Healgen®

Multi-Drug Urine Test Dip card Package Insert

INTENDED USE

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

Drug(Identifier)	Cut-off level
Amphetamine	1,000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Cannabinoids	50 ng/mL
Methamphetamine	1,000 ng/mL
Morphine	2,000 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300ng/mL
2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300ng/mL
Nortriptyline	1,000ng/mL

Configuration of the Healgen Multi-Drug Urine Test DipCard can consist of any combination of the above listed drug analytes up to a maximum of 14 analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Secobarbital, Nortriptyline and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. There are no uniformly recognized drug levels for Buprenorphine, Oxazepam, Secobarbital, Nortriptyline or Oxycodone in urine. 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.

SIMMARY

Healgen® Multi-Drug Urine Test Dip Card is used to test for the presence of certain drugs in a person's urine. If the result is preliminary positive, the result is then confirmed with additional laboratory testing.

PRECAUTIONS

- The test is intended only for use outside the body to test for drugs in a person's urine...
- · It should not be used after the stated expiration date.
- · The package should remain unopened until ready for use.

STORAGE AND STABILITY

Keep Healgen® Multi-Drug Urine Test Dip Card in the package until ready for use. The package may be stored at room temperature or refrigerated (39-86°F). DO NOT FREEZE.

The product will remain stable through the expiration date printed on the sealed pouch. Do not use beyond that date.

SAMPLE COLLECTION AND PREPARATION

The urine sample must be collected in the urine cup provided. Urine may be collected at any time of the

MATERIALS PROVIDED

- · Test Dip Card
- Urine Cup
- Package insert
- · Labeled vials for shipping "preliminary positive" sample to the laboratory
- Plastic transportation bags
- Prepaid mailing boxes

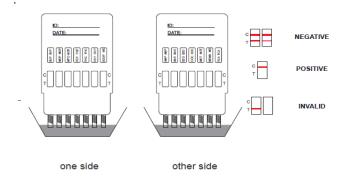
MATERIALS REQUIRED BUT NOT PROVIDE

• Timer or watch

DIDECTIONS FOR USE

- 1) Remove the Dip Card from the foil wrapper.
- 2) Fill the urine cup with fresh urine. Dip the Dip Card into the urine with the arrow end pointing toward the urine and start the timer or note the time on a watch. Do not cover the urine over the MAX (maximum) line. Take the Dip Card out after a minimum of 15 seconds in the urine and lay the Dip Card flatly on a non-absorptive clean surface.
- 3) Read results at 5 minutes.

DO NOT INTERPRET RESULT AFTER 5 MINUTES.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines will appear. One red line is in the control region marked (C), and another is in the test region marked (T). *NOTE: Even a faint pink line is a negative result.

PRELIMINARY POSITIVE: One red line appears in the control region (C). No line appears in the test region (T).

INVALID: Control line fails to appear. If this happens, review the directions for use and repeat the test using a new test device. If the problem persists, contact Healgen at .(866) 982-3818

The tester should be careful in reading the test results. A preliminary positive result does not always mean that someone took illegal drugs. Likewise, a negative result does not always mean that illegal drugs were not taken. This is why further laboratory confirmation for preliminary positive test results is required.

What Is A False Positive Test?

A false positive test result is when the drug is not present, but the test produces a preliminary positive result This can be caused by certain foods and medicines, diet plan drugs and nutritional supplements in the urine.

What Is A False Negative Test?

A false negative test means that the drug is present, but it is not detected by the test. Adding water or some other liquid to the urine before testing can cause this to happen.

LIMITATIONS

- 1. Intentionally adding bleach or other liquids to the urine sample may produce incorrect results.
- 2. The test cannot distinguish between drugs that are abused and some medications.

MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIRMATION TESTING

- Pour urine from the cup into the labeled vial. Ensure that the labeled vial is about two thirds (2/3) full. Close
 the cap.
- Check off the drugs that came up positive on the label.
- Write your cell phone number on the mailing box.
- Place the labeled vial in the plastic bag and seal the plastic bag.
- Place the sealed plastic bag in the pre-addressed mailing box. Close the mailing box and secure it with packing tape.
- Take the mailing box to any US Postal Service Office.

ASSISTANCE

If you have any question regarding the use of this product, please call our Technical Support Number

1-866-982-3818 (9:00 a.m. to 5 p.m. CDT).

QUESTIONS AND ANSWER

1. What is the Healgen® Multi-Drug Urine Test Dip Card?

This test is designed to detect one or more prescription or illegal drugs in a person's urine.

2. What do I do if the test result is preliminary positive ?

The sample must be sent to the lab for an additional test.

. What should I do if the lab test confirms that the urine sample contains one or more prescription or illegal drugs?

It is important to remain calm and consult with your healthcare provider or with our staff for additional information and guidance.

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.

Follow local, state and federal laws and regulations

PERFORMANCE CHARACTERISTICS

Accurac

The accuracy of the test was evaluated by testing 80 clinical urine specimens for each drug in parallel with GC-MS. The results are shown below.

Methamphetamine

		1				
		Drug-free	Low Negative	Near Cutoff	Near Cutoff	High Positive
Test			(Less than	Negative	Positive	(greater than
			half the cutoff	(Between 50%	(Between the	50% above the
			concentration)	below the cutoff	cutoff and	cutoff
				and the cutoff	50% above	concentration)
				concentration)	the cutoff	
					concentration)	
Operator A	Positive	0	0	0	11	27
Operator A	Negative	10	19	15	2	0
O	Positive	0	0	0	11	27
Operator B	Negative	10	19	15	2	0
Omonoton C	Positive	0	0	0	11	27
Operator C	Negative	10	19	15	2	0

[%] agreement among positives is 94.4%

Cocaine

Test		Drug-free	Low Negative (Less than half the cutoff	Near Cutoff Negative (Between 50%	Near Cutoff Positive (Between the	High Positive (greater than 50% above the
			concentration)	below the cutoff and the cutoff concentration)	cutoff and 50% above the cutoff	cutoff concentration)
				,	concentration)	
O	Positive	0	0	0	15	24
Operator A	Negative	10	17	13	1	0
O . D	Positive	0	0	0	14	24
Operator B	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%

[%] agreement among negatives is 100%

	ine		

Morphine	(MOP)					
		Drug-free	Low Negative	Near Cutoff	Near Cutoff	High Positive
Healgen Test			(Less than	Negative	Positive	(greater than
			half the cutoff	(Between 50%	(Between the	50% above the
			concentration)	below the cutoff	cutoff and	cutoff
				and the cutoff	50% above	concentration)
				concentration)	the cutoff	
					concentration)	
O A	Positive	0	0	0	13	25
Operator A	Negative	10	15	15	2	0
Operator B	Positive	0	0	1	14	25
Negative Negative		10	15	15	1	0
Omanatan C	Positive	0	0	0	14	25
Operator C	Negative	10	15	15	1	0

[%] agreement among positives is 90%

Oxazepam

		Drug-free	Low Negative	Near Cutoff	Near Cutoff	High Positive
Test		Drug-nee	(Less than	Negative	Positive	(greater than
			half the cutoff	(Between 50%	(Between the	50% above the
			concentration)	below the cutoff	cutoff and	cutoff
				and the cutoff	50% above	concentration)
				concentration)	the cutoff	
					concentration)	
Operator A	Positive	0	0	0	12	24
Operator A	Negative	10	16	15	4	0
O D	Positive	0	0	1	12	24
Operator B	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%

