

Healstone Accurate™

Drug of Abuse Urine Test Cup Rx

Package insert for testing of any combination of the following drugs: Oxazepam, Nortriptyline, Secobarbital, Methamphetamine, Cocaine, Marijuana, Amphetamine, Propoxyphene, Buprenorphine, Oxycodone, Morphine, Phencyclidine, Methadone, Methylenedioxy-methamphetamine and EDDP.

INTENDED USE

The Healstone Accurate™ Drug of Abuse Urine Test Cup Rx is a rapid qualitative immunoassay. The device provides preliminary results for the detection of potential abuse of one or more drugs. This is not a screening device to monitor prescription medication.

CODE	SUBSTANCE	CUT-OFF (ng/mL)
AMP	Amphetamine	1000 or 500
BUP	Buprenorphine	10
BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Cocaine	300 or 150
EDDP	(2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine)	300
MET/mAMP	Methamphetamine	1000 or 500
MDMA	3,4-methylenedioxy-methamphetamine	500
MOP	Morphine	2000 or 300
MTD	Methadone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	Marijuana	50

This drug test cup may contain any combination of the drug tests listed in the table above.

This drug tests cup provides only a preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. Gas chromatography/mass spectrometry (GC/MS) is the preferred method confirmation test. It is intended for prescription use. For in vitro diagnostic use only.

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 Cup is stable through the expiration date printed on the sealed pouch. The Test Cup must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SAMPLE COLLECTION AND PREPARATION

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

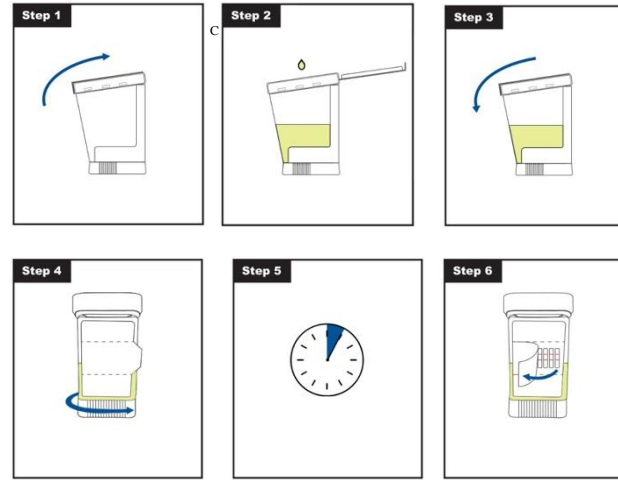
- Test Cup (25 Cups/Box)
- Materials also included:
1. One Package insert per box
 2. One security label per cup
 3. One bag of desiccant per cup

DIRECTIONS FOR USE

Allow the test panel, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. Collect specimen in the cup
3. Secure cap tightly by pressing down on the pull tab until an audible click is heard.
4. Please turn the bottom part of the cup counterclockwise to the closed position.

5. Put the cup on the flat surface and start timer.
6. Peel label to read results. The results should be read at 5 minutes. The drug test results remain stable for up to thirty minutes. See the illustration below.



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.

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..

COD E	NEGATIVE	PRESUMPTIVE POSITIVE	CODE	NEGATIVE	PRESUMPTIVE POSITIVE
BZO			BUP		

BAR			MOP		
COC			MTD		
AMP			EDDP		
TCA			OXY		
MET			PCP		
THC			MDMA		
PPX			INVALID RESULT	Control line (C) does not appear after 5 minutes	

What Is A False Positive Test?

The definition of a false positive test would be an instance where the Healstone Accurate™ Drug of Abuse Urine Test Cup Rx 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 Healstone Accurate™ Drug of Abuse Urine Test Cup Rx. If the sample is diluted, or the sample is contaminated that may cause a false negative result.

LIMITATIONS

1. The Healstone Accurate™ Drug of Abuse Urine Test Cup Rx provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. LC/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. What are drug street names?

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 contact info 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. You should follow federal, state and local guidelines for testing quality control materials.

