McKESSON

Drugs of Abuse Push-Button Test Cup

This is a CLIA-Waived Test. You need a CLIA certificate of waiver to perform the test in waived settings.
Go to http://www.cms. hhs.gov/clia/ for more information.

INTENDED USE

The Drug of Abuse Push-Button Test Cup is a rapid qualitative immunoassay. The device provides preliminary results for the detection of potential abuse of one or more drugs. See list below. This is not a screening device to monitor prescription medication use. It is for in vitro diagnostic home use. Not for internal use.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/ml
BAR*	Barbiturates	200 ng/ml
BUP/NBUP	Buprenorphine/ Norbuprenorphine	10 ng/ml
BZD*	Benzodiazepine	300 ng/ml
COC	Cocaine	300 ng/ml
MET	Methamphetamine	1000 ng/ml
MOR/OPI	Morphine/Opiates	2000 ng/ml
MOR300	Morphine/Opiates	300 ng/ml
MTD	Methadone	300 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
TCA*	Tricyclics	1000 ng/ml
THC	Marijuana/Hashish	50 ng/ml
XTC	MDMA or Ecstasy	500 ng/ml

*The BAR, BZD, TCA test will yield preliminary positive results when BAR, BZD, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant in urine. The Drug of Abuse Push-Button Test Cup shows the drug was or was not present at the cutoff level. The device provides a preliminary test result. Positive results must be confirmed by a more specific analytical method.

SUMMARY

Amphetamine (AMP)

Amphetamines are central nervous system stimulating drugs. Overdose or extended usage may lead to substance abuse. Amphetamine abuse may cause severe or permanent damage to the human nerve system. Amphetamines appear in the urine within three hours of administration. It may be present for about 24-48 hours.

Barbiturates (BAR)

Barbiturates are central nervous system depressants. Overdose or extended usage may lead to severe or permanent damage to the human nervous system. Barbiturates are classified as ultra-short, short-intermediate, and long-acting. The most commonly abused barbiturates are short- and intermediate-acting agents. The ultra short-acting compounds lasts 15 minutes to 6 hours. The intermediate acting compounds lasts 3 to 24 hours. A higher percentage of long-acting barbiturates are excreted in the urine unchanged. Shorter-acting compounds are extensively metabolized and excreted in the urine. A small percentage is unchanged drugs.

Buprenorphine (BUP)

Buprenorphine is an analgesic drug. It is also used in heroin substitution and detoxification treatment. With this increased medical use, it also occurs on the black market as an illicit drug; and fatalities have occurred when used in combination with other drugs. Buprenorphine is administered clinically by intravenous, intramuscular or sublingual routes. Buprenorphine is metabolized by N-dealkylation to form the pharmacologically active Norbuprenorphine. Both buprenorphine and norbuprenorphine are also glucuronidated to the clinically inactive conjugates buprenorphine-3-beta-D-glucuronide and norbuprenorphine-3-beta-D-glucuronide. Buprenorphine and its metabolite norbuprenorphine (along with the glucuronide forms) are both excreted in urine during the course of several days. Buprenorphine and its metabolites are eliminated mainly in the feces (68%), with a small proportion excreted in urine (27%). It was reported that urine samples taken from patients who had received treatment for 2 weeks with 4 mg of buprenorphine daily (sublingually) showed buprenorphine concentrations ranging from 54 to 260 ng/ml 24 hours after the dose. It was found in another study that the concentrations of the unconjugated buprenorphine and unconjugated norbuprenorphine in the urine samples collected 10 hours after a single dose intramuscular injection of 0.3 mg buprenorphine were 500 pg/ml and 2 ng/ml, respectively.

Benzodiazepines (BZD)

Benzodiazepines are sedative, hypnotic and anti-anxiety drugs. Most benzodiazepines are extensively metabolized in the liver. The metabolites excrete in the urine. Benzodiazepines have a low potential for physical or psychological dependence. Overdose and extended usage may lead to coma and possibly death. Benzodiazepines may remain effective for 4-8 hours. They are excreted in the urine primarily as parent compounds or an inactive metabolite, oxazepam glucuronide. They are detectable for one to two days. Oxazepam, a common metabolite of many benzodiazepines, is also a marketed drug.