Marijuana

		Drug-free	Low Negative	Near Cutoff	Near Cutoff	High Positive
Test			(Less than	Negative	Positive	(greater than
			half the cutoff	(Between 50%	(Between the	50% above the
			concentration)	below the cutoff	cutoff and	cutoff
				and the cutoff	50% above	concentration)
				concentration)	the cutoff	
					concentration)	
Omonoton A	Positive	0	0	0	13	26
Operator A	Negative	10	16	16	1	0
Omonoton B	Positive	0	0	0	12	26
Operator B	Negative	10	16	16	2	0
O	Positive	0	0	0	12	26
Operator C	Negative	10	16	16	2	0

[%] agreement among positives is 95.8%

Amphetamine

Amphetan	IIIIC					
Т	`est	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
Operator A	Negative	10	16	14	2	0
Operator B	Positive	0	0	0	13	23
Орегают в	Negative	10	16	14	4	0
Omenator C	Positive	0	0	0	13	23
Operator C	Negative	10	16	14	4	0

[%] agreement among positives is 91.7%

Т	est	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
Operator A	Negative	10	15	15	3	0
O	Positive	0	0	0	14	24
Operator B	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%

Phencyclidine

		Drug-free	Low Negative	Near Cutoff	Near Cutoff	High Positive
Test			(Less than	Negative	Positive	(greater than
			half the cutoff	(Between 50%	(Between the	50% above the
			concentration)	below the cutoff	cutoff and	cutoff
				and the cutoff	50% above	concentration)
				concentration)	the cutoff	
					concentration)	
Operator A	Positive	0	0	0	13	24
Operator A	Negative	10	15	15	3	0
O	Positive	0	0	0	13	24
Operator B	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%

MDMA

Healg	en 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)
Omorroton A	Positive	0	0	0	14	24
Operator A	Negative	10	15	15	2	0
Omorroton B	Positive	0	0	0	15	24
Operator B Negative	Negative	10	15	15	1	0
O	Positive	0	0	0	13	24
Operator C	Negative	10	15	15	3	0

[%] agreement among positives is 95%

Secobarbital

		Drug-free	Low Negative	Near Cutoff	Near Cutoff	High Positive
			(Less than	Negative	Positive	(greater than
	Test		half the cutoff	(Between 50%	(Between the	50% above the
T			concentration)	below the cutoff	cutoff and	cutoff
				and the cutoff	50% above	concentration)
				concentration)	the cutoff	
					concentration)	
O	Positive	0	0	0	14	24
Operator A	Negative	10	15	15	2	0
O D	Positive	0	0	0	14	24
Operator B	Negative	10	15	15	2	0
O	Positive	0	0	0	14	24
Operator C	Negative	10	15	15	2	0

[%] agreement among positives is 95%

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)
Omanatan A	Positive	0	0	0	13	24
Operator A	Negative	10	15	15	3	0
Omanatan D	Positive	0	0	0	14	24
Operator B	Negative	10	15	15	2	0
Omanatan C	Positive	0	0	0	13	24
Operator C	Negative	10	15	15	3	0

[%] agreement among positives is 93.3%

Methadone

Methadone	2					
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)
O	Positive	0	0	0	14	24
Operator A	Negative	10	15	15	2	0
Omanoton D	Positive	0	0	0	14	24
Operator B	Negative	10	15	15	2	0
	Positive	0	0	0	14	24
Operator C	Negative	10	15	15	2	0
0/		050/				

[%] agreement among positives is 95%

EDDP (Methadone Metabolites)

Healgen Test		Drug-free	Low Negative (Less than	Near Cutoff Negative	Near Cutoff Positive	High Positive (greater than
			half the cutoff concentration)	(Between 50% below the cutoff	(Between the cutoff and	50% above the cutoff
	_			and the cutoff	50% above	concentration)
				concentration)	the cutoff	
					concentration)	
O	Positive	0	0	0	14	24
Operator A	Negative	10	15	15	2	0
O P	Positive	0	0	0	13	24
Operator B	Negative	10	15	15	3	0
On anoton C	Positive	0	0	0	14	24
Operator C	Negative	10	15	15	2	0

