T-Dip Multi-Drug Urine Test Panel

Catalogue No. See Box Label

CLIA CATEGORIZATION: WAIVED
URINE SCREENING TEST RESULTS AT 5 MINUTES

The SAFElife™ T-Dip Multi-Drug Urine Test Panel are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Methylenedioxymethamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine with below cutoff concentrations and approximate detection time:

Drug (Identifier)	Calibrator	Cut-off Level	Approximate Minimum Detection Time	Approximate Maximum Detection Time
Amphetamine (AMP500)	d-Amphetamine	500 ng/mL	2-7 hours	1-2 days
Amphetamine (AMP1000)	d-Amphetamine	1000 ng/mL	2-7 hours	1-2 days
Secobarbital (BAR)	Secobarbital	300 ng/mL	2-4 hours	1-4 days
Buprenorphine (BUP)	Buprenorphine	10 ng/mL	4 hours	1-3 days
Oxazepam (BZO)	Oxazepam	300 ng/mL	2-7 hours	1-2 days
Cocaine (COC150)	Benzoylecgonine	150 ng/mL	1-4 hours	2-4 days
Cocaine (COC300)	Benzoylecgonine	300 ng/mL	1-4 hours	2-4 days
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenyl-pyrrolidine	300 ng/mL	3-8 hours	1~3 days
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET500/mAMP500)	D(+)-Methamphetamine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET1000/mAMP1000)	D(+)-Methamphetamine	1000 ng/mL	2-7 hours	2-4 days
Morphine (MOP/OPI300)	Morphine	300 ng/mL	2 hours	2-3 days
Methadone (MTD)	Methadone	300 ng/mL	3-8 hours	1-3 days
Morphine (OPI2000)	Morphine	2000 ng/mL	2 hours	2-3 days
Oxycodone (OXY)	Oxycodone	100 ng/mL	4 hours	1-3 days
Phencyclidine (PCP)	Phencyclidine	25 ng/mL	4-6 hours	7-14days
Propoxyphene (PPX)	d-Propoxyphene	300 ng/mL	2 hours	2-3days
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL	8-12hours	2-7 days
Cannabinoids (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL	2 hours	Up to 5+ days

SAFElife™ T-Dip Multi-Drug Urine Test Panel offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is intended for over-the-counter and for prescription use. For *in vitro* diagnostic use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method.

WARNINGS AND PRECAUTIONS

1. The test kit is for external use only. Do not swallow.
2. Discard after first use. The test kit cannot be used more than once.
3. Do not use the test kit beyond expiration date.
4. Do not use the test kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Read the drug test result at 5 minutes. Do not read the result after 30 minutes.

CONTENT OF THE KIT

1. 25 SAFElife™ T-Dip Multi-Drug Urine Test Panels, each in one pouch with desiccant. The desiccants are for storage purposes only and are not used in the test procedure.
2. One (1) Package Insert
3. 5 Adulteration Color Comparison Charts (If equipped).

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine Collection Cup
2. Timer or Clock

STORAGE AND STABILITY

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

SPECIMEN COLLECTION

WHEN TO COLLECT URINE FOR THE TEST?

You may collect urine samples in minimum detection time later after suspected drug use. Exactly when the urine sample is collected is very important in detecting any drug of abuse. This is because each drug is cleared by the body at different rates. Please refer to the minimum or maximum detection time of each drug in this instruction for use.

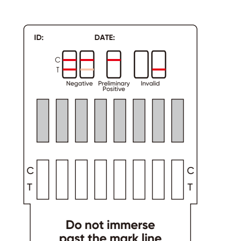
HOW TO COLLECT URINE?

Urinate directly into the urine collection cup.

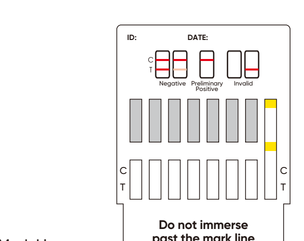
HOW TO DO THE TEST?

Test should be conducted between 65°F-86°F (18°C-30°C).