Cocaine (COC)

Cocaine is a nervous system stimulating drug. It has pharmacological properties such as local anesthetic. It has addictive effects. It may lead to substance abuse. Cocaine may appear in urine for only few hours after use. Benzoylecgonine is a metabolite of cocaine. Benzoylecgonine may be detectable in urine over 2 days after taking cocaine. Its detection in human urine has been widely used to evaluate cocaine usage.

Methamphetamine (MET)

Methamphetamine overdosage causes restlessness, confusion, anxiety, and coma. Chronic abusers may develop paranoid psychosis. D-Methamphetamine is used in the treatment of obesity. Its duration is 2-4 hours. In normal conditions up to 43% of methamphetamine is eliminated unchanged in the 24-hour urine and about 4-7% as amphetamine. In acid urine, up to 76% is parent drug and 7% is amphetamine in 24 hours. In alkaline urine there is 2% parent drug and less than 0.1% amphetamine in 24 hours.

Morphine (MOR)

Morphine is a popular marketed drug. It is used to treat moderate to severe pain. Morphine is also a common metabolite of opiates and heroin. The duration of morphine effect is 3-6 hours. 2-12% of morphine is excreted unchanged in urine. Heroin is rapidly metabolized to morphine in the body. Urinary excretion of heroin is similar to that of morphine. Codeine is also extensively metabolized. 10-15% of the codeine is demethylated to form morphine and norcodeine. Unchanged morphine may remain detectable in urine for up to one week. Morphine has been used as a marker of opiates abuse.

Methadone (MTD)

Methadone possesses many of the pharmacological properties of morphine. However, it produces marked sedative effects with repeated administration. Methadone has been used as opiates substitute in drug treatment clinics. The effective duration of methadone is 12-24 hours. 5-50% of methadone excretes in urine unchanged in 24 hours. Methadone in urine may remain higher than 1,000 ng/ml 24 hours after overdose. Methadone in human urine has been used as a marker of methadone abuse.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structure similar to codeine. It is prescribed for the relief of moderate to severe pain. Like all opiate agonists, oxycodone provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension and respiratory arrest.

Phencyclidine (PCP)

Phencyclidine is a popular drug of abuse. It is also a legitimate veterinary tranquilizer. PCP is self-administered by smoking, nasal insufflation, intravenous injection or oral ingestion. Its duration is 2-4 hours. 30-50% of an intravenous dose excretes unchanged in urine in 72 hours. 2% of a dose excretes in feces. On average 77% of an intravenous dose excretes in urine and feces in 10 days. PCP in human urine has been used as a marker of PCP abuse.

Tricyclics (TCA)

Tricyclic Antidepressants (TCA) are a group of antidepressant drugs that contain three fused rings in their chemical structure. TCA can be taken orally or intramuscularly (IM). The progressive symptomatology of TCA includes agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of

TCA varies from few hours to few days. The commonly used tricyclic antidepressants are excreted with a very low percentage of unchanged drugs in the urine, less than 1%. Therefore, detecting TCA or metabolites of TCA in human urine has been used for screening the abuse of TCA.

Marijuana (THC)
Tetrahydrocannabinol is known as THC, Δ-9-THC, Δ-1-THC. It is the most active of the principal constituents and major metabolite of cannabinoids. Cannabinoids are a group of compounds including marijuana and hashish. Cannabinoids have been used as central nervous system depressants. Overdose and extended usage may lead to substance abuse. Cannabinoids abuse may cause severe or permanent damage to the human nerve system. The detection of THC in human urine has been widely used to assess cannabinoids abuse.

MDMA (Ecstasy, XTC)
MDMA has street names such as Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits, and Shamrocks. MDMA is a stimulant with hallucinogenic tendencies. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or heat stroke. MDMA is administered either by oral ingestion or intravenous injection. The effects of the MDMA begin 30 minutes after taking. They peak in an hour and last for 2-3 hours. 65% of MDMA is excreted unchanged in urine and it is detectible in the urine for up to 3 days after use.

PRINCIPLE OF THE TEST

The Drug of Abuse Push-Button Test Cup consists of one to nine individual test strip(s) for the drug(s). The assay is a one-step qualitative immunoassay. If the drug is absent from the sample, a burgundy color band (T line) will appear. When the drug is present in the sample at or above the cutoff level, the color band will not form. See list in the Intended Use section. The control line (C line) serves as an internal quality control of the system. The C line should always appear regardless of the presence of the drug.