[%] agreement among positives is 94.2%

Nortriptyline

Healgen Test		Drug-free	Low Negative (Less than	Near Cutoff Negative	Near Cutoff Positive	High Positive (greater than
			half the cutoff concentration)	(Between 50% below the cutoff and the cutoff	(Between the cutoff and 50% above	50% above the cutoff concentration)
				concentration)	the cutoff	
					concentration)	
Operator A	Positive	0	0	0	14	24
Operator A	Negative	10	15	15	2	0
O	Positive	0	0	0	14	24
Operator B	Negative	10	15	15	2	0
Omeneton C	Positive	0	0	0	14	24
Operator C	Negative	10	15	15	2	0

[%] agreement among positives is 95%

ANALYTICAL SPECIFICITY

[%] agreement among negatives is 100%

Multi-Drug Urine Test Dip card.

Drug	Concentration (ng/ml)	% Cross-Reactivity
METHAMPHETAMINE	1.000	1000
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	50	1000/
11-nor-Δ9-THC-9-COOH Delta-9-Tetrahydrocannabinol	50 50,000	100% 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(OPI, MOP2000)		
Morphine	2000	100%
O6-Acetylmorphine	2500	80%
Codeine	1000	200%
EthylMorphine	250	800%
Heroin	5000	40%
Hydromorphone	2500	80%
Hydrocodone Oxycodone	5000 75000	40% 3%
Thebaine	13000	15%
Oxazepam		
Alprazolam	200	150%
Bromazepam Chlordiazepoxide HCL	1,560	19% 19%
Clobazam	1,560 100	300%
Clonazepam	780	38%
Clorazepate Dipotassium	200	150%
Delorazepam	1,560	19%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam Flunitrazepam	2,500 400	12% 75%
a-Hydroxyalprazolam	1260	24%
(±) Lorazepam	1,560	19%
RS-Lorazepam glucuronide	160	188%
Midazolam	12,500	2%
Nitrazepam	100	300%
Norchlordiazepoxide Nordiazepom	200 400	150%
Nordiazepam Oxazepam	300	75% 100%
Temazepam	100	300%
Triazolam	2,500	12%
AMPHETANINE		
D-Amphetamine	1,000	100%
D,L - Amphetamine (Amphetamine Sulfate)	1,000 1,250	100%
Phentermine (+/-)-4-Hydroxyamphetamine HCL	600	167%
L-Amphetamine	20,000	5%
(+/-)-Methylenedioxyamphetamine(MDA)	1,500	67%