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

1520 (eighty of each drug) clinical urine specimens were analyzed by LC-MS and by the **Healstone Accurate™ Drug of Abuse Urine Test Cup Rx**. 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:

Oxazepam(BZO)

Urines Sample	Results		BZO300		The Agreement Rate
	+	-	+	-	
Operator A	Above 300ng/mL (+)	40	0	100.0%	97.5%
	Lower 300ng/mL (-)	2	38	95.0%	
	Accuracy				
Operator B	Above 300ng/mL (+)	40	0	100.0%	97.5%
	Lower 300ng/mL (-)	2	38	95.0%	
	Accuracy				
Operator C	Above 300ng/mL (+)	40	0	100.0%	

Lower 300ng/mL (-)	2	38	95.0%
Accuracy	97.5%		

Nortriptyline (TCA)

Urines Sample	Results		TCA1000		The Agreement Rate
	+	-	+	-	
Operator A	Above 1000ng/mL (+)	36	4	90.0%	91.3%
	Lower 1000ng/mL (-)	3	37	92.5%	
	Accuracy				
Operator B	Above 1000ng/mL (+)	38	2	95.0%	93.8%
	Lower 1000ng/mL (-)	3	37	92.5%	
	Accuracy				
Operator C	Above 1000ng/mL (+)	38	2	95.0%	96.3%
	Lower 1000ng/mL (-)	1	39	97.5%	
	Accuracy				

Secobarbital(BAR)

Urines Sample	Results		BAR300		The Agreement Rate
	+	-	+	-	
Operator A	Above 300ng/mL (+)	39	1	97.5%	96.3%
	Lower 300ng/mL (-)	2	38	95.0%	
	Accuracy				
Operator B	Above 300ng/mL (+)	36	4	90.0%	92.5%
	Lower 300ng/mL (-)	2	38	95.0%	
	Accuracy				
Operator C	Above 300ng/mL (+)	37	3	92.5%	96.3%
	Lower 300ng/mL (-)	0	40	100.0%	
	Accuracy				

Methamphetamine(MET)

Urines Sample	Results		MET1000		The Agreement Rate
	+	-	+	-	
Operator A	Above 1000ng/mL (+)	39	1	97.5%	95.0%
	Lower 1000ng/mL (-)	3	37	92.5%	
	Accuracy				
Operator B	Above 1000ng/mL (+)	38	2	95.0%	95.0%
	Lower 1000ng/mL (-)	2	38	95.0%	
	Accuracy				
Operator C	Above 1000ng/mL (+)	38	2	95.0%	95.0%
	Lower 1000ng/mL (-)	2	38	95.0%	
	Accuracy				

Methamphetamine(MET500)

Urines Sample	Results		MET500		The Agreement Rate
	+	-	+	-	
Operator A	Above 500ng/mL (+)	38	2	95.0%	95.0%
	Lower 500ng/mL (-)	2	38	95.0%	
	Accuracy				
Operator B	Above 500ng/mL (+)	37	3	92.5%	95.0%
	Lower 500ng/mL (-)	1	39	97.5%	
	Accuracy				
Operator C	Above 500ng/mL (+)	36	4	90.0%	95.0%
	Lower 500ng/mL (-)	0	40	100.0%	
	Accuracy				

Cocaine (COC)

Urines Sample	Results		COC300		The Agreement Rate
	+	-	+	-	
Operator A	Above 300ng/mL (+)	39	1	97.5%	96.3%
	Lower 300ng/mL (-)	2	38	95.0%	
	Accuracy				
Operator B	Above 300ng/mL (+)	39	1	97.5%	95.0%
	Lower 300ng/mL (-)	3	37	92.5%	
	Accuracy				
Operator C	Above 300ng/mL (+)	38	2	95.0%	95.0%
	Lower 300ng/mL (-)	2	38	95.0%	
	Accuracy				

Cocaine (COC150)

Urines Sample	Results		COC150		The Agreement Rate
	+	-	+	-	
Operator A	Above 150ng/mL (+)	39	1	97.5%	92.5%
	Lower 150ng/mL (-)	3	37	92.5%	
	Accuracy				

Operator B	Above 150ng/mL (+)	39	1	97.5%
	Lower 150ng/mL (-)	2	38	95.0%
	Accuracy	96.3%		
Operator C	Above 150ng/mL (+)	40	0	100.0%
	Lower 150ng/mL (-)	1	39	97.5%
	Accuracy	98.8%		

