Multi-Drug Urine Test Dip card
Package Insert

Package insert for testing of any combination of the following drugs: Methamphetamine, Cocaine, Morphine, Amphetamine, Oxycodone, Ecstasy, Buprenorphine, Phencyclidine, Secobarbital, Methadone, Marijuana and Oxazepam.

INTENDED USE

Healgen Multi-Drug Urine Test DipCard is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine and Methadone in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Cannabinoids	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	2000 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
D,L- Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL

Configuration of the Healgen Multi-Drug Urine Test DipCard can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Secobarbital 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 exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

SUMMARY

The test is intended for use as the first step in a two step process to provide consumers with information concerning the presence or absence of the above stated drugs in a urine sample. Information regarding confirmatory testing – the second step in the process, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is provided in these instructions.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The Test Cup should remain in the sealed pouch until use.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The Test DipCard is stable through the expiration date printed on the sealed pouch. The Test DipCard must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SAMPLE COLLECTION AND PREPARATION

Urine Assay

The urine sample must be collected in a clean and dry container. Urine collected at any time of the day may be used.

MATERIALS

Materials Provided

• Test DipCard • Package insert

Materials also included:

1. Labeled Vials for shipping "preliminary" sample to the laboratory for confirmation
2. Plastic transportation bags
3. Mailing boxes
4. Personal identification numbers

DIRECTIONS FOR USE

If refrigerated, allow the test device to come to room temperature [15-30°C (59-86°F)] prior to testing.

1) Remove the DipCard from the foil wrapper.

2) Fill a specimen cup (not provided) with fresh urine. Dip the DipCard into the urine with the arrow end pointing toward the urine. Do not cover the urine over the MAX (maximum) line. You may leave the DipCard in the urine or you may take the DipCard out after a minimum of 15 seconds in the urine and lay the DipCard flatly on a non-absorptive clean surface.

3) Read results at 5 minutes and do not throw away the urine. Urine used may be needed for confirmation testing. Please see the Results Interpretation and Mailing a Urine Sample sections of this labeling.

DO NOT INTERPRET RESULT AFTER 5 MINUTES.

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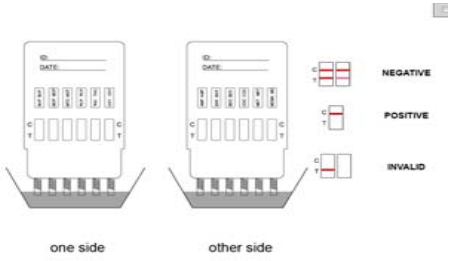

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INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient sample volume or not conducting the test as instructed are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, contact us..

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

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Please refer to the Mailing a Urine Sample section of this labeling.

What Is A False Positive Test?

The definition of a false positive test would be an instance where the Healgen® Multi-Drug Urine Test is positive even though the target drugs are not in the sample. 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 Healgen® Multi-Drug Urine Test. If the sample is diluted, or the sample is contaminated that may cause a false negative result.

LIMITATIONS

1. The Healgen Multi-Drug Urine Test DipCard provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause incorrect results.
3. Substances, such as bleach and/or alum, in urine samples may produce incorrect results regardless of the analytical method used.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

QUESTIONS AND ANSWERS

1. What does the Drug of Abuse Urine Test do?

These tests indicate if one or more prescription or illegal drugs are present in urine. The testing is done in two steps. First, you do a quick at-home test. Second, if the test suggests that drugs may be present, you send the sample to a laboratory for additional testing.

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 is called positive, and below that concentration it is called negative.

3. What are drugs of abuse?

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

4. How accurate is the test?

The tests are sensitive to the presence of drugs in urine sample. These tests 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..

5. Does a preliminary positive screen test mean that you have found of abuse?

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.

6. 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.

MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIRMATION TESTING

1. Pour urine from the cup into the Labeled Vial. Ensure that the Labeled Vial is about two thirds (2/3) full with the urine that gave preliminary positive result(s) and that the cap is tightly closed. Only the urine that gave preliminary positive result(s) should be used for confirmation testing.
2. Please identify on the label, the drug that gave a preliminary positive result.
3. Be sure to write your Cell Phone Number on the mailing box so that the laboratory can send you a message with the confirmed results. The laboratory will also send you a Personal Identification Number.
4. Place the Labeled Vial in the plastic bag and seal the plastic bag.
5. Place the sealed plastic bag in the mailing box. Close the mailing box and secure it with packing tape. The mailing address for the laboratory is already on the mailing box. ***Please note that the mailing box isn't pre-paid. You must attach the proper postage to have a carrier service deliver it.***
6. Place the mailing box in any US Postal Service Office.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Technical Support Number 1-866-982-3818 (9:00 a.m. to 5 p.m. CDT).

QUALITY CONTROL

If you work in a laboratory, you should perform quality control testing and you should read this section.

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control testing should be performed with each new lot, each new shipment and every thirty days to check storage. Please contact our Technical Support at 1-866-982-3818 for controls that work with the device.