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine specimen for approximately 10 seconds. Make sure that the urine level is not above the Mark Line printed on the front of the device.
4. Re-cap the device and lay it flat on a clean, dry, non-absorbent surface.
5. For the adulteration strip(s) if equipped, read results immediately, or at 30 seconds, or at 45 seconds and compare each adulterant pad to verify pad color is within acceptable range according to the Adulteration Color Comparison Chart. If the results indicate adulteration, do not read the drug test results. Obtain a new urine specimen again with new collection cup, and test again with new test device.
6. For the drug tests, read the results for the drugs at 5 minutes. **Do not read after 30 minutes.**



Drug Test



Drug Test with Adulteration Control

Note: Results after more than 30 minutes may be not accurate and should not be read.

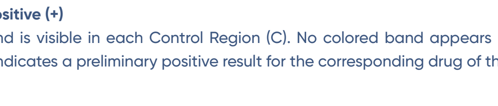
READING THE RESULTS

DRUGS TESTS:

Negative (-)
A colored band is visible in each Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary Positive (+)
A colored band is visible in each Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid
If a colored band is not visible in each of the Control Region (C) or a colored band is only visible in the Test Region (T), the test is invalid. Another test should be run to re-evaluate the specimen. If the new 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 of the test.



Note: There is no meaning attributed to line color intensity or width.

The preliminary positive test result does not always mean that a person took illegal drugs. The negative test result does not always mean that a person did not take illegal drugs. There could be a number of factors that affect the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

What Is the False Positive Test?

The definition of the false positive test would be the instance where a substance is identified incorrectly by SAFElife™ T-Dip Multi-Drug Urine Test Panel. The most common causes of the false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause the false positive test result.

What Is the False Negative Test?

The definition of the false negative test is that the initial drug is present but isn't detected by the SAFElife™ T-Dip Multi-Drug Urine Test Panel. If the specimen is diluted or adulterated, it may cause the false negative result. If suspect someone is taking drugs but get the negative test results, please test again at another time, or test for different drugs.

ADULTERATION CONTROL

Expected Results

Creatinine (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 form of specimen dilution.

Glutaraldehyde (GL): Glutaraldehyde is not a natural component of human urine and it should not be present in normal urine. The presence of glutaraldehyde in the urine sample indicates the possibility of adulteration. However, false positive may result when ketone bodies are present in urine. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolic abnormalities.

Nitrite (NI): Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dL may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. In this adulteration control, nitrite level above 15 mg/dL is considered abnormal.

Oxidants/Bleach (OX): The presence of Bleach and other oxidizing reagents in the urine is indicative of adulteration since oxidizing reagents are not normal constituents of urine. Other oxidizing reagents include Hydrogen Peroxide, Ferricyanide, Persulfate, Pyridinium Chlorochromate etc.

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

Specific Gravity (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.

TEST LIMITATIONS

1. This test has been developed for testing urine specimens only. No other fluids have been evaluated. DO NOT use this device to test anything but urine.
2. Adulterated urine specimens may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a specimen is suspected of being adulterated, obtain a new specimen.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine sample may cause false results.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

QUESTIONS AND ANSWERS

1. *What does SAFElife™ T-Dip Multi-Drug Urine Test Panel do?*
These tests detect if one or more prescription or illegal drugs such as Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Methylenedioxymethamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids are present in urine.

2. *What is "cut-off level"?*
The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test result is called positive, and below that concentration it is called negative.

3. *What are drugs of abuse?*
Drugs of abuse are illegal or prescription drugs (for example, Oxycodone or Valium) that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed or for a purpose other than what the doctor prescribed.

