UScreen^{2}© Drugs of Abuse Cup

CLIA CATEGORIZATION: WAIVED

URINE SCREENING TEST RESULTS IN 5 MINUTES

The UScreen^{2} Drugs of Abuse Cup tests for the possible use of marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Methylenedioxymethamphetamine - ecstasy (MDMA), Morphine 300 (MOP), Morphine 2000 (OPI), Barbiturates (BAR), Benzodiazepines (BZO), Methadone (MTD), Phencyclidine (PCP), Oxycodone, (OXY), Tri-cyclic Antidepressants (TCA) and Buprenorphine(BUP).

The UScreen^{2} test cup is a rapid, screening test for the qualitative detection of multiple drugs in human urine at specified cut off levels.
For Healthcare professionals including professionals at point of care sites.
For in vitro diagnostic use only.

WHAT IS The USCREEN^{2} DRUGS OF ABUSE CUP?

The UScreen^{2} Drugs of Abuse Cup is an immuno-chromatographic assay for the qualitative determination of the presence of drugs listed in the table below. The test you purchased may test for any combination of drugs listed in the table below.

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

Drug(Identifier)	Cut-off level	Minimum detection time	Maximum detection time
Marijuana (THC)	50 ng/mL	2 hours	Up to 5+ days
Cocaine (COC)	300 ng/mL	1-4 hours	2-4 days
Amphetamine (AMP)	1000 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET)	1000 ng/mL	2-7 hours	2-4 days
Morphine (MOP)	300 ng/mL	2 hours	2-3 days
Morphine 2000 (OPI)	2000 ng/mL	2 hours	2-3 days
Methylenedioxymethamphetamine (MDMA)	500 ng/mL	2-7 hours	2-4 days
Barbiturates (BAR)	300 ng/mL	2-4 hours	1-3 weeks
Benzodiazepines (BZO)	300 ng/mL	2-7 hours	1-4 days
Methadone (MTD)	300 ng/mL	3-8 hours	1-3 days
Oxycodone (OXY)	100 ng/mL	1-3 hours	1-2 days
Phencyclidine (PCP)	25 ng/mL	4-6 hours	7-14days
Tri-cyclic Antidepressants (TCA)	1000 ng/mL	8-12hours	2-7 days
Buprenorphine(BUP)	10 ng/mL	4 hours	1-3 days

WARNINGS AND PRECAUTIONS

- This kit is for external use only
- Discard after first use. The test cannot be used more than once
- Keep out of the reach of children
- Do not use if pouch is punctured or not sealed
- Do not use test kit beyond expiration date
- Do not read results after 5 minutes

MATERIAL PROVIDED Delete "OF THE KIT"

- 25 Test devices, one test cup per pouch. Each pouch contains a test cup with integrated test card
- Desiccant Pouch - Remove desiccant from cup. The desiccant is for storage purposes only.
- One (1) Instruction Sheet
- One (1) Adulteration color comparison chart for interpretation of adulteration test results (if equipped)
- 25 Security seals (if Provided)

STORAGE AND STABILITY

- Store at 39 ~ 86 ºF (4 ~ 30 ºC) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

PRINCIPLE

UScreen^{2} Drugs of Abuse Cup is a competitive immunoassay that is used to screen for the presence of various drugs in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is a levels below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, that, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), of each strip, if the test has been performed properly.

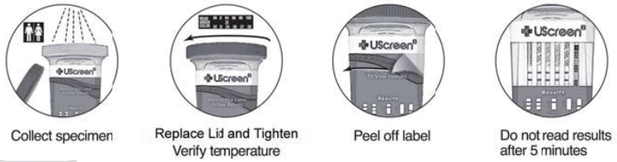
SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?
Collect urine samples after minimum detection time following suspected drug use. Urine collection time is very important in detecting any drug of abuse. Each drug is cleared by the body and is detected in the urine at different times and rates. Please refer to the section "WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIMES?" contained within this package insert, to determine the minimum/maximum detection times, and cut-off level for each drug.

