

Drug Tests (Strip/Card/Device/Cup)

Package Insert for testing of any combination of the following drugs:
TRA/KET/EDDP/FEN/K2/COT/MTHP/MQL/LSD/APAP/ZOLP/MDPV/ETG
Available with Specimen Validity Tests (S.V.T.) for:

Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine
One step, rapid screening tests for the qualitative detection of drug(s) and drug metabolites in human urine.
For forensic use only.

INTENDED USE

Drug Tests (Strip/Card/Device/Cup) is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drug(s) and/or drug metabolites in human urine at the following cut-off concentrations:

Test Name	Calibrator	Cut-off
TRA/Tramadol	Tramadol	300ng/mL
TRA/Tramadol	Tramadol	100ng/mL
KET/Ketamine	Ketamine	1000ng/mL
EDDP	EDDP	300ng/mL
EDDP	EDDP	100ng/ml
FEN/Fentanyl	Fentanyl	100ng/mL
K2	JWH-018/JWH-073	50ng/mL
K2	JWH-018/JWH-073	25ng/mL
COT/Cotinine	Cotinine	200ng/mL
MTHP/Methylphenidate	Methylphenidate	300ng/mL
MQL/Methaqualone	Methaqualone	300ng/mL
LSD/ Lysergic Acid Diethylamide	LSD	10ng/mL
LSD/ Lysergic Acid Diethylamide	LSD	3ng/mL
APAP/ Acetaminophen	Acetaminophen	2000ng/mL
APAP/ Acetaminophen	Acetaminophen	5000ng/mL
ZOLP/ Zolpidem	Zolpidem	10ng/mL
MDPV/ Methylenedioxypropyvalerone	Methylenedioxypropyvalerone	300ng/mL
Ethyl Glucuronide/ETG	Ethyl Glucuronide	500ng/mL

Drug Tests (Strip/Card/Device/Cup) provides only a preliminary analytical test result. The test is not intended to be used in monitoring the drug levels. A more specific alternate method must be used in order to confirm the test result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

Drug Tests (Strip/Card/Device/Cup) is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening specific drugs and their metabolites without the need of instrumentation. The method employs a unique mixture of antibodies to selectively detect the elevated levels of specific drugs and their metabolites in urine.

TRAMADOL / TRA

Tramadol is a centrally acting opioid analgesic, used in treating moderate to severe pain. Tramadol possesses weak agonist actions at the μ -opioid receptor, releases serotonin, and inhibits the reuptake of norepinephrine. Tramadol undergoes hepatic metabolism, being *O*- and *N*- demethylated to five different metabolites. Of these, *O*-desmethytramadol is the most significant. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% of the dose is excreted as metabolites, the remainder is excreted either as unidentified or an unextractable metabolites.

KETAMINE / KET

Ketamine is a drug used in human and veterinary medicine. Ketamine has a wide range of effects in humans, including analgesia, anesthesia, hallucinations and elevated blood pressure. Ketamine is primarily used for the induction and maintenance of general anesthesia, usually in combination with a sedative. The common way to abuse ketamine is smoking, inhalants, intravenous injection or drink. Ketamine is metabolized mostly into metabolites and only 5% of the prototype. The drug is metabolized quickly in the body, and usually can be detected within 2-3 hours after smoking.

EDDP

Methadone, a Schedule II controlled substance, is often used in the treatment of opiate addiction and pain management; it also has a high potential for abuse. Methadone is metabolized primarily into two pharmacologically inactive metabolites, EDDP and EMDP. (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine) represents a better urine marker for

monitoring methadone maintenance than testing for un-metabolized methadone alone.

FENTANYL / FEN

Fentanyl is an extremely fast-acting synthetic narcotic analgesic, of high potency(approximately 100 to 200 times that of morphine) and short duration of action. Pharmaceutical fentanyl has been available since 1963 as an anaesthetic supplement, and is available as a citrate salt for I.V or I.M injection. Transdermal patches are also available for management of chronic pain or for breakthrough cancer pain. Due to the lipophilicity of the drug, fentanyl rapidly crosses the blood-brain barrier, producing fast and pronounced CNS effect, such as a heightened euphoria and respiratory depression, and possible toxic effects which include muscle rigidity, seizures, coma, and hypotension. Fentanyl also has similar tolerance and physical dependence properties to those of morphine.