PERFORMANCE CHARACTERISTICS

Accuracy

960(eighty of each drug) clinical urine specimens were analyzed by GC-MS and by the **Healgen® Multi-Drug Urine Test Dip card**. Each test was performed by three operators. 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:

Methamphetamine

Test	Drug-free	Low Negative (Less than half the cutoff concentration)	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)

Operator A	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Operator B	Positive	0	0	0	11	27
	Negative	10	19	15	2	0
Operator C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

% agreement among positives is 94.4%
% agreement among negatives is 100%

Cocaine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	15	24
	Negative	10	17	13	1	0
Operator B	Positive	0	0	0	14	24
	Negative	10	17	13	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	17	13	2	0

% agreement among positives is 87.5%
% agreement among negatives is 100%

Morphine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Operator B	Positive	0	0	0	12	23
	Negative	10	16	14	5	0
Operator C	Positive	0	0	0	12	23
	Negative	10	16	14	5	0

% agreement among positives is 88.3%
% agreement among negatives is 100%

Oxazepam

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	12	24
	Negative	10	16	15	4	0
Operator B	Positive	0	0	1	12	24
	Negative	10	16	15	4	0
Operator C	Positive	0	0	0	14	24
	Negative	10	16	15	2	0

% agreement among positives is 91.7%
% agreement among negatives is 100%

Marijuana

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	13	26
	Negative	10	16	16	1	0
Operator B	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Operator C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

% agreement among positives is 95.8%
% agreement among negatives is 100%

Amphetamine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Operator B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Operator C	Positive	0	0	0	13	23
	Negative	10	16	14	4	0

% agreement among positives is 91.7%
% agreement among negatives is 100%

Oxycodone

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 93.3%
% agreement among negatives is 100%

Phencyclidine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	12	24
	Negative	10	15	15	4	0

% agreement among positives is 91.7%
% agreement among negatives is 100%

MDMA

Healgen Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator B	Positive	0	0	0	15	24
	Negative	10	15	15	1	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 95%
% agreement among negatives is 100%

Secobarbital

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 95%
% agreement among negatives is 100%

Buprenorphine

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 93.3%
% agreement among negatives is 100%

Methadone

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	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)
Operator A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 95%
% agreement among negatives is 100%

ANALYTICAL SPECIFICITY

The following table lists compounds that are positively detected in urine by the **Healgen® Multi-Drug Urine Test Dip card**.

Drug	**Concentration (ng/ml)**	% Cross-Reactivity
METHAMPHETAMINE		
D-Methamphetamine	1,000	100%
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000	5%
Procaine (Novocaine)	60,000	2%
Trimethobenzamide	20,000	5%
Methamphetamine	1000	100%
Ranitidine (Zantac)	50,000	2%
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2500	40%
Chloroquine	50,000	2%
Ephedrine	100,000	1%
Fenfluramine	50,000	2%
p-Hydroxymethamphetamine	10,000	10%
COCAINE		
Benzoylecogonine	300	100%
Cocaethylene	300	100%
CocaineHCl	300	100%
MARIJUANA		

11-nor-Δ9-THC-9-COOH	50	100%
Delta-9-Tetrahydrocannabinol	50,000	0.1%
11-nor-delta-9-THC-carboxyglucuronide	75	67%
(-)-11-nor-9-carboxy-delta9-THC	75	67%
11-Nor-Δ9-Tetrahydrocannabinol	50	100%
11-Hydroxy-Δ9-Tetrahydrocannabinol	5,000	1%
11-Nor-Δ8-Tetrahydrocannabinol	50	100%
Δ8-THC-COOH	50,000	0.1%
Morphine		
O6-Acetylmorphine	2,500	80%
Codeine	1,000	50%
EthylMorphine	250	800%
Heroin	5,000	40%
Hydromorphone	2,500	80%
Hydrocodone	5,000	50%
Morphine Hydrochloride	2,000	100%
Oxycodone	75,000	3%
Thebaine	13,000	15%
Oxazepam		
Alprazolam	200	150%
Bromazepam	1,560	19%
Chlordiazepoxide HCL	1,560	19%
Clobazam	100	300%
Clonazepam	780	38%
Clorazepate Dipotassium	200	150%
Delorazepam	1,560	19%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	2,500	12%
Flunitrazepam	400	75%
a-Hydroxyalprazolam	1260	24%
(±) Lorazepam	1,560	19%
RS-Lorazepam glucuronide	160	188%
Midazolam	12,500	2%
Nitrazepam	100	300%
Norchlordiazepoxide	200	150%
Nordiazepam	400	75%
Oxazepam	300	100%
Temazepam	100	300%
Triazolam	2,500	12%
AMPHETANINE		
D-Amphetamine	1,000	100%
D,L - Amphetamine (Amphetamine Sulfate)	1,000	100%
Phentermine	1,250	80%
(+/-)-4-Hydroxyamphetamine HCL	600	167%
L-Amphetamine	20,000	5%
(+/-)-Methylenedioxyamphetamine(MDA)	1,500	67%
d-Methamphetamine	>100000	<1%
l-Methamphetamine	>100000	<1%
ephedrine	>100000	<1%
3,4-Methylenedioxyethylamphetamine (MDE)	>100000	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	>100000	<1%
OXYCODONE		
Oxycodone	100	100%
Codeine	50,000	0.2%
Ethyl Morphine	75,000	0.1%
Thebaine	50,000	0.2%
Oxymorphone	750	13%
Dihydrocodeine	12500	0.8%
Hydromorphone	>100000	<0.1%
Hydrocodone	>100000	<0.1%
Morphine	>100000	<0.1%
Acetylmorphine	>100000	<0.1%
Buprenorphine	>100000	<0.1%
Ethylmorphine	>100000	<0.1%
SECOBARBITAL		
Secobarbital	300	100%
Amobarbital	300	100%
Alphenal	750	40%
Aprobarbital	250	120%
Butabarbital	2500	12%