HOW TO COLLECT URINE?
1. Remove a test cup from the foil pouch by tearing at the notch. Use it as soon as possible. Instruct the donor to remove the cap from the test cup, and void directly into the test cup. Instruct the donor to fill the cup to the 30 mL mark. It's acceptable to collect extra sample.
2. Observe the temperature strip affixed on the test cup, immediately, to determine if the urine is diluted by water, substitute urine, or liquid other than urine. The temperature range from 32°C to 38°C (90 ºF-100ºF) is acceptable.

HOW TO PERFORM THE TEST?

Test must be performed at room temperature. 65 - 86ºF (18 - 30ºC).
1. After the urine has been collected, tighten lid, and place the test cup on a flat surface.
2. Read temperature immediately to verify that urine temperature is within the acceptable range. 90 – 100^{o}F (32 – 38^{o}C)
3. Remove Cup label, and verify that adulterant pad colors are within acceptable range according to adulteration guide (If your cup is equipped with specimen validity/adulterant pads.)
4. Remove the label and read the results. Wait 5 minutes to determine a positive result.
5. **Do not read results after 5 minutes.** *Results after more than 5 minutes may be not accurate and should not be read.*



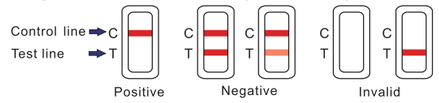
READING THE RESULTS

Preliminary positive (+)
A rose-pink band is visible in each control region. If no color band appears in the appropriate test "T" region, a preliminary positive result is indicated for the corresponding drug of that specific test zone.

Negative (-)
If a rose-pink band is visible in each control region and the appropriate test "T" region, it indicates that the concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.

Invalid
If a color band is not visible in the control "C" region or a color band is only visible in the test "T" region, the test is invalid. Another test should opened and run to re-evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number for the test.

Note: There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line.



Certain lines may appear lighter or thinner than other lines. ANY COLORED LINE VISIBLE IN THE TEST "T" REGION, NO MATTER HOW DARK OR FAINT, SHOULD BE INTERPRETED AS A NEAGATIVE RESULT.

***IMPORTANT*:** 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. GC/MS is the preferred confirmatory method. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

What Is A False Positive Test?
The definition of a false positive test would be an instance where a substance is identified incorrectly by UScreen^{2} Drugs of Abuse Cup. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?
The definition of a false negative test is that the initial drug is present but isn't detected by UScreen^{2} Drugs of Abuse Cup. Diluted or adulterated urine specimens may cause a false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test substances other than urine.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample in a different, unused, cup.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication

ASSISTANCE

If you have any question regarding to the use of this product, please contact US Diagnostics 888-669-4337

SUMMARY

Amphetamine/Methamphetamine **(AMP/MET)** and their metabolites are potent central nervous system stimulants. Acute doses induce euphoria, alertness, and sense of increased energy and power. Responses from chronic use can include anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine and amphetamine are excreted in urine as unchanged drug along with deaminated or hydroxylated derivatives. Methamphetamine also metabolize to amphetamine in the body. As a result, urine specimens from most methamphetamine users contain both unchanged parent drug and the amphetamine metabolite.

Barbiturates **(BAR)** are classified as central nervous system depressants. These products produce a state of intoxication that is similar to alcohol intoxication. Symptoms include slurred speech, loss of motor coordination and impaired judgment. Depending on the dose, frequency, and duration of use, tolerance, physical dependence and psychological dependence on barbiturates can occur. Barbiturates are taken orally, or by intravenous and intramuscular injections. Members of the barbiturate drug class typically excrete in urine as parent compound and metabolites.

Benzodiazepines **(BZO)** are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses, and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection, and are extensively oxidized in the liver to metabolites. Most benzodiazepines are excreted in the urine as conjugates and metabolites.

Cocaine **(COC)** is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant. The psychological effects induced by using cocaine are euphoria, confidence and sense of increased energy. These psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in the urine primarily as benzoylecgonine in a short period of time. Benzoylecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of cocaine (0.5 to 1.5 hour), and can be generally detected for 24 to 60 hours after cocaine use or exposure.