K2

Synthetic cannabis is a psychoactive herbal and chemical product that, when consumed, mimics the effects of cannabis. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic cannabis product. The studies suggest that synthetic cannabinoid intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness. As of March 1, 2011, five cannabinoids, JWH -018, JWH-073, CP-47, JWH-200 and cannabicyclohexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

COTININE / COT

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as Cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. 1. While Cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, Cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. 2. Nicotine and Cotinine are rapidly eliminated by the kidney; the window of detection for Cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

METHYLPHENIDATE / MTHP

Methylphenidate (Ritalin) is a psychostimulant drug approved for treatment of ADHD or attention-deficit hyperactivity disorder, postural orthostatic tachycardia syndrome and narcolepsy. Methylphenidate primarily acts as a norepinephrine-dopamine reuptake inhibitor. Methylphenidate is most active at modulating levels of dopamine and to a lesser extent norepinephrine. Similar to cocaine, methylphenidate binds to and blocks dopamine transporters and norepinephrine transporters. Methylphenidate has both dopamine transporter and norepinephrine transporter binding affinity, with the dextromethylphenidate enantiomers displaying a prominent affinity for the norepinephrine transporter. Methylphenidate may also exert a neuroprotective action against the neurotoxic effects of Parkinson's disease and methamphetamine abuse. Methylphenidate taken orally has a bioavailability of 11-52% with a duration of action around 1-4 hours for instant release, 3-8 hours for sustained release, and 8-12 hours for extended release (Concerta). The half-life of methylphenidate is 2-3 hours, depending on the individual. The peak plasma time is achieved at about 2 hours.

METHAQUALONE / MQL

Methaqualone is a sedative-hypnotic drug that is similar in effect to barbiturates. The sedative-hypnotic activity was first noted by Indian researchers in the 1950s. Its use peaked in the early 1970s as a hypnotic, for the treatment of insomnia, and as a sedative and muscle relaxant. It has also been used illegally as a recreational drug. In 1965 a Methaqualone/antihistamine combination was sold as the sedative drug Mandrax, by Roussel Laboratories (now part of Sanofi-Aventis). Methaqualone is a depressant that increases the activity of the GABA receptors in the brain and nervous system. When GABA activity is increased, blood pressure drops and the breathing and pulse rates slow, leading to a state of deep relaxation. Methaqualone peaks in the bloodstream within several hours, its effects generally lasting four to eight hours. Regular users build up a physical tolerance, requiring larger doses for the same effect. Overdose can lead to nervous system shut down, coma and death.

LYSERGIC ACID DIETHYLAMIDE / LSD

Lysergic acid diethylamide (LSD) is a white powder or a clear, colorless liquid. LSD is manufactured from lysergic acid which occurs naturally in the ergot fungus that grows on wheat and rye. It is a Schedule I controlled substance, available in liquid, powder, tablet (microdots), and capsule form. LSD is recreationally used as a hallucinogen for its ability to alter human perception and mood. LSD is primarily used by oral administration, but can be inhaled, injected, and transdermally applied. LSD is a non-selective 5-HT agonist, may exert its hallucinogenic effect by interacting with 5-HT 2A receptors as a partial agonist and modulating the NMDA receptor-mediated sensory, perceptual, affective and cognitive processes. LSD mimics 5-HT at 5-HT 1A receptors, producing a marked slowing of the firing rate of serotonergic neurons. LSD has a plasma half-life of 2.5-4 hours. Metabolites of LSD include N-desmethyl-LSD, hydroxy-LSD, 2-oxo-LSD, and 2-oxo-3-hydroxy-LSD. These metabolites are all inactive. LSD use can typically be detected in urine for periods of 2-5 days.

