todylaboratories®

Rapid Tests

CE IVD REF C61RT1029 REF C61RT1030

Multi-Drug Rapid Test Panel with/without Adulteration (Urine) Package Insert

Instruction Sheet for testing of any combination of the following drugs: AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/MOP/TCA/FYL Including Specimen Validity Tests (S.V.T.) for: Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde, Creatinine and Bleach

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

INTENDED USE

The Multi-Drug Rapid Test Panel is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP 1,000)	d-Amphetamine	1,000
Barbiturates (BAR 300)	Secobarbital	300
Benzodiazepines (BZO 300)	Oxazepam	300
Buprenorphine (BUP 10)	Buprenorphine	10
Cocaine (COC 300)	Benzoylecgonine	300
Marijuana (THC 50)	11-nor-Δ⁹-THC-9 COOH	50
Methadone (MTD 300)	Methadone	300
Methamphetamine (MET 1,000)	d-Methamphetamine	1,000
Methylenedioxymethamphetamine (MDMA 500)	d,l-Methylenedioxymethamphetamine	500
Morphine/Opiate (MOP/OPI 300)	Morphine	300
Tricyclic Antidepressants (TCA1000)	Nortriptyline	1,000
Fentanyl(FYL20)	Norfentanyl	20

Configurations of the Multi-Drug Rapid Test Panel come with any combination of the above listed drug analytes with or without S.V.T. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The Multi-Drug Rapid Test Panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

Amphetamine (AMP)

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

The Multi-Drug Rapid Test Panel yields a positive result when the concentration of amphetamines in urine exceeds detective level.

Barbiturates (BAR)

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

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

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

The approximate detection time limits for barbiturates are:

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

The Multi-Drug Rapid Test Panel yields a positive result when the concentration of barbiturates in urine exceeds detective level.

Benzodiazepines (BZO)

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

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

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

The Multi-Drug Rapid Test Panel yields a positive result when the concentration of benzodiazepines in urine exceeds detective level.

Buprenorphine (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names SubutexTM, BuprenexTM, TemgesicTM and SuboxoneTM, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range7up to 20 ng/ml in abuse situations. The plasma half -life of Buprenorphine is 2-4 hours. While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days. Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The Multi-Drug Rapid Test Panel yields a positive result when the Buprenorphine in urine exceeds detective level.

Cocaine(COC)

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

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine.3,4 Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.4 The Multi-Drug Rapid Test Panel yields a positive result when the concentration of Cocaine in urine exceeds detective level.

Marijuana (THC)

THC (Δ9-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-Δ9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The Multi-Drug Rapid Test Panel yields a positive result when the concentration of THC-COOH in urine exceeds detective level.

Methadone (MTD)

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

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

The Multi-Drug Rapid Test Panel yields a positive result when the concentration of methadone in urine exceeds detective level.

Methamphetamine (MET)

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

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

The Multi-Drug Rapid Test Panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. The Multi-Drug Rapid Test Panel yields a positive result when the Methamphetamine in urine exceeds detective level.

Methylenedioxymethamphetamine (MDMA)

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

The Multi-Drug Rapid Test Panel yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds detective level.

Morphine/Opiate (OPI)

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

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

The Multi-Drug Rapid Test Panel yields a positive result when the concentration of morphine/Opiate in urine exceeds detective level.

Tricyclic Antidepressants (TCA)

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

The Multi-Drug Rapid Test Panel yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds detective level. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

Fentanyl (FYL)

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

The FYL Rapid Test Panel (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of FYL in urine. The FYL Rapid Test Panel (Urine) yields a positive result when FYL in urine exceeds detective level.

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 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 (Pyridiniumchlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridiniumchlorochromate (sold under the brand name Urine Luck) is a commonly used adulterant.[8] 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 Urin Aid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests.[9] 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.[2] 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.

Bleach tests for the presence of bleach bleach refers to a number of chemicals which remove color, whiten or disinfect, often by oxidation, Bleaches are used as household chemicals to whiten clothes and remove stains and as disinfectants. Normal human urine should not contain bleach.