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

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

Glutaraldehyde: Tests for the presence of exogenous aldehyde. The glutaraldehyde reacts with an indicator to form a pink/purple color complex.

pH: Tests for the presence of acidic or alkaline adulterant. The pH indicator changes color from orange at low pH to yellow and green near neutral to blue at high pH.

Specific Gravity: Tests for sample dilution. This test is based on the apparent pKa change of polyelectrolytes in relation to the ionic concentration. The indicator will turn dark blue or blue-green at low ionic concentration. It turns green and yellow at higher ionic concentration.

Oxidants: Tests for presence of oxidizing reagents. The indicator reacts with oxidants to form a blue or brown color complex. This includes bleach, hydrogen peroxide or pyridinium chlorochromate. Other colors may indicate the presence of other oxidants.

REAGENTS AND MATERIALS SUPPLIED

- 25 cups with built-in test strips & desiccants; each cup sealed in a foil pouch
- 1 package insert (Instructions for Use)

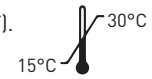
MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- External positive and negative controls

PRECAUTIONS

- Follow instructions exactly to obtain accurate results.
- For professional qualitative in-vitro diagnostic use only.
- Keep test device in the sealed pouch until use.
- Do not use expired devices.
- Dispose of all specimens and used assay materials according to local, state and federal regulations.
- Do not reuse the device.
- Do not use the test if you are color-blind.

STORAGE AND STABILITY



- Store the kit at room temperature 15-30°C (59-86°F).
- Do not open the sealed pouch until use.
- Do not freeze device.
- Each device is good until the expiration date printed on the pouch.

SAMPLE COLLECTION AND HANDLING

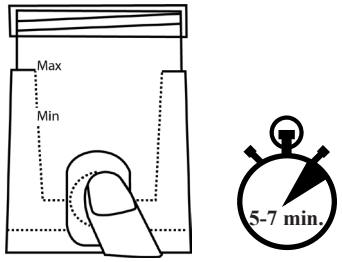
IMPORTANT: Do not open pouch until ready to perform the test.

1. Remove the test cup from the pouch.
2. Label the cup with patient or control identification and the date.
3. Direct the patient to do the following:
   a. Remove the lid.
   b. Urinate directly into the cup. The sample level should be between the Min and Max marks on the cup. Do not over fill.
   c. Put the lid back onto the cup.
   d. Wipe any splashes or spills on the outside of the cup.
4. Immediately check the temperature strip on the cup. The temperature should be between 32-38 °C (90-100 °F). If the temperature is not in this range, the sample may be altered. In this case, collect another sample into a new cup.
5. Make sure the lid is closed tightly on the cup.
6. Use specimens within two hours of collection. **Do not freeze the cup.**

TEST PROCEDURE

IMPORTANT: YOU MUST EQUILIBRATE REFRIGERATED SPECIMENS AND DEVICES TO ROOM TEMPERATURE BEFORE TEST.

1. Find a well-lit place to observe the color change on the test strip.
2. Have a watch or timer ready.
3. Confirm that the level of the urine sample in the cup is between the Min and Max marks.



4. Push the white knob all the way into the body. Make sure the urine flows to the bottom chamber of the cup.
5. Start the timer immediately.
6. Read the test results on all strips at 5 minutes.

INTERPRETATION OF RESULTS

Each test strip is labeled with abbreviations for a test. For example, "COC" is for cocaine test. A complete list for each test can be found in the intended use section on Page 1.

IMPORTANT:

- Read each test independently.
- Do not compare color intensity of one test to another.
- Do not compare color intensity of the T line to the C line.
- Do not read adulteration results after (2) minutes or drug test after seven (7) minutes.

ADULTERATION ASSAY

Between 1-2 minutes after sample addition, compare the color of each pad with that of the corresponding pad in the color chart stapled to the insert. Changes in color after 2 minutes are of no value to interpretation. The 6 pads, from left to right in the sample well, assess CR, NI, GL, pH, SG, OX.

CR (creatinine) tests for sample dilution. Daily creatinine excretion is usually constant in relation to muscle mass of the human body. DOT guideline states that less than 20 mg/dl of creatinine in urine specimens indicates adulteration, regardless of factors such as age, sex, diet, muscle mass and local population distribution.

NI (Nitrite) is not a normal component of urine. Nitrite levels up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper sample storage. A nitrite level above

7.5 mg/dl is considered abnormal.