4. *What are the Common Street Names for the Drugs to be detected?*

Drug	Common Street Names
Amphetamine (AMP)	Speed, Jelly Beans or Super Jellies, Hearts, Uppers, Pick me ups or Wake me ups, Wake ups, Get ups, Boot ups, Sparkles
Secobarbital (BAR)	Amytal, Downers, Nembutal, Phenobarbital, Reds, Red Birds, Red devils, Seconal, Tuninal, Yellowjackets
Buprenorphine (BUP)	Bupe, Subbies, Temmies
Oxazepam (BZO)	Benzos, Downers, Nerve Pills, Tranks
Cocaine (COC)	Blow, C, Candy, Coke, Do a line, Freeze, Girl, Happy dust, Mama coca, Mojo, Monster, Nose, Pimp, Shot, Smoking gun, Snow, Sugar, Sweet stuff, and White powder.
Methylenedioxymethamphetamine (MDMA)	Ecstasy, E, X, XTC, Adam, Clarity, Lover's Speed
Methamphetamine (MET/mAMP)	Speed, Ice, Chalk, Meth, Crystal, Crank, Fire, Glass
Methadone (MTD)	Mixture, meth, linctus, green
Morphine (MOP/OPI)	Aunt Hazel, big H, black pearl, brown sugar, capital H, charley, china white, dope, good horse, H, hard stuff, hero, heroina, little boy, mud, perfect high, smack, stuff and tar.
Oxycodone (OXY)	OC, Ocycotton, OX, and Kicker
Phencyclidine (PCP)	Angel dust, belladonna, black whack, CJ, cliffhanger, crystal joint, Detroit pink, elephant tranquilizer, hog, magic, Peter Pan, sheets, soma, TAC, trank, white horizon and zoom.
Propoxyphene (PPX)	Darvon, Darvocet, Dolene, Propacet 100, Wygesic, SK-65, SK-65 APAP, Trycet, Genagesic, E-Lor, Balacet, Pain Killer, Pinks, Footballs, PP-Cap
Nortriptyline (TCA)	Blue angels, Blue birds, Vivactil, Anafranil, Janimine, Tofranil
Cannabinoids (THC)	420, Aunt Mary, baby, bobby, boom, chira, chronic, ditch, ganja, grass, greens, hash, herb, Mary Jane, nigra, Pot, reefer, rip, root, skunk, stack, torch, weed and zambi.

5. *How accurate is the test?*
The tests are sensitive to drugs and accurate. These tests, however, are not as accurate as lab tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug-testing kits.

6. *If the test results are negative, can the conclusion be that the person is free of drugs?*
This means that if the sample was collected properly and if the test was performed according to direction, then none of the drug screened were present in the urine.

7. *Does a preliminary positive screen test mean that drugs of abuse have been found?*
This means that the test has reacted with something in the sample and the sample must be sent to the lab for a more accurate test.

8. *What should I do if the lab test confirms a positive result?*
If you have received a confirmed positive result, please consult with our staff on a proper course of action. We will help you identify counselors who can help you. It is important that you remain calm and do not react in a negative way to the situation. If you do not believe the test result, please consult with your physician. They will have your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

9. *What is the principle of SAFElife™ T-Dip Multi-Drug Urine Test Panel?*
SAFElife™ T-Dip Multi-Drug Urine Test Panel are competitive immunoassays that is used to screen for the presence of drugs of abuse in urine. When the test is activated, the urine is absorbed into the device by capillary action. Then flowing across the pre-coated membrane, it will be mixed with the respective drug antibody conjugates. If concentrations of sample drugs are below corresponding detected drugs' cutoff, respective drug antibody conjugates bind to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. This produces a colored band in test region that indicates a negative result. On the contrary, if concentrations of sample drugs are at or above corresponding detected drugs' cutoff, the free drugs of sample bind to the respective drug antibody conjugates. It prevents the respective drug antibody conjugates from binding to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. Therefore, there is no colored band in the test region that indicates a preliminary positive result. To serve as a procedure control, if the test has been performed properly, a colored band will appear at the Control Region (C).

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials. Even though there is an internal procedural control line in the test device in the Control Region (C), 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 controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment and each new operator to determine that tests are working properly.

PERFORMANCE CHARACTERISTICS

Accuracy

1520 (eighty for each drug) clinical urine specimens were analyzed by GC-MS or LC/MS-MS and by each corresponding SAFElife™ T-Dip Multi-Drug Urine Test Panel. Each SAFElife™ T-Dip Multi-Drug Urine Test Panel was read by three viewers. Specimens 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 followed:

Drug Test	Result		Drug Free	Less than Half the Cutoff	Near Cutoff Negative (Between 50% below the cutoff and the cutoff)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff)	High Positive (Greater than 50% above the cutoff)	% Agreement with GC/MS or LC/MS
AMP 500	Viewer A	+	0	0	2	30	10	100%
		-	10	17	11	0	0	95%
	Viewer B	+	0	0	1	30	10	100%
		-	10	17	12	0	0	97.5%
	Viewer C	+	0	0	1	30	10	100%
		-	10	17	12	0	0	97.5%
AMP 1000	Viewer A	+	0	0	1	30	10	100%
		-	10	16	13	0	0	97.5%
	Viewer B	+	0	0	1	28	10	95%
		-	10	16	13	2	0	97.5%
	Viewer C	+	0	0	1	28	10	95%
		-	10	16	13	2	0	97.5%
BAR 300	Viewer A	+	0	0	1	29	11	100%
		-	10	19	10	0	0	97.5%
	Viewer B	+	0	0	1	28	11	97.5%
		-	10	19	10	1	0	97.5%
	Viewer C	+	0	0	1	28	11	97.5%
		-	10	19	10	1	0	97.5%
BUP 10	Viewer A	+	0	0	2	28	10	95%
		-	10	18	10	2	0	95%
	Viewer B	+	0	0	2	28	10	95%
		-	10	18	10	2	0	95%
	Viewer C	+	0	0	2	28	10	95%
		-	10	18	10	2	0	95%
BZO 300	Viewer A	+	0	0	2	29	10	97.5%
		-	10	15	13	1	0	95%
	Viewer B	+	0	0	0	28	10	95%
		-	10	15	15	2	0	100%
	Viewer C	+	0	0	3	29	10	97.5%
		-	10	15	12	1	0	92.5%
COC 150	Viewer A	+	0	0	2	31	9	100%
		-	10	18	10	0	0	95%
	Viewer B	+	0	0	1	30	9	97.5%
		-	10	18	11	1	0	97.5%
	Viewer C	+	0	0	2	30	9	97.5%
		-	10	18	10	1	0	95%
COC 300	Viewer A	+	0	0	3	28	11	97.5%
		-	10	13	14	1	0	92.5%
	Viewer B	+	0	0	3	28	11	97.5%
		-	10	13	14	1	0	92.5%
	Viewer C	+	0	0	3	28	11	97.5%
		-	10	13	14	1	0	92.5%
EDDP 300	Viewer A	+	0	0	1	32	8	100%
		-	10	18	11	0	0	97.5%
	Viewer B	+	0	0	1	32	8	100%
		-	10	18	11	0	0	97.5%
	Viewer C	+	0	0	1	32	8	100%
		-	10	18	11	0	0	97.5%
MDMA 500	Viewer A	+	0	0	2	30	10	100%
		-	10	18	10	0	0	95%
	Viewer B	+	0	0	2	30	10	100%
		-	10	18	10	0	0	95%
	Viewer C	+	0	0	2	30	10	100%
		-	10	18	10	0	0	95%
MET 500	Viewer A	+	0	0	2	20	20	100%
		-	10	15	13	0	0	95%
	Viewer B	+	0	0	2	20	20	100%
		-	10	15	13	0	0	95%
	Viewer C	+	0	0	3	20	20	100%
		-	10	15	12	0	0	92.5%
MET 1000	Viewer A	+	0	0	2	24	15	97.5%
		-	10	18	10	1	0	95%
	Viewer B	+	0	0	2	24	15	97.5%
		-	10	18	10	1	0	95%
	Viewer C	+	0	0	2	24	15	97.5%
		-	10	18	10	1	0	95%
MOP 300	Viewer A	+	0	0	0	29	10	97.5%
		-	10	18	12	1	0	100%
	Viewer B	+	0	0	0	29	10	97.5%
		-	10	18	12	1	0	100%
	Viewer C	+	0	0	0	29	10	97.5%
		-	10	18	12	1	0	100%
MTD 300	Viewer A	+	0	0	2	28	12	100%
		-	10	18	10	0	0	95%
	Viewer B	+	0	0	1	27	12	97.5%
		-	10	18	11	1	0	97.5%
	Viewer C	+	0	0	2	27	12	97.5%
		-	10	18	10	1	0	95%
OPI 2000	Viewer A	+	0	0	2	30	10	100%
		-	10	18	10	0	0	95%
	Viewer B	+	0	0	3	30	10	100%
		-	10	18	9	0	0	92.5%
	Viewer C	+	0	0	1	30	10	100%
		-	10	18	11	0	0	97.5%
OXY 100	Viewer A	+	0	0	1	30	10	100%
		-	10	18	11	0	0	97.5%
	Viewer B	+	0	0	1	29	10	97.5%
		-	10	18	11	1	0	97.5%
	Viewer C	+	0	0	0	29	10	97.5%
		-	10	18	12	1	0	100%
PCP 25	Viewer A	+	0	0	1	28	10	95%
		-	10	20	9	2	0	97.5%
	Viewer B	+	0	0	1	29	10	97.5%
		-	10	20	9	1	0	97.5%
	Viewer C	+	0	0	1	29	10	97.5%
		-	10	20	9	1	0	97.5%
PPX 300	Viewer A	+	0	0	2	31	8	97.5%
		-	10	17	11	1	0	95%
	Viewer B	+	0	0	2	31	8	97.5%
		-	10	17	11	1	0	95%
	Viewer C	+	0	0	2	31	8	97.5%
		-	10	17	11	1	0	95%
TCA 1000	Viewer A	+	0	0	2	29	10	97.5%
		-	10	18	10	1	0	95%
	Viewer B	+	0	0	2	29	10	97.5%
		-	10	18	10	1	0	95%
	Viewer C	+	0	0	2	29	10	97.5%
		-	10	18	10	1	0	95%
THC 50	Viewer A	+	0	0	2	30	10	100%
		-	10	19	9	0	0	95%
	Viewer B	+	0	0	2	30	10	100%
		-	10	19	9	0	0	95%
	Viewer C	+	0	0	2	30	10	100%
		-	10	19	9	0	0	95%