PRINCIPLE (FOR DOA TESTS EXCLUDING ALCOHOL)

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

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

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

PRINCIPLE (FOR ALCOHOL)

The urine Alcohol Rapid Test consists of a plastic strip with a reaction pad attached at the tip. On contact with alcohol, the reaction pad will change colors depending on the concentration of alcohol present. This is based on the high specificity of alcohol oxidase for ethyl alcohol in the presence of peroxidase and enzyme substrate such as TMB.

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REAGENTS (FOR DOA TESTS EXCLUDING ALCOHOL)
Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

REAGENTS (FOR ALCOHOL)
Tetramethylbenzidine • Alcohol Oxidase• Peroxidase

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Creatinine	0.04%	99.96%
Nitrite	0.07%	99.93%
Bleach	0.39%	99.71%
Glutaraldehyde	0.02%	99.98%
pH	0.06%	99.94%
Specific Gravity	0.25%	99.75%
Oxidants / PCC	0.36%	99.64%

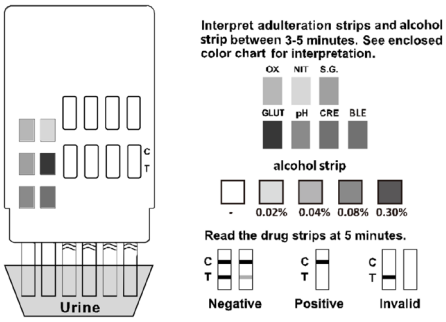
PRECAUTIONS
• For healthcare professionals including professionals at point of care sites.
• Immunoassay for *in vitro* diagnostic use only. The Test Panel should remain in the sealed pouch until use.
• All specimens should be considered potentially hazardous and handled in the same manner as an infectious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

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

SPECIMEN COLLECTION AND PREPARATION
Urine Assay
The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.
Specimen Storage
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing. When testing cards with S.V.T. or Alcohol storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing.

MATERIALS
Materials provided
• Test Panels • Package Insert • Adulteration Color Chart (when applicable)
Materials required but not provided
• Timer

DIRECTIONS FOR USE
Allow the test, urine specimen, and/or controls to reach room temperature (15-30oC) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. **Immerse the dipstick to at least the level of the wavy lines, but not above the arrow on the test panel.**
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. **Read the adulteration strips and Alcohol strip between 3-5 minutes** according to color chart provided separately/on foil pouch. Refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen in case of any positive result for any adulteration test.
7. The drug strip result should be read at **5 minutes**. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above)
NEGATIVE:* A colored line appears in the Control region (C) and colored lines appear in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.
***NOTE**: The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.
POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.
INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

INTERPRETATION OF RESULTS (S.V.T./ADULTERATION)
(Please refer to the color chart)
Semi Quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart.
No instrumentation is required.

INTERPRETATION OF RESULTS (ALCOHOL STRIP)
Negative: Almost no color change by comparing with the background. The negative result indicates that the urine alcohol level is less than 0.02%.
Positive: A distinct color developed all over the pad. The positive result indicates that the urine alcohol concentration is 0.02% or higher.
Invalid: The test should be considered invalid If only the edge of the reactive pad turned color that might be ascribed to insufficient sampling. The subject should be re-tested. Besides, if the color pad has a blue color before applying urine sample, do not use the test.

QUALITY CONTROL
A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS
1. The Multi-Drug Rapid Test Panel 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.[1,10]
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements. Alcohol in the atmosphere, such as spray from perfumes, deodorizers, glass cleaners etc. can affect the Alcohol Rapid Tests. Therefore, adequate measures should be taken to avoid undue interference from such atmospheric agents in the testing area.
8. The test is only for detection of presence/ absence of alcohol in the urine, which may result from habitual drinking or medications and does not discriminate the two.

S.V.T./ADULTERATION 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. 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.
5. 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.
6. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.
7. Bleach: Normal human urine should not contain bleach. The presence of high levels of bleach in the specimen may result in false negative results for the bleach pad.

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

PERFORMANCE CHARACTERISTICS
Accuracy
A side-by-side comparison was conducted using the Multi-Drug Rapid Test Panel and commercially available drug rapid tests. Testing was performed on approximately hundred specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS.