GL (Glutaraldehyde) is not a natural component of human urine. Its presence indicates adulteration. False positive results may arise when ketone bodies are present. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolically abnormal conditions.

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

SG (Specific Gravity): Random urine samples may vary in specific gravity from 1.003-1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016-1.022. Elevated urine specific gravity may be obtained in the presence of moderate quantities of protein. DOT guidelines state that a urine specimen with specific gravity level less than 1.003 is an indication of adulteration. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is adulterated.

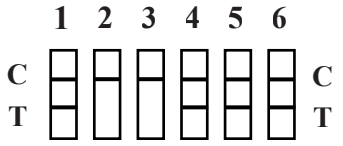
OX (Oxidants): Oxidizing reagents are not normal constituents of urine. The presence of oxidizing reagents in the urine is indicative of adulteration. Oxidizing reagents include bleach, Hydrogen Peroxide, Pyridinium Chlorochromate, etc.

If test pads indicate an invalid sample for the assays, note the information on the sample record.

DRUG SCREENING ASSAY

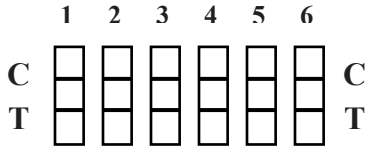
Preliminary Positive:
If the C line appears and there is no T line, the test is positive for that drug. More than one test may be Preliminary Positive.

Note: Preliminary positive results should be confirmed with a more specific method. GC/MS or HPLC is a preferred confirmatory method.



Preliminary Positive for test 2 and test 3

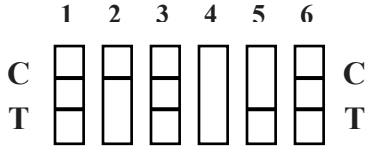
Negative:
If both C line and T line appear on a test, the test is negative for that drug. If both C line and T line appear for all tests, the urine specimen is negative for all the drugs tested.



Negative for all 6 drugs tested

Note: Even a very faint T line is negative.

Invalid:
If no C line develops within 5 minutes on any test strip, the test is invalid. In this case, do not report test results. Repeat the assay with a new test device. If the result is still invalid, stop using the test device. Contact the manufacturer.



Invalid for test 4 and test 5

QUALITY CONTROL

Built-in Control Features:
This test contains a built-in control feature, the C line. If C line appears, the test performs properly. The C line should always appear. If the C line does not develop within 5 minutes, review the entire procedure. Repeat the test with a new device.

External Quality Control:
You should run positive and negative quality controls monthly, with a new shipment or new lot of test device. Contact device manufacturer at 1-877-204-5071 for assistance in obtaining external quality controls.

LIMITATIONS

1. This kit is for professional use only.
2. This device is a qualitative test. You must use a more specific method to confirm a positive test result. GC/MS or HPLC is the preferred method.
3. This device is for human urine test only.
4. Adulterants such as bleach or alum in urines may produce erroneous test results. When suspected, collect a fresh specimen. Repeat the test with a new device.
5. Do not use the device if you are color-blind.
6. Dark urine samples may interfere with the test.
7. Urine samples containing structurally related compounds might interfere with the test. See the Cross Reactivity section.

EXPECTED VALUES

This test can detect one or more drug and/or drug metabolite in human urine. See list in the Intended Use section on page 1.

PERFORMANCE CHARACTERISTICS

Accuracy
A comparison study was performed at two Physician's Office Laboratories (POL) and a Reference Laboratory. Samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested at each site, with the multi-drug of abuse urine test device, and compared to GC/MS or HPLC/MS results. The test results are grouped into drug free, below 75% cutoff (Negative), above 125% cutoff (Positive), between 75% cutoff and cutoff, between cutoff and 125% cutoff according to the analyte concentrations from GC/MS for all analytes except BUP and TCA, which was tested with HPLC/MS. Overall, this device agrees with the results from the selected analytical method more than 90% for each analyte. The test results are tabulated below.