ACETAMINOPHEN / APAP

Acetaminophen is one of the most commonly used drugs, yet it is also an important cause of serious liver injury. Acetaminophen is the generic name of a drug found in many common brand name over-the-counter (OTC) products, such as Tylenol, and Prescription (Rx) products, such as Vicodin and Percocet. Acetaminophen is an important drug, and its effectiveness in relieving pain and fever is widely known. Unlike other commonly used drugs to reduce pain and fever (e.g., nonsteroidal antiinflammatory drugs (NSAIDs), such as aspirin, ibuprofen, and naproxen), at recommended doses acetaminophen does not cause adverse effects, such as stomach discomfort and bleeding, and acetaminophen is considered safe when used according to the directions on its OTC or Rx labeling. However, taking more than the recommended amount can cause liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death. Many cases of overdose are caused by patients inadvertently taking more than the recommended dose (i.e., 4 grams a day) of an particular product, or by taking more than one product containing acetaminophen (e.g., an OTC product and an Rx drug containing acetaminophen). The mechanism of liver injury is not related to acetaminophen itself, but to the production of a toxic metabolite. The toxic metabolite binds with liver proteins, which cause cellular injury. The ability of the liver to remove this metabolite before it binds to liver protein influences the extent of liver injury.

ZOLPIDEM / ZOLP

Zolpidem (brand names Ambien, Ambien CR, Intermezzo, Stilnox, Stilnoct, Sublinox, Hypnogen, Lunata, Zonadin, Sanval, Zolsana and Zolfresh) is a prescription medication used for the treatment of insomnia and some brain disorders.It is a short-acting nonbenzodiazepine hypnotic of the imidazopyridine class that potentiates GABA, an inhibitory neurotransmitter, by binding to GABAA receptors at the same location as benzodiazepines.It works quickly, usually within 15 minutes, and has a short half-life of two to three hours.Zolpidem has not adequately demonstrated effectiveness in maintaining sleep, unless delivered in a controlled-release (CR) form. However, it is effective in initiating sleep. Its hypnotic effects are similar to those of the benzodiazepine class of drugs, but it is molecularly distinct from the classical benzodiazepine molecule and is classified as an imidazopyridine. Zolpidem has slight muscle relaxant and anticonvulsant properties, but has not been approved for use in muscle relaxation or seizure prevention. This is because the dosage of drug needed to cause muscle relaxation is 10 times the sedating dose, and the dosage needed for preventing seizures is 20 times the sedating dose;high dosages are more likely to cause unpleasant side effects such as hallucinations and amnesia.

METHYLENEDIOXYPYROVALERONE / MDPV

Methylenedioxypropyvalerone (MDPV) is a psychoactive recreational drug with stimulant properties which acts as a norepinephrine-dopamine reuptake inhibitor (NDRI). MDPV remained an obscure stimulant until around 2004 when it was reportedly sold as a designer drug. Products labeled as bath salts containing MDPV were previously sold as recreational drugs in gas stations and convenience stores in the United States, similar to the marketing for Spice and K2 as incense. MDPV is illegal to use in United States for any medical purposes as it is a psychotropic drug. One year ban was also put on this drug by Drug enforcement administration (DEA) in October 2011. This drug is also prohibited in many European countries.

ETHYL GLUCURONIDE / ETG

Ethyl Glucuronide (ETG) is a metabolite of ethyl alcohol which is formed in the body by glucuronidation following exposure to ethanol, such as by drinking alcoholic beverages. It is used as a biomarker to test for ethanol use and to monitor alcohol abstinence in situations where drinking is prohibited, such as in the military, in professional monitoring programs (health professionals, attorneys, airline pilots in recovery from addictions), in schools, in liver transplant clinics, or in recovering alcoholic patients. ETG can be measured in urine up to approximately 80 hours after ethanol is ingested. ETG is a more

accurate indicator of the recent exposure to alcohol than measuring for the presence of ethanol itself.

S.V.T. SUMMARY

The strips contain chemically treated reagent pads. Three to five minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help to assess the integrity of the urine sample.

WHAT IS ADULTERATION?

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in Drug Tests (Strip/Card/Device/Cup) by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results. One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, specific gravity and creatinine and to detect the presence of oxidants/PCC, nitrites or glutaraldehyde in urine.

Oxidants/PCC (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLuck) is a commonly used adulterant.6 Normal human urine should not contain oxidants of PCC.

Specific gravity tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

pH tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.

Nitrite tests for commonly used commercial adulterants such as Klear and Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.⁹ Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.

Creatinine is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.⁸ A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to “flush” the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of Creatinine (<5 mg/dl) is indicative of a specimen not consistent with human urine.