d-Methamphetamine	>100000	<1%
1-Methamphetamine	>100000	<1%
ephedrine	>100000	<1%
3,4-Methylenedioxyethylamphetamine (MDE)	>100000	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	>100000	<1%
э, г поспутеленняху теннипристипне (1715/1712)	× 100000	17.0
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%
Ethylinorphine	>100000	<0.1%
GEGORA PRITA		
SECOBARBITAL	200	4000
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%
remodarbitar	2300	1270
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
Trydromorphone	riegative at 100000	Tior detected
METHADONE		
		100%
	200	
Methadone	300	
Methadone Doxylamine	5,000	6%
Methadone Doxylamine EDDP	5,000 Negative at 100,000	6% Not Detected
Methadone Doxylamine EDDP EMDP	5,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected
Methadone Doxylamine EDDP EMDP LAAM HCl	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected Not Detected
Methadone Doxylamine EDDP EMDP	5,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected
Methadone Doxylamine EDDP EMDP LAAM HCl	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected Not Detected
Methadone Doxylamine EDDP EMDP LAAM HCl	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected Not Detected
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected Not Detected
Methadone Doxylamine EDDP EMDP LAAM HCl Alpha Methadol PHENCYCLIDINE	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected Not Detected Not Detected Not Detected
Methadone Doxylamine EDDP EMDP LAAM HCl Alpha Methadol PHENCYCLIDINE Phencyclidine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected Not Detected Not Detected Not Detected 100%
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected Not Detected Not Detected Not Detected 100%
Methadone Doxylamine EDDP EMDP LAAM HCl Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 25 90	6% Not Detected Not Detected Not Detected Not Detected Not Detected 100% 28%
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000	6% Not Detected Not Detected Not Detected Not Detected Not Detected 100%
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA MDMA ML-3,4-Methylenedioxymethamphetamine (MDMA)	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Possitive at 100,000 Segative at 100,000 100 100 100 100 100 100 100 100	6% Not Detected Not Detected Not Detected Not Detected Not Detected 100% 28%
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA)	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 25 90 500 3,000	6% Not Detected Not Detected Not Detected Not Detected Not Detected 100% 28%
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D.L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA)	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 Segative at 100,000 25 90 500 3,000 3,000 300	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167%
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 100 100 100 100 100 100 100 100	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20%
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine d-amphetamine d-amphetamine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 100 100 100 100 100 100 100 100	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 100 100 100 100 100 100 100 100	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20%
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine d-amphetamine d-amphetamine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 100 100 100 100 100 100 100 100	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine d-amphetamine l-amphetamine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 25 90 500 3,000 3,000 300 2500 >100000 >100000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine d-amphetamine l-amphetamine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 25 90 500 3,000 3,000 300 2500 >100000 >100000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA 3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine d-amphetamine l-amphetamine l-methamphetamine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 25 90 500 3,000 300 2500 >100000 >100000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected Not detected
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D.L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine d-amphetamine l-amphetamine l-methamphetamine l-methamphetamine EDDP(Methadone Metabolites) EDDP	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 25 90 500 3,000 300 2500 >100000 >100000 >100000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D.L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyamphetamine HCI (MDA)	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 25 90 500 3,000 300 2500 >100000 >100000 >100000 300 50,000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected Not detected 100% 100%
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine d-amphetamine l-amphetamine l-amphetamine l-methamphetamine l-methamphetamine DPP(Methadone Metabolites) EDDP Disopyramide Methadone	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 25 90 500 3,000 3,000 2500 >100000 >100000 >100000 >50,000 >100,000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected Not detected 100% 100% 17% 167% 20% 100% 100% 100% 100% 100% 100% 100%
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D.L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyamphetamine HCI (MDA)	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 25 90 500 3,000 300 2500 >100000 >100000 >100000 300 50,000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected Not detected 100% 100%
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D.L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine d-amphetamine l-amphetamine l-methamphetamine l-methamphetamine EDDP(Methadone Metabolites) EDDP Disopyramide Methadone EMDP	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 25 90 500 3,000 3,000 2500 >100000 >100000 >100000 >50,000 >100,000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected Not detected 100% 100% 17% 167% 20% 100% 100% 100% 100% 100% 100% 100%
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyamphetamine (MDEA) d-methamphetamine d-amphetamine l-amphetamine l-methamphetamine l-methamphetamine DPP(Methadone Metabolites) EDDP Disopyramide Methadone EMDP Nortriptyline	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 Negative at 100,000 25 90 500 3,000 3,000 300 2500 >100000 >100000 50,000 >100,000 500	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected Not detected 100% 17% 167% 20% 167% 167% 20% 167% 167% 167% 167% 167% 167% 167% 167
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine d-amphetamine l-amphetamine l-methamphetamine l-methamphetamine l-methamphetamine DPP(Methadone Metabolites) EDDP Disopyramide Methadone EMDP Nortriptyline Nortriptyline	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 25 90 500 3,000 3,000 300 2500 >100000 >100000 300 50,000 >100,000 500 1,000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected 100% 100% 17% 167% 20% 100% 100% 100% 100%
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D.L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine l-amphetamine l-methamphetamine l-methamphetamine PEDDP(Methadone Metabolites) EDDP Disopyramide Methadone EMDP Nortriptyline Nortriptyline Amitriptyline	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 Negative at 100,000 25 90 500 3,000 3,000 300 2500 >100000 >100000 50,000 >100,000 500	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected Not detected 100% 17% 167% 20% 167% 167% 20% 167% 167% 167% 167% 167% 167% 167% 167
Methadone Doxylamine EDDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D,L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine 1-amphetamine 1-amphetamine 1-methamphetamine 1-methamphetamine D-DP(Methadone Metabolites) EDDP Disopyramide Methadone EMDP Nortriptyline Nortriptyline	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 25 90 500 3,000 3,000 300 2500 >100000 >100000 300 50,000 >100,000 500 1,000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected 100% 100% 17% 167% 20% 100% 100% 100% 100%
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA D.L-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyethyla-amphetamine (MDEA) d-methamphetamine l-amphetamine l-methamphetamine l-methamphetamine PEDDP(Methadone Metabolites) EDDP Disopyramide Methadone EMDP Nortriptyline Nortriptyline Amitriptyline	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 25 90 500 3,000 300 2500 >100000 >100000 >100,000 50,000 1,000 1,500	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected Not detected 100% 60.6% 17%
Methadone Doxylamine EDDP EMDP EMDP LAAM HCI Alpha Methadol PHENCYCLIDINE Phencyclidine 4-Hydroxy Phencyclidine MDMA DL-3,4-Methylenedioxymethamphetamine (MDMA) 3,4-Methylenedioxyamphetamine HCI (MDA) 3,4-Methylenedioxyamphetamine (MDEA) d-methamphetamine d-amphetamine l-methamphetamine l-methamphetamine PEDDP(Methadone Metabolites) EDDP Disopyramide Methadone EMDP Nortriptyline Nortriptyline Nortriptyline Clomipramine	5,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Negative at 100,000 Segative at 100,000 Negative at 100,000 25 90 500 3,000 300 2500 >100000 >100000 >100,000 50,000 1,000 1,500 50,000 1,500 50,000	6% Not Detected Not Detected Not Detected Not Detected 100% 28% 100% 17% 167% 20% Not detected Not detected Not detected Not detected 100% 17% 167% 20% 167% 17% 167% 167% 167% 167% 17% 167% 18% 18% 19% 19% 19% 100% 100% 100% 100% 100% 1