Marijuana(THC)

Urines Sample	Results		THC50		The Agreement Rate
	+	-	+	-	
Operator A	Above 50ng/mL (+)	37	3	92.5%	95.0%
	Lower 50ng/mL (-)	1	39	97.5%	
	Accuracy				
Operator B	Above 50ng/mL (+)	36	4	90.0%	95.0%
	Lower 50ng/mL (-)	0	40	100.0%	
	Accuracy				
Operator C	Above 50ng/mL (+)	37	3	92.5%	95.0%
	Lower 50ng/mL (-)	1	39	97.5%	
	Accuracy				

Amphetamine (AMP)

Urines Sample	Results		AMP1000		The Agreement Rate
	+	-	+	-	
Operator A	Above 1000ng/mL (+)	36	4	90.0%	93.8%
	Lower 1000ng/mL (-)	1	39	97.5%	
	Accuracy				
Operator B	Above 1000ng/mL (+)	37	3	92.5%	91.3%
	Lower 1000ng/mL (-)	4	36	90.0%	
	Accuracy				
Operator C	Above 1000ng/mL (+)	38	2	95.0%	95.0%
	Lower 1000ng/mL (-)	2	38	95.0%	
	Accuracy				

Amphetamine (AMP500)

Urines Sample	Results		AMP500		The Agreement Rate
	+	-	+	-	
Operator A	Above 500ng/mL (+)	38	2	95.0%	95.0%
	Lower 500ng/mL (-)	2	38	95.0%	
	Accuracy				
Operator B	Above 500ng/mL (+)	37	3	92.5%	95.0%
	Lower 500ng/mL (-)	1	39	97.5%	
	Accuracy				
Operator C	Above 500ng/mL (+)	38	2	95.0%	96.3%
	Lower 500ng/mL (-)	1	39	97.5%	
	Accuracy				

Propoxyphene(PPX)

Urines Sample	Results		PPX300		The Agreement Rate
	+	-	+	-	
Operator A	Above 300ng/mL (+)	39	1	97.5%	96.3%
	Lower 300ng/mL (-)	2	38	95.0%	
	Accuracy				
Operator B	Above 300ng/mL (+)	37	3	92.5%	96.3%
	Lower 300ng/mL (-)	0	40	100.0%	
	Accuracy				
Operator C	Above 300ng/mL (+)	39	1	97.5%	96.3%
	Lower 300ng/mL (-)	2	38	95.0%	
	Accuracy				

Buprenorphine(BUP)

Urines Sample	Results		BUP10		The Agreement Rate
	+	-	+	-	
Operator A	Above 10ng/mL (+)	37	3	92.5%	96.3%
	Lower 10ng/mL (-)	0	40	100.0%	
	Accuracy				
Operator B	Above 10ng/mL (+)	37	3	92.5%	95.0%
	Lower 10ng/mL (-)	1	39	97.5%	
	Accuracy				
Operator C	Above 10ng/mL (+)	40	0	100.0%	96.3%
	Lower 10ng/mL (-)	3	37	92.5%	
	Accuracy				

Oxycodone(OXY)

Urines Sample	Results	OXY100		The Agreement Rate
		+	-	
Operator A	Above 100ng/mL (+)	37	3	92.5%
	Lower 100ng/mL (-)	0	40	100.0%
	Accuracy	96.3%		
Operator B	Above 100ng/mL (+)	39	1	97.5%
	Lower 100ng/mL (-)	1	39	97.5%
	Accuracy	97.5%		
Operator C	Above 100ng/mL (+)	37	3	92.5%
	Lower 100ng/mL (-)	1	39	97.5%
	Accuracy	95.0%		

Morphine (MOP)

Urines Sample	Results	MOP300		The Agreement Rate
		+	-	
Operator A	Above 300ng/mL (+)	38	2	95.0%
	Lower 300ng/mL (-)	1	39	97.5%
	Accuracy	96.3%		
Operator B	Above 300ng/mL (+)	39	1	97.5%
	Lower 300ng/mL (-)	0	40	100.0%
	Accuracy	98.8%		
Operator C	Above 300ng/mL (+)	39	1	97.5%
	Lower 300ng/mL (-)	0	40	100.0%
	Accuracy	98.8%		