Precision and Sensitivity

To investigate the precision and sensitivity, each drug samples were 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 or LC/MS method. The study was performed 2 runs /day and lasted 25 days using three different lots of the SAFElife™ T-Dip Multi-Drug Urine Test Panel. Totally 3 operators participated in the study of the corresponding SAFElife™ T-Dip Multi-Drug Urine Test Panel. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs per day), for a total of 50 determinations per concentration per lot of the SAFElife™ T-Dip Multi-Drug Urine Test Panel.

Drug Test	Approximate Concentration of Sample (ng/mL)	Number of Determinations per Lot	Results (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
AMP 500	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	11/39	10/40	10/40
	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
AMP 1000	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	7/43	8/42	7/43
	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 300	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	8/42	8/42	7/43
	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
BUP 10	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	10/40	10/40	9/41
	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
BZO 300	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	8/42	7/43	8/42
	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 150	0	50	50/0	50/0	50/0
	37.5	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	112.5	50	50/0	50/0	50/0
	150	50	10/40	10/40	10/40
	187.5	50	0/50	0/50	0/50
	225	50	0/50	0/50	0/50
	262.5	50	0/50	0/50	0/50
	300	50	0/50	0/50	0/50
COC 300	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	10/40	10/40	11/39
	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
EDDP 300	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	9/41	9/41	8/42
	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
MDMA 500	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	10/40	10/40	11/39
	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
MET 500	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	10/40	10/40	10/40
	625	50	50/0	0/50	0/50
	750	50	50/0	0/50	0/50
	875	50	0/50	0/50	0/50
MET 1000	1000	50	0/50	0/50	0/50
	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	8/42	8/42	7/43
	1250	50	50/0	0/50	0/50
	1500	50	50/0	0/50	0/50
	1750	50	50/0	0/50	0/50
	2000	50	50/0	0/50	0/50
MOP 300	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	11/39	11/39	11/39
	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 300	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	8/42	9/41	9/41
	375	50	0/50	0/50	0/50
	450	50	0/50	0/50	0/50
	525	50	0/50	0/50	0/50
OPI 2000	0	50	50/0	50/0	50/0
	500	50	50/0	50/0	50/0
	1000	50	50/0	50/0	50/0
	1500	50	50/0	50/0	50/0
	2000	50	10/40	11/39	10/40
	2500	50	0/50	0/50	0/50
	3000	50	0/50	0/50	0/50
	3500	50	0/50	0/50	0/50
	4000	50	0/50	0/50	0/50
OXY 100	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	8/42	9/41	9/41
	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
PCP 25	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	6/44	6/44	7/43
	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
PPX 300	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	10/40	10/40	11/39
	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
TCA 1000	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	11/39	10/40	11/39
	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
THC 50	0	50	50/0	50/0	50/0
	12.5	50	50/0	50/0	50/0
	25	50	50/0	50/0	50/0
	37.5	50	50/0	50/0	50/0
	50	50	11/39	10/40	10/40
	62.5	50	0/50	0/50	0/50
	75	50	0/50	0/50	0/50
	87.5	50	0/50	0/50	0/50
	100	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.