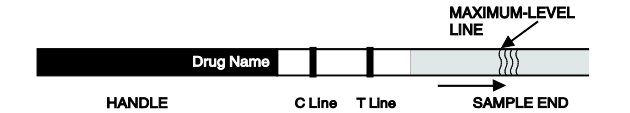
S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants / PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

PRINCIPLE OF TEST

Drug Tests (Strip/Card/Device/Cup) is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of urine specimen is applied to the sample pad of the test device, the urine specimen migrates through the test device by capillary action. If the drug or drug metabolite concentration in the specimen is below the cut-off level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the urine specimen is above the cut-off level, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will be developed in the test region, which indicates a positive result.

A **NEGATIVE** specimen produces two distinct red colored bands in both T line and c line
A **POSITIVE** specimen produces only one distinct red colored band in the C line.



REAGENTS
Drug Tests (Strip/Card/Device/Cup) contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold-protein conjugate at the C zone, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against Tramadol, Ketamine, EDDP, Fentanyl, K2, Cotinine, Methylphenidate, Methaqualone, Lysergic Acid Diethylamide, Zolpidem, Methylenedioxypyrovalerone, Ethyl Glucuronide.

MATERIALS PROVIDED

- 1. Test strip/card/device/cup
- 2. Product Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- 1. Clock or timer .
- 2. Specimen collection containers.
- 3. External controls.

PRECAUTIONS

- 1. For *forensic* use only.
- 2. Do not use after the expiration date.
- 3. The test kits should remain in the sealed pouch until use.
- 4. All specimens should be considered potentially hazardous and handle in the same way as an infectious material.
- 5. All used tests should be discarded according to federal, state and local regulation.

STORAGE AND STABILITY

Store test kits in the sealed pouch at 2°C to 30°C. The test kits are stable through the expiration date printed on the sealed pouch. The test kits must remain in the sealed pouch until use. If store at 2°C to 8°C, allow the test kits to reach room temperature (15°C to 28°C) before performing the test. Do not freeze, do not use beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

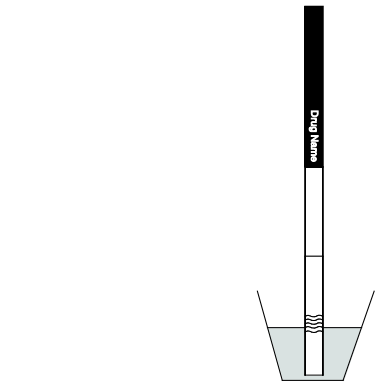
Fresh urine specimens should be collected directly into a clean and dry container. Urine collected at any time of the day may be used for testing. Urine specimen exhibiting visible precipitates should be centrifuged, filtered or allowed the precipitates to settle to obtain a clear specimen for testing.

For best results, test a fresh specimen immediately following collection. Storage of specimens should not exceed 2 hours at room temperature or 4 hours refrigerated (2-8°C) prior to using.

TEST PROCEDURE

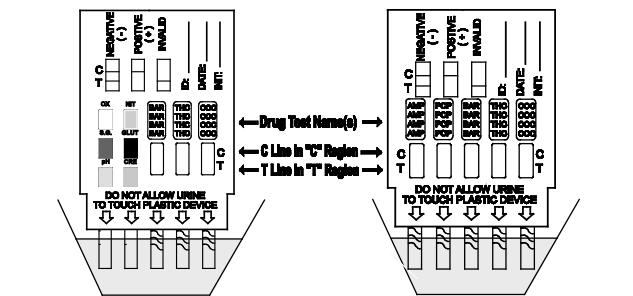
For Drug Test Strip:

- 1. Equilibrate the test strip, urine specimens or external controls to room temperature (15 -30°C) prior to testing.
- 2. Remove the test strip from the sealed pouch and dip the end of the strip into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip just below the top line of the wave line on the test strips.
- 3. Place the test strip on a flat dry surface.
- 4. Read the results at 5 to 10 minutes.