Morphine (MOP2000)

Urines Sample	Results	MOP2000		The Agreement Rate
		+	-	
Operator A	Above 2000ng/mL (+)	36	4	90.0%
	Lower 2000ng/mL (-)	0	40	100.0%
	Accuracy	95.0%		
Operator B	Above 2000ng/mL (+)	37	3	92.5%
	Lower 2000ng/mL (-)	0	40	100.0%
	Accuracy	96.3%		
Operator C	Above 2000ng/mL (+)	36	4	90.0%
	Lower 2000ng/mL (-)	1	39	97.5%
	Accuracy	93.8%		

Phencyclidine(PCP)

Urines Sample	Results	PCP25		The Agreement Rate
		+	-	
Operator A	Above 25ng/mL (+)	39	1	97.5%
	Lower 25ng/mL (-)	1	39	97.5%
	Accuracy	97.5%		
Operator B	Above 25ng/mL (+)	39	1	97.5%
	Lower 25ng/mL (-)	2	38	95.0%
	Accuracy	96.3%		
Operator C	Above 25ng/mL (+)	39	1	97.5%
	Lower 25ng/mL (-)	0	40	100.0%
	Accuracy	98.8%		

Methadone(MTD)

Urines Sample	Results	MTD300		The Agreement Rate
		+	-	
Operator A	Above 300ng/mL (+)	39	1	97.5%
	Lower 300ng/mL (-)	1	39	97.5%
	Accuracy	97.5%		
Operator B	Above 300ng/mL (+)	37	3	92.5%
	Lower 300ng/mL (-)	0	40	100.0%
	Accuracy	96.3%		
Operator C	Above 300ng/mL (+)	39	1	97.5%
	Lower 300ng/mL (-)	1	39	97.5%
	Accuracy	97.5%		

Methylenedioxy-methamphetamine (MDMA)

Urines Sample	Results	MDMA500		The Agreement Rate
		+	-	
Operator A	Above 500ng/mL (+)	39	1	97.5%
	Lower 500ng/mL (-)	3	37	92.5%
	Accuracy	95.0%		
Operator B	Above 500ng/mL (+)	37	3	92.5%
	Lower 500ng/mL (-)	3	37	92.5%
	Accuracy	92.5%		
Operator C	Above 500ng/mL (+)	37	3	92.5%

	Lower 500ng/mL (-)	1	39	97.5%

EDDP

Urines Sample	Results	EDDP300		The Agreement Rate
		+	-	
Operator A	Above 300ng/mL (+)	38	2	95.0%
	Lower 300ng/mL (-)	3	37	92.5%
	Accuracy	93.8%		
Operator B	Above 300ng/mL (+)	39	1	97.5%
	Lower 300ng/mL (-)	1	39	97.5%
	Accuracy	97.5%		
Operator C	Above 300ng/mL (+)	39	1	97.5%
	Lower 300ng/mL (-)	1	39	97.5%
	Accuracy	97.5%		

ANALYTICAL SPECIFICITY

The following table lists compounds that are likely to cross-react in urine samples and are positively detected by the **Healstone Accurate™ Drug of Abuse Urine Test Cup Rx**.