10,000	10%
100,000	1%
10,000	10%
50,000	2%
2,500	40%
50,000	2%
5,000	20%
50,000	2%
	100,000 10,000 50,000 2,500 50,000 5,000

PRECISION

This study was 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	-	Lot1		Lot2		Lot3	
	(ng/mL)	n		+		+		+
	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
Methamphetamine	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
	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
Benzovlecogonine	300	50	20	30	20	30	20	30
Benzoyiecogonine	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
	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
						_		_
1 40 577 0 0 0007	37.5	50	50	0	50	0	50	0
1-nor-∆9-THC-9-COOH	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
	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
Oxazepam	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
	0	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	1000	50	50	0	50	0	50	0
14 11 (077	1500	50	50	0	50	0	50	0
Morphine (OPI,	2000	50	22	28	22	28	22	28
MOP2000)	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
	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
Amphetamine	1000	50	20	30	20	30	20	30
Ampuetamine								
	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

Drugs	Concentration		Lot1		Lot2		Lot3	
2.460	(ng/mL)	n	-	+	-	+		+
	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
	150 175	50 50	0	50 50	0	50 50	0	50 50
	200	50	0	50	0	50	0	50
	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
Methadone	300 375	50 50	28	22 50	24	26 50	27	23 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
	0	50	50	0	50	0	50	0
	125	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
MDMA (Footoore)	375 500	50	50 24	0	50 24	0	50	0
MDMA(Ecstasy)	500 625	50 50	0	26 50	0	26 50	24	26 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
	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150 225	50 50	50 50	0	50 50	0	50 50	0
Secobarbital	300	50	23	27	21	29	23	27
Second blan	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
	0	50	50	0	50	0	50	0
	2.5 5	50 50	50 50	0	50 50	0	50 50	0
	7.5	50	50	0	50	0	50	0
Buprenorphine	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
	6	50 50	50 50	0	50 50	0	50 50	0
	12.5	50	50	0	50	0	50	0
	19	50	50	0	50	0	50	0
Phencyclidine	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
	50 50	50 50	0	50 50	0	50 50	0	50 50
	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
EDDP	300	50	21	29	26	24	22	28
	375	50	0	50	0	50	0	50
	450 525	50 50	0	50 50	0	50 50	0	50 50
	600	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
Nortriptyline	1,000	50	22	28	26	24	18	32
	1,250	50 50	0	50 50	0	50 50	0	50 50
	1,500 1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
	_,500							

