoxyphene. Ninety one (91) propoxyphene positive specimens with GC/MS confirmed nor-Propoxyphene concentration and forty (40) were evaluated in this study. The results are summarized as below:

Positive % agreement: 100, Negative % agreement:100

16. **THC** The accuracy of the THC test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 50 ng/ml of 11-nor- Δ^9 -THC-9-COOH. Three hundred and forty four (344) urine specimens which composed of seventy eight (78) THC positive samples and two hundred sixty six (266) negative samples were evaluated in this study. The results are summarized as below:T

Positive % agreement: 100, Negative % agreement: 99

17. **Tramadol** The accuracy of the tramadol test was evaluated in comparison to GC/MS at a cut-off of 200 ng/ml of tramadol Eighty one (81) urine specimens with GC/MS confirmed tramadol concentration were evaluated in this study. The results are summarized and presented below:

Positive % agreement: 95, Negative % agreement: 98

18. **TCA** The accuracy of the TCA test was evaluated in comparison to GC/MS at a cut-off of 1000 ng/ml of Nortriptyline. One hundred (100) urine specimens with GC/MS confirmed Nortriptyline concentration were evaluated in this study. The results are summarized and presented below:

Positive % agreement: 98, Negative % agreement: 95

B. Sensitivity

The cut-off concentrations (sensitivity level) of the DOA/Alcohol RapiDip™ InstaTest Device are determined to be: AMP 1000 ng/ml, BAR, 300 ng/ml, BZO 300 ng/ml, BUP 10 ng/ml, COC 300 ng/ml, EDDP 100 ng/ml, KET 1000 ng/ml, MTD 300 ng/ml, MET 1000 ng/ml, MDMA 500 ng/ml, OPI 300 ng/ml, OPI II 2000 ng/ml, OXY 100 ng/ml, PCP 25 ng/ml , PPX 300 ng/ml, THC 50 ng/ml, 200ng/ml of TRA and TCA 1000 ng/ml.

C. Precision

The precision of the DOA/Alcohol RapiDip™ InstaTest Device was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 40 samples each of 50% above and 50% below cut-off specimens are 100% agreed by three observers. The test results were found to have no significant differences between these three observers.

D. Specificity

The specificity for the DOA/Alcohol RapiDip™ InstaTest Device was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing

The performance of the DOA/Alcohol RapiDip™ InstaTest Device at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.5 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed did not interfere with the DOA/Alcohol RapiDip™ InstaTest Device at the concentrations listed below.

Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

2. Specificity

The following table lists compounds that are detected by the DOA/Alcohol RapiDip™ InstaTest Device which produced positive results when tested at levels equal or greater than the concentrations listed below:

Tests	Compounds	Cut-off (ng/ml)
Amphetamine	D-Amphetamine	1,000
	D/L-Amphetamine	2,000
	(±)3,4Methylenedioxyamphetamine	2,500
	l-Amphetamine	30,000
	(+)methamphetamine	> 100 µg/ml
	(±)3,4Methylenedioxymethamphetamine (MDA)	> 100 µg/ml
Barbiturate	Alphenal	100
	Barbital	150
	Pentobarbital	150
	Phenobarbital	150
	Amobarbital	300
	Secobarbital	300
	Butalbital	5,000
Benzodiazepines	Nitrazepam	100
	Chloradiazepoxide HCl	300
	Clobazam	300
	Desmethyldiazepam	300
	Oxazepam	300
	Temazepam	300
	Alprazolam	1000
	Bromazepam	1000
	Diazepam	1000
	Flunitrazepam	1000
	Lorazepam	1000
	Clonazepam	2000
	Flurazepam	100
Buprenorphine	Buprenorphine-3-β-d-glucoronide	10
	Buprenorphine	200
Cocaine	Benzoyllecgonine	300
	Cocaine	30,000
EDDP	EDDP	100
	EMDP	200,000
	Methadone	500,000