Drug	Concentration (ng/ml)	% Cross-Reactivity
Oxazepam (BZO)		
a-Hydroxyalprazolam	1,260	23.8%
Alprazolam	200	150%
Bromazepam	1,560	19.2%
Chlordiazepoxide	1,560	19.2%
Clobazam	100	300%
Clonazepam	2,500	12%
Clorazepate Dipotassium	200	150%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	2,500	12%
Flunitrazepam	400	75%
D,L-Lorazepam	1,560	19.2%
Midazolam	12,500	2.4%
Nitrazepam	100	300%
Norchlordiazepoxide	200	150%
Nordiazepam	400	75%
Oxazepam	300	100%
R,S-Lorazepam glucuronide	160	187.5%
Temazepam	100	300%
Triazolam	2,500	12%
Demoxepam	2,000	15%
Flurazepam	500	60%
Delorazepam	>100,000	--
Nortriptyline(TCA)		
Amitriptyline	1,500	66.7%
Chlorpheniramine	50,000	2%
Clomipramine	10,000	10%
Cyclobenzaprine Hydrochloride	5,000	20%
Desipramine	1,000	100%
Doxepine	2,000	50%
Duloxetine	10,000	10%
Imipramine	1,000	100%
Norclomipramine	12,500	8%
Nordoxepine	1,000	100%
Nortriptyline	1,000	100%
Promazine	50,000	2%
Trimipramine	10,000	10%
Maprotiline	>100,000	--
Promethazine hydrochloride	>100,000	--
Secobarbital (BAR)		
Alphenal	150	200%
Amobarbital	300	100%
Aprobarbital	250	120%
Butobarbital	2,500	12%
Butethal	100	300%
Cyclopentobarbital	600	50%
Pentobarbital	250	120%
Phenobarbital	250	120%
Secobarbital	300	100%
Butalbital	2,500	12%

Methamphetamine (MET)		
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000	5%
(+/-)3,4-Methylenedioxyamphetamine (MDMA)	2,500	40%
D-Methamphetamine	1,000	100%
L-Methamphetamine	25,000	4%
Fenfluramine	50,000	2%
p-Hydroxymethamphetamine	10,000	10%
D,L-Methamphetamine	1,000	100%
β-Phenylethylamine	50,000	2%
Mephetermine	50,000	2%
L-Amphetamine	75,000	1.33%
D-Amphetamine	>100000	--
D,L-Amphetamine	>100000	--
Chloroquine	>100000	--
Ephedrine HCl	>100000	--
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000	--
Trimethobenzamide	>100000	--
L-Phenylephrine	>100000	--
(1R,2S)-(-)-Ephedrine	>100000	--
Methamphetamine (MET500)		
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	10,000	5%
(±)-MDMA	1,250	40%
D-Methamphetamine	500	100%
L-Methamphetamine	12,500	4%
Fenfluramine	25,000	2%
p-Hydroxymethamphetamine	5,000	10%
D,L-Methamphetamine	500	100%
β-Phenylethylamine	25,000	2%
Mephetermine	25,000	2%
L-Amphetamine	40,000	1.25%
Ephedrine HCl	100,000	0.5%
(1R,2S)-(-)-Ephedrine	100,000	0.5%
D-Amphetamine	>100,000	--
Chloroquine	>100,000	--
(+/-)3,4-Methylenedioxyamphetamine(MDA)	>100,000	--
L-Phenylephrine	>100,000	--
Cocaine (COC)		
Benzoylcocaine	300	100%
Cocacethylene	300	100%
Cocaine HCl	300	100%
Ecgonine	50,000	0.6%
Norcocaine	100,000	0.3%
Ecgonine methyl ester	>100,000	--
Cocaine (COC150)		
Benzoylcocaine	150	100%
Cocacethylene	150	100%
Cocaine HCl	150	100%
Ecgonine	25,000	0.6%
Norcocaine	50,000	0.3%
Ecgonine methyl Ester	>100000	--
Marijuana (THC)		
11-nor-Δ8-THC -9-COOH	30	166.7%
(-)-11-nor-9-carboxy-Δ9-THC	50	100%
(±)-11-nor-9-Carboxy-Δ9-THC	50	100%
11-nor-Δ9-THC -carboxy glucuronide	100	50%
11-hydroxy-Δ9-Tetrahydrocannabinol	5,000	1%
Δ8- Tetrahydrocannabinol	1,300	3.8%
Δ9- Tetrahydrocannabinol	5,000	1%
Cannabinol	20,000	0.25%
Cannabidiol	>100,000	--
Amphetamine (AMP)		
Hydroxyamphetamine	8000	12.5%
(+/-)-Methylenedioxyamphetamine(MDA)	400	250%
D,L-Amphetamine	1,000	100%
D-Amphetamine	1,000	100%
Diethylstilbestrol	5,000	20%
L-Amphetamine	50,000	2%