Method			GC/MS					
Test Device			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	Overall
Drug	Cutoff (ng/ml)							
AMP	1000	Positive	0	0	37	15	148	/
		Negative	176	76	23	1	0	/
		Total	176	76	60	16	148	476
		Agreement	100%	100%	38.3%	93.8%	100%	92%
BAR	200	Positive	0	0	0	27	140	/
		Negative	200	12	20	1	0	/
		Total	200	12	20	28	140	400
		Agreement	100%	100%	100%	96.4%	100%	99.8%
BZD	300	Positive	0	0	7	32	144	/
		Negative	168	24	25	0	0	/
		Total	168	24	32	32	144	400
		Agreement	100%	100%	78%	100%	100%	98.3%
COC	300	Positive	0	0	9	24	164	/
		Negative	188	4	11	0	0	/
		Total	188	4	20	24	164	400
		Agreement	100%	100%	55%	100%	100%	97.8%
MET	1000	Positive	0	0	12	24	136	/
		Negative	200	16	12	0	0	/
		Total	200	16	24	24	136	400
		Agreement	100%	100%	50%	100%	100%	97%
MOR	2000	Positive	0	0	2	28	144	/
		Negative	132	64	30	0	0	/
		Total	132	64	32	28	144	400
		Agreement	100%	100%	93.8%	100%	100%	99.5%
MTD	300	Positive	/	0	10	36	144	/
		Negative	/	192	18	0	0	/
		Total	/	192	28	36	144	400
		Agreement	/	100%	64.3%	100%	100%	97.5%
PCP	25	Positive	/	0	8	32	160	/
		Negative	/	184	16	0	0	/
		Total	/	184	24	32	160	400
		Agreement	/	100%	66.7%	100%	100%	98%
THC	50	Positive	0	0	11	17	156	/
		Negative	160	36	13	3	0	/
		Total	160	36	24	20	156	396
		Agreement	100%	100%	54.2%	85%	100%	96.5%
MDMA	500	Positive	0	0	2	9	10	/
		Negative	40	10	9	0	0	/
		Total	40	10	11	9	10	80
		Agreement	100%	100%	82%	100%	100%	97.5%

Method			HPLC/MS					Overall
Multi-Drug of Abuse Urine Test			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	
Drug	Cutoff (ng/ml)							
BUP	10	Positive		0	1	18	19	
		Negative		49	5	2	0	
		Total		49	6	20	19	94
		Agreement		100%	83.3%	90%	100%	96.8%
TCA	1000	Positive	0	0	2	8	12	/
		Negative	40	10	8	0	0	/
		Total	40	10	10	8	12	80
		Agreement	100%	100%	80%	100%	100%	97.5%

A clinical field study was performed at 3 separate locations. The test results are tabulated as follows.

Method			HPLC/MS					Overall
Multi-Drug of Abuse Urine Test			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	
Drug	Cutoff (ng/ml)							
MOR300	300	Positive	0	0	3	39	76	/
		Negative	211	41	38	0	0	/
		Total	211	41	41	39	76	408
		Agreement	100%	100%	92.7%	100%	100%	99.3%
OXY	100	Positive	0	0	1	35	197	/
		Negative	84	44	43	4	0	/
		Total	84	44	44	39	197	408
		Agreement	100%	100%	97.7%	89.7%	100%	98.8%
OXY	300	Positive	0	0	7	39	76	/
		Negative	43	209	34	0	0	/
		Total	43	209	41	39	76	408
		Agreement	100%	100%	82.9%	100%	100%	98.3%

Reproducibility

Reproducibility of each test was determined by replicate assays of three different production lots with four levels of samples: drug-free, 75% cutoff, 125% cutoff and 300% cutoff. For AMP, COC, THC and MDMA tests, the devices were tested for three consecutive days, six replicates per day, for a total of eighteen tests for each control. For BAR, BZD, MET, MOR, MTD, PCP and TCA tests, the devices were tested for five consecutive days, five times per day, for a total of 25 assays for each control. The results indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation across the three different lots of devices.

Cross Reactivity

Drug free urines spiked with structurally related compounds were tested on test devices. Compounds producing positive response on the device are listed below.