Ketamine	Ketamine	1,000
	Norketamine	500
	Phencyclidine	25,000
	Tetrahydrozoline	50,000
	Chlopheniramine	100,000
	Dextromethorphan	100,000
	Lidocaine	100,000
	Promethazine	100,000
	Pseudoephedrine	100,000
	d-Amphetamine	100,000
MDMA (Ecstasy)	(±)MDMA	500
	(±)MDEA	500
	(±)MDA	2,000
	(±)MBDB	5,000
Methadone	Methadone	300
	Methadol	300
Methamphetamine Including MDMA (Ecstasy)	(+)Methamphetamine	1,000
	(±)3,4Methylenedioxymethamphetamine (MDMA)	1,000
	d-Amphetamine	> 100 µg/ml
	l-Amphetamine	> 100 µg/ml
	(±)3,4Methylenedioxyamphetamine	> 100 µg/ml
	Chloroquine	> 100 µg/ml
	(-)Ephedrine	> 100 µg/ml
	β-Phenylethylamine	> 100 µg/ml
	Procaine	> 100 µg/ml
	d-Pseudoephedrine	> 100 µg/ml
Opiate	Randitidinr	> 100 µg/ml
	Morphine	300
	Morphine-3-β-glucuronide	300
	Codeine	300
	Ethylmorphine	300
	Hydromrphone	300
	Nalorphine	750
	Heroin	1250
	Hydrocodone	1250
	Normorphine	2000
	Norcodeine	2500
	Naloxone	25,000
	Natrexone	100,000
	Oxycodone	> 100 µg/ml
Opiate II	Ethylmorphine	1,000
	Morphine	2,000
	Morphine-3-β-glucuronide	2,000
	Codeine	2,000
	6-Acetylmorphine	2,000
	Dihydrocodone	2,000
	Heroin	5,000
	Hydrocodone	7,500
	Hydromrphone	7,500
	Nalorphine	15,000
	Normorphine	20,000
	Norcodeine	100,000
	Naloxone	100,000

Oxycodone	Oxycodone	100,000
	Oxycodone	100
	Dihydrocodeine	20,000
	Codeine	100,000
	Hydromorphone	100,000
	Morphine	> 100 µg/ml
	Acetylmorphine	> 100 µg/ml
	Buprenorphine	> 100 µg/ml
	Ethylmorphine	> 100 µg/ml
Phencyclidine	PCP	25
Propoxyphene	Propoxyphene	200
	Nor-propoxyphene	300
THC	11-nor- Δ^9 -THC-9-COOH	50
		37.5
	11-nor- Δ^8 -THC-9-COOH	5000
	11-hydroxy- Δ^9 -THC	15000
		25000
	Δ^8 -Tetrahydrocannabinol	
	Δ^9 -Tetrahydrocannabinol	
Tramadol	Tramadol	200
	N-desmethyl-tramadol	500
	O-desmethyl-tramadol	20,000
TCA	Desipramine	1,000
	Nortriptyline	1,000
	Imipramine	1,000
	Amitriptyline	2,000
	Doxepin	2,000
	Protriptyline	2,000
	Trimipramine	5,000

The following compounds show no cross-reactivity at concentration up to 100 ng/ml unless specified.

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid	Amikacin
Arterenol	Aspartame	Ascorbic acid	Atrophine
Caffeine	Camphor	Chloroquine	Chlopheniramine
Cortisone	Deoxyephedrine	Dextromethorphan	Digitoxin
Digoxin	Diphenhydramine	Ecgonine	Ecgonine methyl ester
Ephedrine	Epinephrine	Gentisic acid	Guaiacol glycer ester
Histamine	Hydrochlorothiazide	Homatrophine	Ibuprofen
Isoproterenol	Lidocaine	Meperidine	Methaqualon
Methylphenidate	Neomycin	Niacinamide	Perphenazine
Penicillin G	Phenylethylamine-□	Phenylpropanolamine	Promethazine
Pseudoephedrine	Quinine antidine	Salicylic acid	Tetracycline
Tetrahydrozoline	Theophylline	Thioridazine	Trifluoperazine
Tryptophan	Tyramine		

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