Substance	Conc. (ng/mL)	Substance	Conc. (ng/mL)
AMP 500			
d-Amphetamine	500	l-Amphetamine	25,000
d,l- Amphetamine	1,500	(+/-) 3,4- Methylenedioxyamphetamine (MDA)	2,500
Phentermine	1,500	Hydroxyamphetamine	8,000
d-methamphetamine	>100,000	l-methamphetamine	>100,000
(+/-)3,4-Methylenedioxyethylamphetamine (MDE)	>100,000	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100,000
Ephedrine	>100,000	ρ-Methylamphetamine	100,000
Tyramine	100,000	(±)Phenylpropanolamine	>100,000
Phenylpropanolamine	>100,000	(±)-Norephedrine	>100,000
d,l-Norephedrine	100,000	Benzphetamine	>100,000
l-Ephedrine	>100,000	ρ- Hydroxymorephedrine	100,000
d,l-Epinephrine	>100,000	ρ- Hydroxyamphetamine	100,000
AMP 1000			
d-Amphetamine	1,000	l-Amphetamine	50,000
d,l-Amphetamine	3,000	(+/-)3,4-Methylenedioxyamphetamine (MDA)	5,000
Phentermine	3,000	d-Methamphetamine	>100,000
l-Methamphetamine	>100,000	Ephedrine	>100,000
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100,000	Hydroxyamphetamine	8,000
p-Hydroxymethamphetamine	15,000	(-)-Methamphetamine	12,500
l-methamphetamine	10,000	d-Methamphetamine	25,000
l-Methamphetamine	37,500	Chloroquine	10,000
(+/-)-Ephedrine	25,000	d/l-Methamphetamine	500
(+/-)3,4-Methylenedioxyamphetamine (MDA)	500	(+/-)3,4Methylenedioxy-n-ethylamphetamine (MDEA)	500
l-Phenylephrine	100,000	ρ-Phenylethylamine	25,000
Trimethobenzamide	5,000	d,l-Amphetamine	75,000
(1R,2S)-(-)-Ephedrine	50,000	Mephentermine	25,000
AMT 1000			
d-methamphetamine	1,000	l-phenylephrine	>100,000
p-Hydroxymethamphetamine	30,000	Mephentermine	50,000
l-methamphetamine	25,000	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	1,000
D,l,-Methamphetamine	1,000	D-Amphetamine	100,000
L-Amphetamine	75,000	Chloroquine	50,000
(+/-)-Ephedrine	50,000	(-)-Methamphetamine	25,000
(+/-)3,4-Methylenedioxyamphetamine (MDA)	1,000	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	4,000
l-Phenylethylamine	50,000	Trimethobenzamide	10,000
d,l-Amphetamine	100,000	(1R,2S)-(-)-Ephedrine	100,000
MOP 300			
Morphine	300	Morphinie-3-β-d-glucuronide	1,000
Codeine	300	Norcodeine	6,250
Ethyl Morphine	100	Normorphine	300
Heroin	300	Oxycodone	>100,000
Hydromorphone	5,000	Oxymorphone	10,000
Hydromorphone	1,000	Procaine	150,000
6-Monoacetylmorphine (6-MAM)	150	Thebaine	3,000
Levorphanol	10,000		
MTD 300			
Methadone	300	Doxylamine	50,000
EMDP	>100,000	EDDP	>100,000
LAAM	>100,000	Alpha Methadol	>100,000
OPI 2000			
Morphine	2,000	Morphinie-3-β-D-glucuronide	2,000
Codeine	2,000	Norcodeine	12,500
Ethyl Morphine	1,500	Normorphine	50,000
Heroin	2,000	Oxycodone	25,000
Hydrocodone	12,500	Oxymorphone	25,000
Hydromorphone	1,500	Procaine	150,000
6-Monoacetylmorphine (6-MAM)	1,500	Thebaine	5,000
Levorphanol	75,000		
OXY 100			
Oxycodone	100	Codeine	100,000
Dihydrocodeine	20,000	Ethyl Morphine	>100,000
Hydrocodone	10,000	Hydromorphone	32,000
Oxymorphone	1,000	Thebaine	>100,000
Acetylmorphine	>100,000	Morphine	>100,000
Buprenorphine	>100,000		
3,4-Methylenedioxyamphetamine (MDA)	3,000	d-Methamiphetamine	>100,000
l-methamphetamine	50,000	l-amphetamine	>100,000
d-orephetamine	>100,000		
MET 500			
d-methamphetamine	500	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	2,000
p-Hydroxymethamphetamine	15,000	(-)-Methamphetamine	12,500
l-methamphetamine	10,000	d-Methamphetamine	25,000
l-Methamphetamine	37,500	Chloroquine	10,000
(+/-)-Ephedrine	25,000	d/l-Methamphetamine	500
(+/-)3,4-Methylenedioxyamphetamine (MDA)	500	(+/-)3,4Methylenedioxy-n-ethylamphetamine (MDEA)	500
l-Phenylephrine	100,000	ρ-Phenylethylamine	25,000
Trimethobenzamide	5,000	d,l-Amphetamine	75,000
(1R,2S)-(-)-Ephedrine	50,000	Mephentermine	25,000
MET 1000			
d-methamphetamine	1,000	l-phenylephrine	>100,000
p-Hydroxymethamphetamine	30,000	Mephentermine	50,000
l-methamphetamine	25,000	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	1,000
D,l,-Methamphetamine	1,000	D-Amphetamine	100,000
L-Amphetamine	75,000	Chloroquine	50,000
(+/-)-Ephedrine	50,000	(-)-Methamphetamine	25,000
(+/-)3,4-Methylenedioxyamphetamine (MDA)	1,000	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	4,000
l-Phenylethylamine	50,000	Trimethobenzamide	10,000
d,l-Amphetamine	100,000	(1R,2S)-(-)-Ephedrine	100,000
MOP 300			
Morphine	300	Morphinie-3-β-d-glucuronide	1,000
Codeine	300	Norcodeine	6,250
Ethyl Morphine	100	Normorphine	300
Heroin	300	Oxycodone	>100,000
Hydromorphone	5,000	Oxymorphone	10,000
Hydromorphone	1,000	Procaine	150,000
6-Monoacetylmorphine (6-MAM)	150	Thebaine	3,000
Levorphanol	10,000		
MTD 300			
Methadone	300	Doxylamine	50,000
EMDP	>100,000	EDDP	>100,000
LAAM	>100,000	Alpha Methadol	>100,000
OPI 2000			
Morphine	2,000	Morphinie-3-β-D-glucuronide	2,000
Codeine	2,000	Norcodeine	12,500
Ethyl Morphine	1,500	Normorphine	50,000
Heroin	2,000	Oxycodone	25,000
Hydrocodone	12,500	Oxymorphone	25,000
Hydromorphone	1,500	Procaine	150,000
6-Monoacetylmorphine (6-MAM)	1,500	Thebaine	5,000
Levorphanol	75,000		
OXY 100			
Oxycodone	100	Codeine	100,000
Dihydrocodeine	20,000	Ethyl Morphine	>100,000
Hydrocodone	10,000	Hydromorphone	32,000
Oxymorphone	1,000	Thebaine	>100,000
Acetylmorphine	>100,000	Morphine	>100,000
Buprenorphine	>100,000		