Butethal	2500	12%
Butalbital	2500	12%
Cyclopentobarbital	500	60%
Pentobarbital	2500	12%
BUPRENORPHINE		
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	20	50%
Morphine	Negative at 100000	Not detected
Oxymorphone	Negative at 100000	Not detected
Hydromorphone	Negative at 100000	Not detected
METHADONE		
Methadone	300	100%
Doxylamine	5,000	6%
EDDP	Negative at 100,000	Not Detected
EMDP	Negative at 100,000	Not Detected
LAAM HCl	Negative at 100,000	Not Detected
Alpha Methadol	Negative at 100,000	Not Detected
PHENCYCLIDINE		
Phencyclidine	25	100%
4-Hydroxy Phencyclidine	90	28%
MDMA		
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000	17%
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300	167%
d-methamphetamine	2500	20%
d-amphetamine	>100000	Not detected
l-amphetamine	>100000	Not detected
l-methamphetamine	>100000	Not detected

PRECISION

This study is performed 2 runs/day and lasts 25 days for each drug with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day. A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

Drugs	Concentration (ng/mL)	n	Lot1		Lot2		Lot3	
			-	+	-	+	-	+
Methamphetamine	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
	1,000	50	24	26	24	26	24	26
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
Benzoylecogonine	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	20	30	20	30	20	30
	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
11-nor-Δ9-THC-9-COOH	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	20	30	20	30	20	30
	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
Oxazepam	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0

Drugs	Concentration (ng/mL)	n	Lot1		Lot2		Lot3	
			-	+	-	+	-	+
	225	50	50	0	50	0	50	0
	300	50	18	32	18	32	18	32
	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
Morphine	0	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	1,000	50	50	0	50	0	50	0
	1,500	50	50	0	50	0	50	0
	2,000	50	22	28	22	28	22	28
	2,500	50	0	50	0	50	0	50
	3,000	50	0	50	0	50	0	50
	3,500	50	0	50	0	50	0	50
	4,000	50	0	50	0	50	0	50
Amphetamine	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
	1000	50	20	30	20	30	20	30
	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
Oxycodone	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	24	26	24	26	24	26
	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
Methadone	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	28	22	24	26	27	23
	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(Ecstasy)	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	24	26	24	26	24	26
	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
Secobarbital	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	23	27	21	29	23	27
	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
Buprenorphine	0	50	50	0	50	0	50	0
	2.5	50	50	0	50	0	50	0
	5	50	50	0	50	0	50	0
	7.5	50	50	0	50	0	50	0
	10	50	28	22	22	28	28	22
	12.5	50	0	50	0	50	0	50
	15	50	0	50	0	50	0	50
	17.5	50	0	50	0	50	0	50
	20	50	0	50	0	50	0	50
Phencyclidine	0	50	50	0	50	0	50	0
	6	50	50	0	50	0	50	0
	12.5	50	50	0	50	0	50	0

Drugs	Concentration (ng/mL)	n	Lot1		Lot2		Lot3	
			-	+	-	+	-	+
	19	50	50	0	50	0	50	0
	25	50	22	28	22	28	22	28
	31	50	0	50	0	50	0	50
	37.5	50	0	50	0	50	0	50
	44	50	0	50	0	50	0	50
	50	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **Healgen® Multi-Drug Urine Test Dip card** was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The **Healgen® Multi-Drug Urine Test Dip card**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine, Cocaine, Morphine, Amphetamine, Oxycodone, Ecstasy, Buprenorphine, Phencyclidine, Secobarbital, Methadone, Marijuana and Oxazepam positive urine. The following compounds show no cross-reactivity when tested with the **Healgen® Multi-Drug Urine Test Dip card** at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

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

Lay User Study

A lay user study was performed at three intended user sites with 160 lay persons. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled samples and a device. The typical results are summarized below.

Drugs	% of Cutoff	Number of samples	Lay person results		The percentage agreement (%)
			No. of Positive	No. of Negative	
Methamphetamine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Cocaine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Cannabinoids	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Morphine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Oxazepam	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Amphetamine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Oxycodone	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Methadone	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Secobarbital	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Buprenorphine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
Phencyclidine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%
MDMA	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	20	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	20	0	100%
	+75% Cutoff	20	20	0	100%

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3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
5. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.

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.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

Center for Substance Abuse Treatment www.health.org 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 2°C and 30°C

Keep dry

Do not re-use