Drug	Related Compounds	Concentration (ng/ml)	Related Compounds	Concentration (ng/ml)
AMP	*d-Amphetamine*	*1000*	*d-,l-Amphetamine*	*1000*
	l-Amphetamine	*20,000*	*3,4-methylenedioxyamphetamine (MDA)*	3000
BAR	*Amobarbital*	*250*	*Phenobarbital*	*200*
	Barbital	*250*	*Pentobarbital*	*250*
	Butabarbital	*300*	*Secobarbital*	*200*
	Butalbital	*200*		
BUP	*Buprenorphine-3-β-d-glucuronide*	*750*	*Norbuprenorphine-3-β-d-glucuronide*	*30,000*
	Nalorphine	*100,000*		
BZD	*Alprazolam*	*300*	*Lormetazepam*	*300*
	Bromazepam	*500*	*Medazepam*	*300*
	Clobazem	*1500*	*Nitrazepam*	*250*
	Chlonazepam	*500*	*Nordiazepam*	*400*
	Diazepam	*200*	*Prazepam*	*250*
	Desmethyldiazepam	*300*	*Triazolam*	*300*
	Flurazapam	*300*	*Oxazepam*	*300*
	Lorazepam	*450*		
COC	*Cocaine*	*300*	*Isoxsuprine*	*1500*
	Benzoylecgonine	*300*		
MET	*d-Amphetamine*	*50,000*	*3,4-methylenedioxyamphetamine (MDA)*	*50,000*
	l-Amphetamine	*10,000*		
MOR	*Codeine*	*2000*	*Morphine- glucuronide*	*3000*
	Ethyl Morphine	*2000*		
	Hydro morphine	*2500*	*Meperidine*	*30,000*
MOR 300	*Morphine*	*300*	*Morphine-glucuronide*	*500*
	Codeine	*300*		
	Ethyl Morphine	*300*	*Meperidine*	*30,000*
	Hydromorphine	*400*	*Oxycodone*	*1000*
MTD	*(-)-a-Methadol*	*800*	*(-)-a-Acetylmethadol (LAAM)*	*1000*
OXY	*Oxycodone*	*100*	*Hydrocodone*	*100,000*
	Morphine	*20,000*	*Ethyl Morphine*	*100,000*
PCP	*Methylphenidate*	*25,000*	*Tenocyclidine*	2,000
	Pheniramine	*25,000*		
TCA	*Nortriptyline*	*1,000*	*Clomipramine*	*5,000*
	Amitriptyline	*1,000*	*Doxepin*	*3,000*
	Imipramine	*800*	*Protriptyline*	*2,000*
	Desipramine	*800*	*Perphenazine*	*75,000*
	Nordoxepine	*1,000*	*Promazine*	*15,000*
	Cycolbenzaprine	*1,500*	*Trimipramine*	*2,000*
THC	*11-nor-D-8-THC-9-COOH*	*50*	*11-hydroxy-D-9-THC*	*100*
	11-nor-D-9-THC-9-COOH	*50*	*9-Tetrahydrocannabinol*	*10,000*
	Cannabonol	*10,000*		
MDMA	*methylenedioxyampphetamine (MDA) (MDA)*	*2000*	*Methylenedioxyethylamphetamine(MDEA)*	*1000*

Interference

Drug-free urines and urines spiked with a drug at the cutoff level were tested on the test device. Results are listed in the table below.

Common substances listed in this table were found not to interfere with the test results at 100 µg/ml		
Acetaminophen	*Oxalic Acid*	*Ethanol*
Acetylsalicylic Acid	*Caffeine*	*Lidocaine*
Amikacin	*(+)-Chlorpheniramine*	*Penicillin-G*
Amitriptyline	*Cocaine*	*Phenylpropanalamine*
Ampicillin	*Codeine*	*Ranitidine*
Arterenal	*Cortisone*	*Salicyclic Acid*
Aspirin	*Methadone*	*Thioridazine*
Atropine	*Methanol*	*Trifluoperazine*
Benzoic Acid		

Biological Analytes	Concentration	Biological Analytes	Concentration
Albumin	*200 µg/ml*	*pH*	*5.0 – 9.0*
Bilirubin	*100 µg/ml*	*Specific Gravity*	*1.002 – 1.035 g/ml*
Creatine	*100 µg/ml*	*Uric Acid*	*100 µg/ml*
Glucose	*200 µg/ml*	*Vitamin C (L-Ascorbic Acid)*	*100 µg/ml*
Hemoglobin	*100 µg/ml*		

It is possible that substances or factors not listed above may interfere with the test. (e.g., technical or procedural errors)

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SYMBOL GLOSSARY

⚠	Consult accompanying documents
⊘	Single use only. Do not reuse.
IVD	For In-Vitro Diagnostic Use
EXP	Do not use this product past the indicated expiration as sterility cannot be assured beyond this date.
LOT	Lot information

Avoid storage in direct sunlight/fluorescent lighting and store in a cool, dry, and well-ventilated area.
General Questions? Call 1-800-777-4908

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