p-Hydroxyamphetamine	100,000	1%
Phentermine	8,000	12.5%
β-Phenylethylamine	100,000	1%
Tyramine	100,000	1%
p-Hydroxynorephedrine	100,000	1%
D,L-Norephedrine	100,000	1%
D-Methamphetamine	>100000	--
L-Methamphetamine	>100000	--
Ephedrine HCl	>100000	--
(+/-)3,4-Methylenedioxyamphetamine (MDMA)	>100000	--
Phenylpropanolamine	>100000	--
Benzphetamine	>100000	--
L-Ephedrine	>100,000	--
L-Epinephrine	>100,000	--
D,L-Epinephrine	>100,000	--
Amphetamine (AMP500)		
Hydroxyamphetamine	4,000	12.5%
(+/-)-Methylenedioxyamphetamine(MDA)	200	250%
D,L-Amphetamine	500	100%
D-Amphetamine	500	100%
Diethylstilbestrol	2,500	20%
L-Amphetamine	25,000	2%
p-Hydroxyamphetamine	50,000	1%
Phentermine	4,000	12.5%
β-Phenylethylamine	50,000	1%
Tyramine	50,000	1%
p-Hydroxynorephedrine	50,000	1%
D,L-Norephedrine	50,000	1%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	100,000	0.5%
D-Methamphetamine	>100,000	--
L-Methamphetamine	>100,000	--
(+/-)3,4-Methylenedioxyamphetamine (MDMA)	>100,000	--
Ephedrine HCl	>100,000	--
Phenylpropanolamine	>100,000	--
Benzphetamine	>100,000	--
L-Ephedrine	>100,000	--
L-Epinephrine	>100,000	--
D,L-Epinephrine	>100,000	--
Propoxyphene (PPX)		
Norpropoxyphene	300	100%
Propoxyphene	300	100%
Buprenorphine (BUP)		
Buprenorphine	10	100%
Buprenorphine-3-D-Glucuronide	160	6.25%
Norbuprenorphine	10	100%
Norbuprenorphine-3-D-Glucuronide	200	5%
Morphine	>100,000	--
Oxymorphone	>100,000	--
Hydromorphone	>100,000	--
Oxycodone (OXY)		
Ethyl Oxycodone	75,000	0.13%
Hydrocodone	5,000	2%
Hydromorphone	25,000	0.4%
Levorphanol tartrate	25,000	0.4%
Naloxone hydrochloride	10,000	1%
Naltrexone hydrochloride	50,000	0.2%
Oxycodone	100	100%
Oxymorphone	200	50%
Oxymorphone-D3	200	50%
Dihydrocodeine	>100,000	--
Codeine	>100,000	--
Morphine	>100,000	--
Acetylmorphine	>100,000	--
Buprenorphine	>100,000	--
Ethylmorphine	>100,000	--
Thebaine	>100,000	--

Morphine (MOP)		
6-acetylmorphine	400	75%
Codeine	300	100%
Dihydrocodeine	1,000	30%
EthylMorphine	100	300%
Heroin	600	50%
6-Monoacetylmorphine	150	200%
Hydrocodone	10,000	3%
Hydromorphone	500	60%
Levorphanol tartrate	10,000	3%
Morphine	300	100%
Nalorphine HCl	50,000	0.6%
Thebaine	6,240	4.8%
s-Monoacetylmorphine	300	100%
Morphine-3-β-d-glucuronide	1,000	30%
Normorphine	>100,000	--
Oxycodone	>100000	--
Oxymorphone	>100000	--
Norcodeine	>100000	--
Procaine	>100000	--
Morphine (MOP2000)		
6-acetylmorphine	2,500	80%
Codeine	1,000	200%
Dihydrocodeine	1,500	133.3%
EthylMorphine	2,500	80%
Heroin	5,000	40%
6-Monoacetylmorphine	1,500	133%
Hydrocodone	5,000	40%
Hydromorphone	25,000	8%
Levorphanol tartrate	10,000	20%
Morphine	2,000	100%
Nalorphine HCl	5,000	40%
Norcodeine	4,000	50%
Normorphine	5,000	40%
Oxymorphone	75,000	2.7%
s-Monoacetylmorphine	2,000	100%
Thebaine	13,000	15.4%
Morphine 3-β-D-glucuronide	2,000	100%
Oxycodone	>100,000	--
Procaine	>100,000	--
Phencyclidine (PCP)		
PCP (Phencyclidine)	25	100%
4-Hydroxyphencyclidine	12,500	0.2%
Methadone (MTD)		
(±)-Methadone	300	100%
EDDP	>100,000	--
EMDP	>100,000	--
LAAM	>100,000	--
Alpha Methadol	>100,000	--
Doxylamine	>100,000	--
Methylenedioxy-methamphetamine (MDMA)		
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	300	166.7%
(+/-)-Methylenedioxyamphetamine(MDA)	3,000	16.7%
(±)-MDMA	500	100%
L-Methamphetamine	50,000	1%
D-Methamphetamine	>100,000	--
D-Amphetamine	>100,000	--
L-Amphetamine	>100,000	--
EDDP		
EDDP perchlorate	300	100%
Methadone	>100,000	--
EMDP	>100,000	--
Doxylamine	>100,000	--
Disopyramide	>100,000	--
LAAM (Levo-alpha-acetylmethadol) HCl	>100,000	--
Alpha Methadol	>100,000	--