Method		GC/MS		% agreement with GC/MS
Multi-Drug Rapid Test Panel		Positive	Negative	
AMP 1,000	Positive	103	3	98.1%
	Negative	2	142	97.9%
BAR 300	Positive	98	2	96.1%
	Negative	4	146	98.6%
BZO 300	Positive	121	1	98.4%
	Negative	2	126	99.2%
BUP 10	Positive	105	0	99.1%
	Negative	1	144	>99.9%
COC 300	Positive	111	3	98.2%
	Negative	2	134	97.8%
THC 50	Positive	92	3	97.9%
	Negative	2	153	98.1%
MTD 300	Positive	89	2	98.9%
	Negative	1	158	98.8%
MET 1,000	Positive	76	5	96.2%
	Negative	3	166	97.1%
MDMA 500	Positive	102	1	98.1%
	Negative	2	145	99.3%
MOP/OPI 300	Positive	95	7	95.0%
	Negative	5	143	95.3%
TCA 1,000	Positive	91	13	94.8%
	Negative	5	141	91.6%
FYL 20	Positive	79	1	98.8%
	Negative	1	169	99.4%

% Agreement with Commercial Kit

	AMP 1,000	BAR 300	BZO 300	BUP 10	COC 300	THC 50	MTD 300	MET 1,000	MDMA 500	MOP/OPI 300	TCA 1,000	FYL 20
Positive Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	*	*
Negative Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	*	*
Total Results	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	*	*

*** Note: Based on GC/MS data instead of Commercial Kit.**
Precision
A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of ±50% and ±25% cut-off level, was labeled, blinded and tested at each site. The results are given below:
AMPHETAMINE (AMP 1,000)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1,250	10	1	9	2	8	2	8
1,500	10	0	10	0	10	0	10

BARBITURATES (BAR 300)

Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	8	2	9	1
375	10	2	8	1	9	2	8
450	10	0	10	0	10	0	10

BENZODIAZEPINES (BZO 300)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

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BUPRENORPHINE (BUP 10)

Buprenorphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	9	1	9	1	8	2
12.5	10	1	9	1	9	1	9
15	10	0	10	0	10	0	10

COCAINE (COC 300)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

MARIJUANA (THC50)

11-nor-Δ9-THC-9 COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	8	2	9	1
62.5	10	1	9	1	9	2	8
75	10	0	10	0	10	0	10

METHADONE (MTD300)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

METHAMPHETAMINE (MET1,000)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	9	1	9	1
1,250	10	1	9	2	8	1	9
1,500	10	0	10	0	10	0	10

METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500) Ecstasy

Methylenedioxymethamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	8	2	9	1	9	1
625	10	1	9	1	9	1	9
750	10	0	10	0	10	0	10

MORPHINE (MOP/OPI 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	9	1	9	1	9	1
375	10	1	9	1	9	1	9
450	10	0	10	0	10	0	10

TRICYCLIC ANTIDEPRESSANTS (TCA1000)

Nortriptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	8	2
1,250	10	1	9	1	9	1	9
1,500	10	0	10	0	10	0	10

FENTANYL (FYL20)

FYL conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
10	10	10	0	10	0	10	0
15	10	9	1	9	1	9	1
25	10	1	9	1	9	1	9
30	10	0	10	0	10	0	10

Analytical Sensitivity

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

Drug Concentration Cut-off Range	AMP 1,000		BAR 300		BZO 300		BUP 10		COC 300		THC 50		MTD 300		MET 1,000		MDMA 500		MOP/OPI 300		TCA 1,000		FYL 20	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0%Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50%Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25%Cut-off	26	4	27	3	27	3	26	4	26	4	26	4	26	4	27	3	25	5	27	3	25	5	27	3
Cut-off	15	15	16	14	15	15	14	16	13	17	14	16	14	16	16	14	14	16	15	15	15	15	14	16
+25%Cut-off	3	27	4	26	3	27	3	27	3	27	3	27	3	27	3	27	4	26	5	25	4	26	4	26
+50%Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+300%Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the Multi-Drug Rapid Test Panel at 5 minutes.