Effect of Urinary Specific Gravity

Urinary specific gravity is the density of the urine. A test was conducted to see if different density of urine could affect the test results. Fifteen (15) urine samples of different urine density were used. The Healgen® Multi-Drug Urine Test Dip Card was tested twice using drug-free urine and spiked urine samples. The results showed that varying urine density did not affect the test results.

Effect of Urinary pH

When someone describes something as being acidic or basic they are referring to its pH. A study was conducted to see if different pHs could change test results. In this study, the pH of a sample of negative urine was changed. It was then measured in 1pH unit increments between a basic and acidic pH. In addition, it was spiked with the target drug at both a negative and postive level. The spiked, pH-adjusted urine was tested with the Test Dip Card. The results show that varying ranges of pH do not change the test results.

Cross-Reactivity

A study was done to understand how certain medications used to treat medical conditions would interact with the test kit. A test kit with drug free urine was used as a control. Over 100 commonly used medications were found to have no influence on the test kit's ability to detect the specified drugs. The following table is a complete list of drugs that did not interact with the test kit.

Non Cross-Reacting Compounds

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

av User Study

A study was done at three sites with 320 untrained lay users to see how well they could read prepared urine samples. Samples were prepared at seven different amounts of drug and read by the lay users. Results were as follows:

		Number	Lay pe	erson results	The percentage
Drugs	% of Cutoff	of	No. of	No. of	agreement
		samples	Positive	Negative	(%)
	-100% Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
Methamphetamine	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
Cocaine	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20 20	100%
	-75% Cutoff -50% Cutoff	170	0	170	100% 100%
Cannabinoids	-25% Cutoff	20	2	18	90%
Califiabiliolus	+25% Cutoff	20	19	1	95%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
Morphine	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
Oxazepam	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20	100%
	-75% Cutoff			20	100%
Ammhatanina	-50% Cutoff -25% Cutoff	170 20	2	170 18	100% 90%
Amphetamine	+25% Cutoff	20	19	1	95%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
Oxycodone	-25% Cutoff	20	1	19	95%
•	+25% Cutoff	20	19	1	95%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
Methadone	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
Canalas de les 1	-50% Cutoff	170	0	170	100%
Secobarbital	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	0	95%
	+50% Cutoff	50 20	50 20	0	100% 100%
	+75% Cutoff -100% Cutoff	20	20 0	20	100%
Buprenorphine	-75%Cutoff	20	0	20	100%
Duprenorphine	-50% Cutoff	170	0	170	100%
	50% Cutoff	170		170	10070

	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
Phencyclidine	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100%Cutoff	20	0	20	100%
	-75% Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
MDMA	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100% Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
EDDD (Male de	-50% Cutoff	170	0	170	100%
EDDP (Methadone Metabolites)	-25% Cutoff	20	1	19	95%
Metabonies)	+25% Cutoff	20	19	1	95%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%
	-100%Cutoff	20	0	20	100%
	-75% Cutoff	20	0	20	100%
	-50% Cutoff	170	0	170	100%
Nortriptyline	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	50	50	0	100%
	+75% Cutoff	20	20	0	100%

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- 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 1-800-729-6686

Substance Abuse and Mental Health Center/HHS SAMHSA <u>www.samhsa.gov</u>

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



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Web: www.Healgen.com

Manufacturer