Methylenedioxymethamphetamine **(MDMA)** is classified as both a stimulant and a hallucinogen. Like methamphetamine, adverse effects of 3,4-methylenedioxymethamphetamine use include jaw clenching, teeth grinding, dilated pupils, perspiring, anxiety, blurred vision, vomiting, and increased blood pressure and heart rate. Overdose of 3,4-methylenedioxymethamphetamine may cause heart failure or extreme heat stroke. 3,4-methylenedioxymethamphetamine is taken orally in tablets or capsules and excreted in urine as parent compound and metabolizes including methylenedioxyamphetamine (MDA).

Methadone **(MTD)** is a synthetic analgesic drug originally used for the treatment of narcotic addiction and pain management. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver and has a biological half-life of 15-60 hours.

Opiates **(OPI/MOP)** such as heroin, morphine, and codeine, are central nervous system (CNS) depressants. The use of opiates at high doses produces euphoria and release from anxiety. Physical dependence is apparent in users and leads to depressed coordination, disrupted decision making, decreased respiration, hypothermia and coma. Heroin is quickly metabolized to 6-acetylmorphine (6-AM), morphine, and morphine glucuronide. Codeine also partially metabolizes to morphine and morphine glucuronide. Thus, the presence of morphine or morphine glucuronide in the urine can indicate heroin, morphine, and/or codeine use.

Oxycodone **(OXY)** is a semi-synthetic opioid with a structural similarity to codeine. It produces potent euphoria, analgesic and sedative effects, and has a dependence liability similar to morphine. Oxycodone is most often administered orally and is metabolized by demethylation to noroxycodone and oxymorphone followed by glucuronidation. The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

Phencyclidine **(PCP),** commonly known as "angel dust" and "crystal cyclone", is an arylcyclohexylamine that is originally used as an anesthetic agent and a veterinary tranquilizer. The drug is abused by oral or nasal ingestion, smoking, or intravenous injection. It produces hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It is well absorbed following all routes of administration. Unchanged PCP is excreted in urine in moderate amounts (10% of the dose).

Tetrahydrocannabinol **(THC)** is generally accepted to be the principle active component in marijuana. When ingested or smoked, it produces euphoric effects. Abusers exhibit central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. The primary metabolite of marijuana excreted in the urine is 11-nor-Δ-9-tetrahydrocannabinol-9-carboxylic acid. The elimination of THC and metabolites in urine is highly dependent on frequency of drug use and physiology of the user.
Tricyclic Antidepressants **(TCA)** have been prescribed for depression and compulsive disorders. Because of the possibility of causing serious cardiac complications, TCAs can be lethal if misused at high doses. TCAs are taken orally or sometimes by injection. TCAs and their metabolites are excreted in urine (mostly in the form of metabolites) for up to ten days.
Buprenorphine (BUP) is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™; all of which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. A 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. 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 detection window for the parent drug in urine is thought to be approximately 3 days.

QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.
Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

PERFORMANCE CHARACTERISTICS

Accuracy
1120 (eighty of each drug) clinical urine specimens were analyzed by GC-MS and by each corresponding UScreen^{2} drug of abuse Test. Each UScreen^{2} test was read by three viewers. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	UScreen^{2} Result		Drug Free	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive greater than 50% above the cutoff concentration)	%Agreement with GC/MS (95%CI)
AMP	Viewer A	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	18	10	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	18	10	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	11	29	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
BAR	Viewer A	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
BZO	Viewer A	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
COC	Viewer A	+	0	0	1	11	29	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
THC	Viewer A	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
MET	Viewer A	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	16	13	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	20	20	100% (I84.5% - 100%)
		-	10	16	12	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	16	13	0	0	97.5% (82% - 100%)
MDMA	Viewer A	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
MOP	Viewer A	+	0	0	1	20	20	100% 84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	19	9	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
MTD	Viewer A	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 100%)
PCP	Viewer A	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	13	15	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	13	15	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	13	15	0	0	95% (79.5% - 100%)
TCA	Viewer A	+	0	0	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)