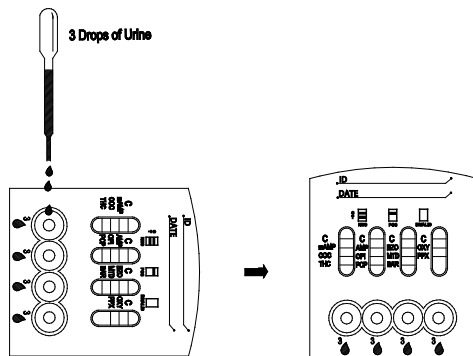
For Drug Test Card:

- 1. Equilibrate the test card, or the test strip, urine specimens or external controls to room temperature(15-30°C) prior to testing.
- 2. Removing the test card from the sealed pouch and dip the card into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip(s) of the test card just below the top line of the wave line on the test strips; do not dip the card above the top line.
- 3. Place the test card or the test strip on a flat dry surface.
- 4. Read the adulteration strips between 3 to 5 minutes (when applicable) by comparing the colors in the adulteration pads to the enclosed color chart. If the specimen indicates adulteration , refer to your Drug Free Policy for guidelines on adulterated specimens. We recommended not to interpret the drug test results and suggest you to retest the urine by using another specimen.
- 5. Read the results at 5 to 10 minutes.



For Drug Test Device:

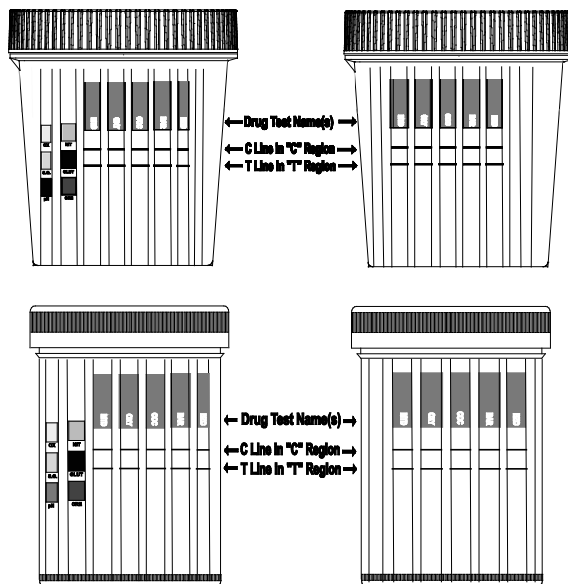
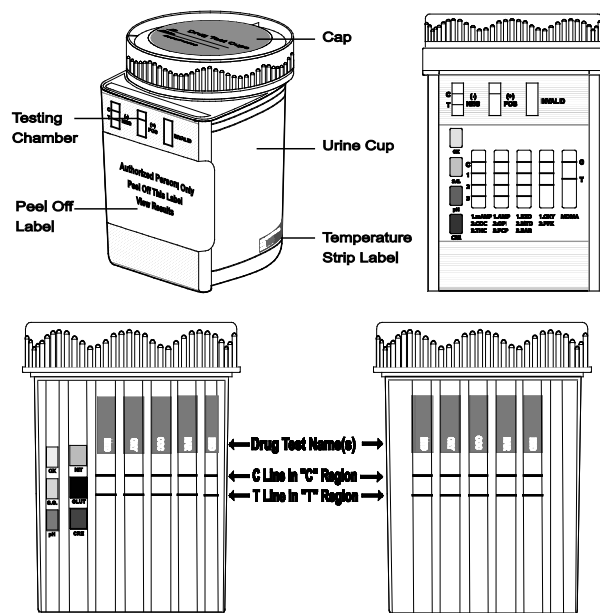
- Allow the test device, urine specimen, and/or controls to equilibrate to room temperature(15-30°C) prior to testing.
- 1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- 2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- 3. Wait for the colored line(s) to appear. The result should be read at 5 to 10 minutes. It is important that the background is clear before the result is read.



For Drug Test Cup:

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

1. Remove the cup from the sealed pouch and use it as soon as possible.
2. Collect specimen in the cup and secure the cap tightly.
3. If the temperature strip is included with Drug Test Cup, please read urine temperature between 2-4 minutes after voiding to verify the temperature ranges between 90-100°F, (33-38°C).
4. Place the cup on a flat surface.
5. Date and initial the security seal, and place the security seal on the cap.
6. Peel off the label on the cup to view the results.
7. If adulteration test is included on the test cup, read the adulteration test results between 2 to 5 minutes. See the color chart for interpretation. If the specimen indicates adulteration, we recommend not to interpret the drug test results and either retest the urine or collect another specimen.
8. Read the results at 5 to 10 minutes. See the illustration below. For detailed operation instructions, please refer to the Procedure Card.