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	
			-	+	-	+	-	+
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
	225	50	48	2	48	2	49	1
	300	50	24	26	23	27	22	28
	375	50	1	49	1	49	2	48
	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
Nortriptyline	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	23	27	22	28	22	28
	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
Secobarbital	150	50	50	0	50	0	50	0
	225	50	49	1	48	2	49	1
	300	50	24	26	25	25	21	29
	375	50	1	49	2	48	1	49
	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
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
Methamphetamine	750	50	50	0	50	0	50	0
	1,000	50	24	26	23	27	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
	125	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	375	50	49	1	49	1	48	2
Methamphetamine 500	500	50	26	24	26	24	25	25
	625	50	1	49	2	48	1	49
	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	50	50	0	50	0	50	0
	225	50	49	1	48	2	49	1
	300	50	22	28	22	28	24	26
Benzoylcegonine	375	50	1	49	1	49	1	49
	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
	37.5	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	112.5	50	49	1	48	2	49	1
	150	50	22	28	21	29	23	27
	187.5	50	2	48	1	49	1	49
Benzoylcegonine150	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
	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	49	1	48	2	49	1
	50	50	23	27	22	28	23	27
	62.5	50	2	48	2	48	2	48
	75	50	0	50	0	50	0	50

Drugs	Concentration (ng/mL)	n	Lot1		Lot2		Lot3	
			-	+	-	+	-	+
			87.5	50	0	50	0	50
100	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	
1,000	50	26	24	26	24	27	23	
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	
125	50	50	0	50	0	50	0	
250	50	50	0	50	0	50	0	
375	50	48	2	48	2	49	1	
500	50	24	26	26	24	25	25	
625	50	2	48	1	49	2	48	
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	50	50	0	50	0	50	0	
225	50	48	2	49	1	48	2	
300	50	26	24	26	24	25	25	
375	50	1	49	0	50	2	48	
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	50	50	0	50	0	50	0	
5	50	50	0	50	0	50	0	
7.5	50	49	1	48	2	47	3	
10	50	25	25	26	24	27	23	
12.5	50	2	48	2	48	1	49	
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	
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	49	1	49	1	48	2	
100	50	25	25	24	26	27	23	
125	50	2	48	1	49	2	48	
150	50	0	50	0	50	0	50	
175	50	0	50	0	50	0	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	49	1	48	2	49	1	
300	50	23	27	24	26	23	27	
375	50	2	48	2	48	1	49	
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	
1500	50	50	0	50	0	50	0	
2000	50	24	26	23	27	24	26	
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	
6	50	50	0	50	0	50	0	
12.5	50	50	0	50	0	50	0	
19	50	48	2	49	1	48	2	
25	50	22	28	22	28	23	27	
31	50	1	49	2	48	2	48	
37.5	50	0	50	0	50	0	50	

Drugs	Concentration (ng/mL)	n	Lot1		Lot2		Lot3	
			-	+	-	+	-	+
			44	50	0	50	0	50
50	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	49	1	48	2	48	2	
300	50	23	27	23	27	24	26	
375	50	1	49	2	48	2	48	
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	
375	50	49	1	48	2	48	2	
500	50	22	28	21	29	23	27	
625	50	2	48	2	48	1	49	
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	50	50	0	50	0	50	0	
225	50	49	1	50	0	49	1	
300	50	23	27	21	29	22	28	
375	50	1	49	2	48	1	49	
450	50	0	50	0	50	0	50	
525	50	0	50	0	50	0	50	
600	50	0	50	0	50	0	50	