OXY	Viewer A	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	20	8	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	20	8	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
BUP	Viewer A	+	0	0	1	16	24	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	16	24	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	16	24	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)

Precision and Sensitivity

To investigate the precision and sensitivity, each drug sample was analyzed at the following concentrations: cutoff - 100%, cutoff - 75%, cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, cutoff + 50%, cutoff + 75% and the cutoff + 100%. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots of the corresponding UScreen^2 drugs of abuse test. In total, 3 operators participated in the study of the corresponding UScreen^2 drugs of abuse test. Each of the 3 operators tested 2 aliquots at each concentration for each lot per day (2 runs /day), for a total of 50 determinations per concentration per lot of the corresponding UScreen^2 drugs of abuse test.

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
AMP	0	50	50/0	50/0	50/0
	250	50	50/0	50/0	50/0
	500	50	50/0	50/0	50/0
	750	50	50/0	50/0	50/0
	1000	50	5/45	5/45	4/46
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
BAR	0	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	150	50	50/0	50/0	50/0
	225	50	50/0	50/0	50/0
	300	50	7/43	5/45	5/45
	375	50	0/50	0/50	0/50
	450	50	0/50	0/50	0/50
	525	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
BZO	0	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	150	50	50/0	50/0	50/0
	225	50	50/0	50/0	50/0
	300	50	7/43	6/44	5/45
	375	50	0/50	0/50	0/50
	450	50	0/50	0/50	0/50
	525	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
COC	0	50	0/50	0/50	0/50
	75	50	50/0	50/0	50/0
	150	50	50/0	50/0	50/0
	225	50	50/0	50/0	50/0
	300	50	5/45	5/45	5/45
	375	50	0/50	0/50	0/50
	450	50	0/50	0/50	0/50
	525	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
THC	0	50	50/0	50/0	50/0
	12.5	50	50/0	50/0	50/0
	25.0	50	50/0	50/0	50/0
	37.5	50	50/0	50/0	50/0
	50.0	50	5/45	6/44	5/45
	62.5	50	0/50	0/50	0/50
	75.0	50	0/50	0/50	0/50
	87.5	50	0/50	0/50	0/50
	100.0	50	0/50	0/50	0/50
MET	0	50	50/0	50/0	50/0
	250	50	50/0	50/0	50/0
	500	50	50/0	50/0	50/0
	750	50	50/0	50/0	50/0
	1000	50	4/46	5/45	5/45
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
MDMA	0	50	50/0	50/0	50/0
	125	50	50/0	50/0	50/0
	250	50	50/0	50/0	50/0
	375	50	50/0	50/0	50/0
	500	50	6/44	5/45	6/44
	625	50	0/50	0/50	0/50
	750	50	0/50	0/50	0/50
	875	50	0/50	0/50	0/50
	1000	50	0/50	0/50	0/50
MOP	0	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	150	50	50/0	50/0	50/0
	225	50	50/0	50/0	50/0
	300	50	5/45	6/44	5/45
	375	50	0/50	0/50	0/50
	450	50	0/50	0/50	0/50
	525	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
MTD	0	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	150	50	50/0	50/0	50/0
	225	50	50/0	50/0	50/0
	300	50	6/44	4/46	5/45
	375	50	0/50	0/50	0/50
	450	50	0/50	0/50	0/50
	525	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
PCP	0	50	50/0	50/0	50/0
	6.25	50	50/0	50/0	50/0
	12.5	50	50/0	50/0	50/0
	18.75	50	50/0	50/0	50/0
	25	50	5/45	4/46	5/45
	31.25	50	0/50	0/50	0/50
	37.5	50	0/50	0/50	0/50
	43.75	50	0/50	0/50	0/50
	50	50	0/50	0/50	0/50
TCA	0	50	50/0	50/0	50/0
	250	50	50/0	50/0	50/0
	500	50	50/0	50/0	50/0
	750	50	50/0	50/0	50/0
	1000	50	5/45	6/44	5/45
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
OXY	0	50	50/0	50/0	50/0
	25	50	50/0	50/0	50/0
	50	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	100	50	6/44	6/44	5/45
	125	50	0/50	0/50	0/50
	150	50	0/50	0/50	0/50
	175	50	0/50	0/50	0/50
	200	50	0/50	0/50	0/50
BUP	0	50	50/0	50/0	50/0
	2.5	50	50/0	50/0	50/0
	5.0	50	50/0	50/0	50/0
	7.5	50	50/0	50/0	50/0
	10.0	50	6/44	4/46	4/46
	12.5	50	0/50	0/50	0/50
	15.0	50	0/50	0/50	0/50
	17.5	50	0/50	0/50	0/50
	20.0	50	0/50	0/50	0/50