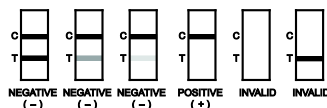
INTERPRETATION OF RESULTS

Positive: One colored line appears in the Control zone (C). No line appears in the Test Zone (T). The absence of a line in the test region (T line) indicates a positive result. The positive result indicates that the drug level is above the detectable level.

Note: The samples with positive results should be confirmed with more specific method.

Negative: One colored line appears in the Control zone, and another colored line appears in the Test zone. The negative result indicates the drug or its metabolite level is below the detectable level.

Invalid: No line appears in the Control zone. If no C line or no C line and T line develop within 5 to 10 minutes, the test is invalid. The test should be repeated with a new test device. Insufficient specimen volume or the incorrect procedural techniques are the most likely reasons for invalid result. Review the procedure and repeat the test using a new test strip or device. If the problem persists, discontinue using the current lot and contact your suppliers.



QUALITY CONTROL

The test contains a built-in control feature, the C line. The presence of the C line indicates that the test is performed properly. If a C line does not form, the test is considered invalid. In this case, the testing should be repeated with a new test.

S.V.T. ADULTERATIONS LIMITATIONS

1. The adulteration tests included with the product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an "all-inclusive" representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. pH tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
5. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in

urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.

6. Glutaraldehyde: is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.

7. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

LIMITATIONS

1. **Drug Tests (Strip/Card/Device/Cup)** provides only a qualitative, preliminary testing result. A more specific testing method must be used in order to obtain a confirmed testing result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants such as bleach or other oxidizing agents may produce erroneous results. If suspected, the test should be repeated with a fresh specimen and a new device.
4. The urine specimens with bacterial contamination should not be used for testing, as these contaminations may interfere with the test and cause false results.
5. A positive result does not indicate level or intoxication, administration route or concentration in urine.
6. 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 test.
7. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Sensitivity:

Sensitivity of **Drug Tests (Strip/Card/Device/Cup)** was characterized by validating the test performance around the claimed cut-off concentration of each test. The cut-off of each test was determined by the lowest concentration of drug which produces at least 50% positive testing results in total numbers of determinations. The results were summarized as the following:

Drug concentration Cut-off Range	n	TRA 300		TRA 100		KET 1000	
		-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0
-25% Cut-off	20	19	1	18	2	19	1
+25% Cut-off	20	0	20	0	20	0	20
+50% Cut-off	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	EDDP 300		EDDP 100		FEN 100	
		-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0
-25% Cut-off	20	19	1	20	0	19	1
+25% Cut-off	20	0	20	6	14	0	20
+50% Cut-off	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	K2 50		K2 25		COT 200	
		-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0
-25% Cut-off	20	18	2	20	0	15	5
+25% Cut-off	20	2	18	5	15	4	16
+50% Cut-off	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	MTHP 300		MQL 300		LSD 10	
		-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0
-25% Cut-off	20	20	0	20	0	17	3
+25% Cut-off	20	7	13	7	13	0	20
+50% Cut-off	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	LSD 3		APAP 2000		APAP 5000	
		-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0
-25% Cut-off	20	17	3	19	1	18	2
+125% Cut-off	20	0	20	4	16	0	20
+150% Cut-off	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	ZOLP 10		MDPV 300		ETG 500	
		-	-	-	+	-	+
0% Cut-off	20	20	20	20	0	20	0
-50% Cut-off	20	20	20	20	0	20	0
-25% Cut-off	20	19	19	19	1	20	0
+125% Cut-off	20	0	0	2	18	7	13
+150% Cut-off	20	0	0	0	20	0	20

Precision / Reproducibility:

Reproducibility was determined by replicating tests on five different concentrations of each drug in urine specimens: negative, 50% below cut-off, 25% below cut-off, 25% above cut-off and 50% above cut-off. Each drug test was tested four times daily for five consecutive days with a total 20 assays at each concentration. The data are summarized below:

Tramadol 300 Precision/Reproducibility Study:

Tramadol 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	19/1	95%
375	20	0/20	100%
450	20	0/20	100%

Tramadol 100 Precision/Reproducibility Study:

Tramadol 100 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
50	20	20/0	100%
75	20	18/2	90%
125	20	0/20	100%
150	20	0/20	100%

Ketamine 1000 Precision/Reproducibility Study:

Ketamine 1000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	19/1	95%
1250	20	0/20	100%
1500	20	0/20	100%