Analytes	**Conc. (ng/mL)**		
AMPHETAMINE (AMP 1,000)			
D,L-Amphetamine sulfate	300	Maprotiline	50,000
L-Amphetamine	25,000	Methoxyphenamine	6,000
(±) 3,4-Methylenedioxy amphetamine	500	D-Amphetamine	1,000
Phentermine	1,000		
BARBITURATES (BAR 300)			
Amobarbital	5,000	Alphenol	600
5,5-Diphenylhydantoin	8,000	Aprobarbital	500
Allobarbital	600	Butabarbital	200
Barbital	8,000	Butalbital	5,000
Talbutal	200	Butethal	300
Cyclopentobarbital	30,000	Phenobarbital	200
Pentobarbital	8,000	Secobarbital	200
BENZODIAZEPINES (BZO 300)			
Alprazolam	100	Delorazepam	900
a-hydroxyalprazolam	1,500	Desalkylflurazepam	200
Clobazam	200	Flunitrazepam	200
Clonazepam	500	(±) Lorazepam	3,000
Clorazepatedipotassium	500	RS-Lorazepamglucuronide	200
Midazolam	6,000	Oxazepam	300
Bromazepam	900	Temazepam	100
Chlordiazepoxide	900	Diazepam	300
Nitrazepam	200	Estazolam	6,000
Norchlordiazepoxide	100	Triazolam	3,000
Nordiazepam	900	Midazolam	6,000
BUPRENORPHINE (BUP 10)			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
COCAINE (COC 300)			
Benzoylecgonine	300	Cocaethylene	20,000
Cocaine HCl	200	Ecgonine	30,000
MARIJUANA (THC50)			
Cannabinol	35,000	Δ8-THC 30	17,000
11-nor-Δ8-THC-9 COOH	30	Δ9-THC	17,000
11-nor-Δ9-THC-9 COOH	50		
METHADONE (MTD300)			
Methadone	300	Doxylamine	100,000
METHAMPHETAMINE (MET1, 000)			
ρ-Hydroxymethamphetamine	25,000	D-Methamphetamine	1,000
(±)-3,4-Methylenedioxy-methamphetamine	12,500	L-Methamphetamine	20,000
Mephentermine	50,000		
METHYLENEDIOXYMETHAMPHETAMINE (MDMA500) Ecstasy			
(±) 3,4-Methylenedioxy methamphetamine HCl	500		
(±) 3,4-Methylenedioxyampheta mine HCl	3,000		
3,4-Methylenedioxyethyl-amphetamine	300		
MORPHINE (MOP/OPI 300)			
Codeine	200	Norcodeine	6,000
Levorphanol	1,500	Normorphone	50,000
Morphine-3-β-D-Glucuronide	800	Oxycodone	30,000
Ethylmorphine	6,000	Oxymorphone	50,000
Hydrocodone	50,000	Procaine	15,000
Hydromorphone	3,000	Thebaine	6,000
6-Monoacethylmorphine	300	Morphine	300
TRICYCLIC ANTIDEPRESSANTS (TCA1000)			
Nortriptyline	1,000	Imipramine	400
Nordoxepine	500	Clomipramine	50,000
Trimipramine	3,000	Doxepine	2,000
Amitriptyline	1,500	Maprotiline	2,000
Promazine	3,000	Promethazine	50,000
Desipramine	200	Perphenazine	50,000
Cyclobenzaprine	2,000	Dithiaden	10,000
FENTANYL (FYL20)			
Alfentanyl	600,000	Buspirone	15,000
Fenfluramine	50,000	Fentanyl	100
Norfentanyl	20	Sufentanyl	50,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005-1.045) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Multi-Drug Rapid Test Panel was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Multi-Drug Rapid Test Panel. 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 above related calibrator substances. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test Panel at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

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

ALCOHOL PERFORMANCE CHARACTERISTICS

The detection limit on the Urine Alcohol Rapid Test is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the Urine Alcohol Rapid Test can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

ALCOHOL ASSAY SPECIFICITY

The Urine Alcohol Rapid Test will react with methyl, ethyl and allyl alcohols.

ALCOHOL INTERFERING SUBSTANCES

The following substances may interfere with the Urine Alcohol Rapid Test when using samples other than urine. The named substances do not normally appear in sufficient quantity in urine to interfere with the test.

A. Agents which enhance color development
- Peroxidases
- Strong oxidizers

B. Agents which inhibit color development
- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

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