Specificity and cross reactivity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Amphetamine (AMP)	Concentration (ng/ml)	**Cocaine (COC)**	Concentration (ng/ml)
d-Amphetamin	1.000	Benzoylecgonine	300
d,l-Amphetamine	3.000	Cocaine HCl	750
l-Amphetamine	50.000	Cocaethylene	12.500
(+/-) 3,4-methylenedioxyamphetamine (MDA)	5.000	Ecgonine	32.000
Phentermine	3.000	**Methadone (MTD)**	
d-methamphetamine	>100.000	Methadone	300
l-methamphetamine	>100.000	Doxylamine	50.000
3,4-Methylenedioxyethylamphetamine(MDE)	100.000	**Methamphetamine (MET)**	
(+/-)3,4-methylenedioxumethamphetamine (MDMA)	100.000	D(+)-Methamphetamine	1.000
Secobarbital (BAR)		D-Amphetamine	50.000
Secobarbital	300	Chloroquine	50.000
Amobarbital	300	(+/-)-Ephedrine	50.000
Alphenol	150	(-)-Methamphetamine	25.000
Aprobarbital	200	(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2.000
Butabarbital	75	ß-Phenylethylamine	50.000
Butathal	100	Trimethobenzamide	10.000
Butalbital	2.500	**Methylenedioxymethamphetamine (MDMA)**	
Cyclopentobarbital	600	3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
Pentobarbital	300	3,4-Methylenedioxyamphetamine HCl (MDA)	3.000
Phenobarbital	10.000	3,4-Methylenedioxyethylamphetamine (MDE)	300
Oxazepam(BZO)		**Morphine (MOP)**	
Oxazepam	300	Morphine	300
Alprazolam	200	Codeine	300
a-Hydroxyalprazolam	1.500	Ethyl Morphine	300
Bromazepam	1.500	Hydrocodone	5.000
Chlordiazepoxide	1.500	Hydromorphone	5.000
Clonazepam HCl	800	Morphinie-3-ß-d-glucuronide	1.000
Clobazam	100	Thebaine	30.000
Clonazepam	800	**Phencyclidine (PCP)**	
Clorazepate dipotassium	200	Phencyclidine	25
Delorazepam	1.500	4-Hydroxyphencyclidine	12500
Desalkylflurazepam	400	**Notriptyline (TCA)**	
Diazepam	200	Notriptyline	1.000
Estazolam	2.500	Nordoxepine	1.000
Flunitrazepam	400	Trimipramiine	3,000
D,L-Lorazepam	1.500	Amitriptyline	1,500
Midazolam	12.500	Promazine	1.500
Nitrazepam	100	Desipramine	200
Norchlordiazepoxide	200	Imipramine	400
Nordiazepam	400	Clomipramine	12.500
Temazepam	100	Doxepine	2,000
Trazolam	2.500	Maprotiline	2,000
Cannabinoids (THC)		Promethazine	25,000
11-nor-Δ9-THC-9-COOH	50	**Oxycodone(OXY)**	
11-nor-Δ8-THC-9-COOH	30	Oxycodone	100
11-hydroxy-Δ9-Tetrahydrocannabinol	2.500	Dihydrocodeine	20.000
Δ8- Tetrahydrocannabinol	7.500	Codeine	100.000
Δ9- Tetrahydrocannabinol	10.000	Hydromorphone	100.000
Cannabinol	100.000	Morphine	>100.000
Cannabidiol	100.000	Acetylmorphine	>100.000
Buprenorphine(BUP)		Buprenorphine	>100.000
Buprenorphine	10	Ethylmorphine	>100.000
Buprenorphine -3-D-Glucuronide	15		
Norbuprenorphine	20		
Norbuprenorphine 3-D-Glucuronide	200		