PCP 25			
Phencyclidine	25	4-Hydroxyphencyclidine	12,500
PPX 300			
d-propoxyphene	300	d-Norpropoxyphene	300
TCA 1000			
Nortriptyline	1,000	Promazine	1,500
Amitriptyline	1,500	Maprotiline	2,000
Clomipramine	12,500	Nordoxepin	1,000
Desipramine	200	Promethazine	25,000
Doxepin	2,000	Trimipramine	3,000
Imipramine	400	Cyclobenzaprine	800
Norclomipramine	12,500		
THC 50			
11-nor-Δ9-THC-9-COOH	50	Δ9-Tetrahydrocannabinol	5,000
11-hydroxy-Δ9-Tetrahydrocannabinol	50	Cannabinol	20,000
11-nor-Δ8-THC-9-COOH	30	Cannabidiol	100,000
11-hydroxy-Δ9-Tetrahydrocannabinol	5,000	11-nor-Δ9-THC-carboxy-glucuronide	100
Δ8-Tetrahydrocannabinol	1,300		

Effect of Urinary Specific Gravity

The results demonstrate that the urinary specific gravity range of 1.000–1.035 does not affect the test result.

Effect of Urinary pH

The results demonstrate that the range of pH from 4 to 9 does not interfere with the performance of the test.

Interfering Substances

The following compounds were added to drug-free urine, urine with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff for the corresponding drug 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.