EDDP 300 Precision/Reproducibility Study:

EDDP 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	19/1	95%
375	20	0/20	100%
450	20	0/20	100%

EDDP 100 Precision/Reproducibility Study:

EDDP 100 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
50	20	20/0	100%
75	20	20/0	100%
125	20	6/14	70%
150	20	0/20	100%

Fentanyl 100 Precision/Reproducibility Study:

Fentanyl 100 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
50	20	20/0	100%
75	20	20/0	100%
125	20	4/16	80%
150	20	0/20	100%

K2 50 Precision/Reproducibility Study:

K2 50 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
25	20	20/0	100%
37.5	20	18/2	90%
62.5	20	2/18	90%
75	20	0/20	100%

K2 25 Precision/Reproducibility Study:

K2 25 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
12.5	20	20/0	100%
18.75	20	20/0	100%
31.25	20	5/15	75%
37.5	20	0/20	100%

COT 200 Precision/Reproducibility Study:

COT 200 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
100	20	20/0	100%
150	20	15/5	75%
250	20	4/16	80%
300	20	0/20	100%

MTHP 300 Precision/Reproducibility Study:

MTHP 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	7/13	65%
450	20	0/20	100%

MQL 300 Precision/Reproducibility Study:

MQL 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	18/2	90%
375	20	1/19	95%
450	20	0/20	100%

LSD 10 Precision/Reproducibility Study:

LSD 10 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
5	20	20/0	100%
7.5	20	17/3	15%
12.5	20	0/20	100%
15	20	0/20	100%

LSD 3 Precision/Reproducibility Study:

LSD 3 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
1.5	20	20/0	100%
2.25	20	17/3	15%
3.75	20	0/20	100%
4.5	20	0/20	100%

APAP 2000 Precision/Reproducibility Study:

APAP 2000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
1000	20	20/0	100%
1500	20	19/1	95%
2500	20	4/16	80%
3000	20	0/20	100%

APAP 5000 Precision/Reproducibility Study:

APAP 5000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
2500	20	20/0	100%
3750	20	17/3	85%
6250	20	0/20	100%
7500	20	0/20	100%

ZOLP 10 Precision/Reproducibility Study:

ZOLP 10 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
15	20	20/0	100%
7.5	20	19/1	95%
12.5	20	0/20	100%
5	20	0/20	100%

MDVP 300 Precision/Reproducibility Study:

MDVP 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	19/1	95%
300	20	2/18	90%
375	20	0/20	100%

Ethyl Glucuronide 500 Precision/Reproducibility Study:

Ethyl Glucuronide 500 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
250	20	20/0	100%
375	20	20/0	100%
625	20	7/13	65%
750	20	0/20	100%

The data presented here demonstrates excellent precision/reproducibility of **Drug Tests (Strip/Card/Device/Cup)** across multiple concentrations of human urine.

Analytical Specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine/a negative control. Analyzing various concentration of each compound by using **Drug Tests (Strip/Card/Device/Cup)**, the concentration of the drug that produced a response approximately equivalent to the cut-off concentration of the assay was determined. Results of those studies appear in the table(s) below:

Drug Compound	Response equivalent to cutoff in ng/mL
Tramadol 300 (TRA)	
Tramadol	300
(+/-) Chlorpheniramine	>100,000
Diphenhydramine	>100,000
Pheniramine	>100,000
Tramadol 100 (TRA)	
Tramadol	100
(+/-) Chlorpheniramine	>100,000
Diphenhydramine	>100,000
Pheniramine	>100,000
Ketamine (KET)	
Ketamine	1000
methamphetamine	25,000
EDDP300	
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
Methadone	3750
Doxylamine	>100,000
EDDP100	
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Methadone	1250
Doxylamine	>100,000
Fentanyl (FEN)	
Fentanyl	100
NorFentanyl	50,000
Morphine	>100,000
Hydromorphone	>100,000
Oxycodone	>100,000
Oxymorphone	>100,000
K2 50	
JWH-018 N-(5-hydroxypentyl) metabolite	50
JWH-073 N-(4-hydroxybutyl) metabolite	50
JWH-018 pentanoic acid	50
JWH-073 butanoic acid	50
JWH-018	15,000
JWH-073	15,000
JWH 019 N-(5-hydroxyhexyl) metabolite	100
JWH 081 N-(5-hydroxypentyl) metabolite	3000
JWH 122 N-(5-hydroxypentyl) metabolite	150
JWH 200 5-hydroxyindole metabolite	150
JWH 203 N-(5-hydroxypentyl) metabolite	10000
JWH 210 N-(5-hydroxypentyl) metabolite	1500
JWH 250 N-(5-hydroxypentyl) metabolite	>100,000
JWH 398 N-(5-hydroxypentyl) metabolite	150
AM2201 N-(4-hydroxypentyl) metabolite	100
AM694 N-(5-hydroxypentyl) metabolite	250
PB-22 N-(5-hydroxypentyl) metabolite	>100,000
AKB48 N-(5-hydroxypentyl) metabolite	>100,000
K2 25	
JWH-018 N-(5-hydroxypentyl) metabolite	25
JWH-073 N-(4-hydroxybutyl) metabolite	25
JWH-018 pentanoic acid	25
JWH-073 butanoic acid	25
JWH-018	10,000
JWH-073	10,000
JWH 019 N-(5-hydroxyhexyl) metabolite	50
JWH 081 N-(5-hydroxypentyl) metabolite	1500
JWH 122 N-(5-hydroxypentyl) metabolite	75
JWH 200 5-hydroxyindole metabolite	75
JWH 203 N-(5-hydroxypentyl) metabolite	5000
JWH 210 N-(5-hydroxypentyl) metabolite	750
JWH 250 N-(5-hydroxypentyl) metabolite	>100,000
JWH 398 N-(5-hydroxypentyl) metabolite	75
AM2201 N-(4-hydroxypentyl) metabolite	50
AM694 N-(5-hydroxypentyl) metabolite	125
PB-22 N-(5-hydroxypentyl) metabolite	>100,000
AKB48 N-(5-hydroxypentyl) metabolite	>100,000
Cotinine (COT)	
Cotinine	200
Nicotine	6000
Methylphenidate (MTHP)	
Methylphenidate	300
Methaqualone (MQL)	
Methaqualone	300

Phenytoin	40000
Primidone	20000
Theophylline	40000
Lysergic Acid Diethylamide 10 (LSD)	
LSD	10
Fentanyl	15
Lysergic Acid Diethylamide 3 (LSD)	
LSD	3
Fentanyl	3.75
Acetaminophen 2000 (APAP)	
Acetaminophen	2000
Acetaminophen 5000 (APAP)	
Acetaminophen	5000
Zolpidem 10 (ZOLP)	
Zolpidem	10
Zolpidem Phenyl-4-carboxylic acid	10
D-Amphetamine	100000
+Methamphetamine	100000
(+/-)-3,4-Methylenedioxymethamphetamine (MDMA)	10000
Methylenedioxypropylvalerone 300 (MDPV)	
Methylenedioxypropylvalerone	300
alpha-PVP	75,000
Mephedrone	75,000
Mephramate	> 100,000
D-Amphetamine	100000
+Methamphetamine	100000
(+/-)-3,4-Methylenedioxymethamphetamine (MDMA)	10000
Ethyl Glucuronide 500 (ETG)	
Ethyl- β -D-Glucuronide	500
Ethanol	>100,000
Propyl β-D-glucuronide	50000
Butanol	>100,000
Glucuronic Acid	>100,000
Methanol	>100,000
Morphine 3β-glucuronide	>100,000
Morphine 6β-glucuronide	>100,000

INTERFERING COMPOUNDS

The following compounds in both drug-free urine and drug positive urines show no cross-reactivity when tested with **Drug Tests (Strip/Card/Device/Cup)** at a concentration of 100 ug/ml.

Common Substances:

Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic Acid	Ethanol	Phenothiazine
Aspartame	Furosemide	L-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Tyramine
Creatine	(+)-Naproxen	4-Dimethylaminoantipyrine
Dexbrompheniramine	Niacinamide	(1R,2S)-(-)-N-Methyl-Ephedrine
Dextromethorphan	Nicotine	
Diphenhydramine	(+/-)-Norephedrine	

Biological Materials:

Albumin	Vitamin(L-Ascorbic Acid)
Bilirubin	Uric Acid
Creatine	Urine pH 4.5-9.0
Hemoglobin	Urine Specific Gravity 1.002-1.035 g/mL
Glucose	

(There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results.)

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