Adulteration/Specimen Validity Test

Cr: Creatinine reacts with a creatinine indicator in an alkaline medium to form a purplish-brown color complex if creatinine in the urine is present at the normal level. The color intensity is directly proportional to the concentration of creatinine. A urine sample with creatinine concentration of less than 20 mg/dL produces a very light, or no pad color change, which indicates adulteration in the from of specimen dilution.

Adulteration/Specimen Validity Test

S.G.: The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. The pad colors will change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. A urine specific gravity below 1.003 or above 1.025 is considered abnormal.

OX: Bleach or other oxidizing agents react with an oxidant indicator to form a color complex. Observation of a blue-green, medium to dark brown, or orange color indicates adulteration with bleach or other oxidizing agents.

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff and were tested with the UScreen^2 drugs of abuse test. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

Acetominophen (4-Acetamidophenol) **(except OXY test)**
Acetophenetidin
N-Acetylprocainamide **(except OXY test)**
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
Apomorphine
Aspartame
Atropine **(except BAR test)**
Benzilic acid
Benzoic acid
Benzoylecgonine **(except COC,OXY test)**
Bilirubin
Cannabidiol **(except THC, OXY tests)**
Chloralhydrate
Chloramphenicol
Chlorothiazide
Chlorpromazine
Chlorquine
Cholesterol
Clonidine
Codeine **(except MOP, BZO, OXY tests)**
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Ecgonine methyl ester
Erythromycin **(except BZO test)**
β-Estradiol **(except BZO test)**
Fenoprofen
Furosemide
Gentisic acid
Hydralazine **(except BZO test)**
Hydrochlorothiazide **(except BZO test)**
Hydrocodone **(exceptBZO,MOP,OXY test)**
Hydrocortisone
O-Hydroxyhippuric acid
3-Hydroxytyramine
Ibuprofen **(except OXY test)**
D,L-Isoproterenol **(except AMP, BAR test)**
Isoxsuprine
Ketamine **(except OXY test)**
Ketoprofen
Labetalol
Loperamide
Maprotiline **(except TCA, OXY tests)**
Meperidine **(except THC, OXY tests)**
Meprobamate
Methadone **(except MTD, OXY tests)**
Methoxyphenamine **(exceptAMP,BAR test)**
Morphinie-3-β-d-glucuronide **(except BZO, MOP tests)**
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein **(except MOP, BZO, OXY tests)**
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam **(except BZO, OXY tests)**
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentobarbital **(except BZR, OXY test)**
Perphenazine
Phenelzine
Phencyclidine**(except PCP, OXY tests)**
Prednisone
Procaine **(except BZO, MOP, OXY tests)**
DL-Propranolol
D-Propoxyphene **(except OXY, test)**
D-Pseudoephedrine**(except AMP, BAR tests)**
Quinine
Ranitidine
Salicylic acid
Secobarbital **(except BAR, OXY tests)**
Serotonin (5- Hydroxytyramine)
Sulfamethazine
Sulindac
Tetrahydrocortisone, 3-acetate **(except AMP, BAR, OXY tests)**
Tetrahydrocortisone 3-(ß-Dglucuronide) **(except AMP, BAR, OXY tests)**
Tetrahydrozoline
Thiamine
Thioridazine
Triamterene
DL-Tyrosine
Trifluoperazine
Trimethoprim
D L-Tryptophan **(except AMP, BAR tests)**
Tyramine **(except AMP, BAR tests)**
Uric acid
Verapamil
Zomepirac

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INDEX OF SYMBOLS

Keep away from sunlight

Store between 4°C and 30°C

Keep dry

Do not re-use

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