Acetaminophen
Acetophenetidin
Acetylsalicylic Acid
Acyclovir
Ahtin
Albumin (100mg/dL)
Aminophylline
Aminopyrine
Amlodarone Hydochloride
Amlodipine Mesylate
Amoxicillin
Ampicillin
Apomorphine
Aripiprazole
Aspartame
Atomoxetine
Atorvastatin Calcium
Atropine
Benzilic Acid
Benzoic Acid
Bilirubin
Bupropion
Captopril
Carbamazepine
Cefradine
Efferxor
Enalapril Maleate
Erythromycin
Esomeprazole Magnesium
β-Estradiol
17α Ethanol
Fenofibrate
Fenoprofen
Fentanyl Citrate
Fluoxetine Hydrochloride
Fluvoxamine
Furosemide
Gabapentin
Gentisic Acid
Glibenclamide
Gliclazide
Glipizide
Glucose
Haloperidol
Hemoglobin
Hydrochlorothiazide
Hydrocortisone
5-Hydroxytryramine
Isosorbide Dinitrate
Isoxsuprine
Nimodipine
Nitroglycerin
Norethindrone
N-Acetylprocainamide
O-Hydroxyhippuric Acid
Olanzapine
Omeprazole
Oxalic Acid
Oxolinic Acid
Oxymetazoline
Ondansetron
Paliperidone
Pantoprazole
Papaverine
Paroxetine Hydrochloride
Penfluridol
Penicillin/ Potassium
Penicillin-G
Phenelzine
Pioglitazone Hydrochloride
Piracetam
Pravastatin Sodium
Prednisone
Propylthiouracil
Quetiapine Fumarate
Quinine
Ranitidine
Rifampicin
Risperidone
Salicylic Acid
Serotonin
Sertraline Hydrochloride
Sildenafil Citrate
Simvastatin
Sodium Valproate
Spironolactone
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone 3 - acetate
Tetrahydrocortisone 3-(β-D glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
Topiramate
Tramadol Hydrochloride
Trazodone Hydrochloride
Triamterene
Trifluoperazine
Trimethoprim
Uric Acid
Valproate
Verapamil
Vitamin B2
Vitamin C
Cephalexin
Chloral Hydrate
Chloramphenicol
Chlorothiazide
Cholesterol
Ciprofloxacin Hydrochloride
Citalopram
Clarithromycin
Clonidine
Clopidogrel Hydrogen Sulphate
Clozapine
Conjugated Estrogens
Cortisone
Creatinine
(-) Cotinine
Chlorpheniramine
D,L-Octopamine
D,L-Propranolol
D,L-Tyrosine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Dirithromycin
Domperidone
D-Pseudoephedrine
Duloxetine
Dicyclomine
Ibuprofen
Ketoconazole
Ketoprofen
Ketamine
Kratom powder
Labetalol
Lamotrigine
Levofloxacin Hydrochloride
Levonorgestrel
Levothyroxine Sodium
Lidocaine Hydrochloride
Lisinopril
Lithium Carbonate
Liverite
Loperamide
Loratadine
Magnesium
Meperidine
Mesoridazine
Metoprolol Tartrate
Mifepristone
Mirtazapine
Montelukast Sodium
Mosapride Citrate
Nabumetone
Nalidixic Acid
Naproxen
Nefazodone
Nifedipine
Nikethamide

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-888-444-3657 (9:00 a.m. to 5:30 p.m. CDT M-F).

BIBLIOGRAPHY OF SUGGESTED READING

Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elsevier Science Publishing Company, Inc., New York, 1988.
Gilman, A., G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR (ed): Drug Addiction I, New York, Spring – Verlag, 1977.
Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992.
Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse, National Institute for Drug Abuse (NIDA), Research Monography 73, 1986.
Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
McBay, A. J. Drug-analysis technology--pitfalls and problems of drug testing. Clin. Chem. 33,338-408, 1987.

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.
Drug & Alcohol Clearinghouse https://clearinghouse.fmcsa.dot.gov/; 1-800-832-5660
Center for Substance Abuse Treatment https://www.samhsa.gov/about-us/who-we-are/offices-centers/csat 1-800-662-HELP
The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL
American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS

Keep away from sunlight
Store between 39°F–86°F (4°C–30°C)
Keep dry
Do not re-use
Consult instructions for use

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Bolingbrook, IL 60440
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Made in China

Rev. A4
Rel.: 2024/10/11