Effect of Urinary Specific Gravity

Urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **Healstone Accurate™ Drug of Abuse Urine Test Cup Rx** 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 50% below and 50% above Cutoff levels. The spiked, pH-adjusted urine was tested with the **Healstone Accurate™ Drug of Abuse Urine Test Cup Rx**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Interference

A study was conducted to determine the potential interference of the test with compounds in either drug-free urine or Oxazepam, Nortriptyline, Secobarbital, Methamphetamine, Cocaine, Marijuana, Amphetamine, Propoxyphene, Buprenorphine, Oxycodone, Morphine, Phencyclidine, Methadone, Methylenedioxy-methamphetamine and EDDP positive urine. The following compounds show no interference when tested with the **Healstone Accurate™ Drug of Abuse Urine Test Cup Rx** at a concentration of 100 µg/mL (Albumin at 100mg/dL and Ethanol at 1%).

Non Interference Compounds

(-) Cotinine	Diphenhydramine HCl	Noscapine
(±)4-Methylephedrine-D3	D.L-Propranolol	O-Hydroxyhippuric acid
3-Hydroxytyramine	D.L-Tyrosine	Olanzapine
Acetaminophen	Doxylamine	Oxalic acid
Acetophenetidin	D-Pseudoephedrine	Oxolinic acid
Acetylsalicylic acid	Egocaine methyl ester	Oxymetazoline
Albumin(100mg/dL)	EMDP	Papaverine
Alpha Methadol	Erythromycin	Penicillin-G
Aminopyrine	Ethanol(1%)	Perphenazine
Amoxicillin	Fenoprofen	Phenacetin
Ampicillin	Furosemide	Phenelzine
Apomorphine	Gabapentin	Phenethylamine
Ascorbic acid	Gatifloxacin	Phenylpropanolamine
Aspartame	Gentisic acid	Prednisone
Aspirin	Glucose	Procaine
Atropine	Hemoglobin	Promethazine
Azithromycin	Hydralazine	Quetiapine
Benzilic acid	Hydrochlorothiazide	Quinine
Benzoic acid	Hydrocortisone	Ranitidine
Benzphetamine	Ibuprofen	Salicylic acid
Bilirubin	Isoxsuprine	Serotonin
Cannabidiol	Ketamine	Serotonin(5-

Carfentanil	Ketoprofen	Hydroxytyramine)
Chloralhydrate	LAAM HCl	Sertraline
Chloramphenicol	Labetalol	Sulfamethazine
Chloroquine	L-Ephedrine	Sulindac
Chlorothiazide	L-Epinephrine	Telmisartan
chlopromazine	Loperamide	Tetrahydrocortisone 3-(β-Dglucuronide)
Cholesterol	Loratadine	Tetrahydrocortisone, 3-acetate
Clonidine	L-phenylephrine	Tetrahydrozoline
Cortisone	Magnesium	Thiamine
Creatinine	Maprotiline	Thioridazine
D.L-Tryptophan	Meperidine	Triamterene
D.L-Isoproterenol	Meprobamate	Trifluoperazine
D.L-Octopamine	Methoxyphenamine	Trimethoprim
D.L-Epinephrine	N-Acetylprocainamide	Uric acid
Delorazepam	Nalidixic acid	Verapamil
Deoxycorticosterone	Naproxen	Vitamin B2
Desloratadine	Niacinamide	Vitamin C
Dextromethorphan	Nicotine	Zaleplon
Diclofenac	Nifedipine	Zomepirac
Diclofenac sodium	Nordoxepin	β-Estradiol
Diffunisal	Norethidrone	
Digoxin	Norfentanyl	

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



Manufacturer

Healstone Biotech Inc.
650-655 W Kent N.
Vancouver, BC V6P6T7
Canada
1-866-982-3818(9:00 a.m. to 5 p.m. CDT)