	MD-U632	Package Insert
For forensic use only		
	INTENDED USE	

The Drugs of Abuse Integrated Cup (Urine) is a rapid visual immunoassay for the qualitative. presumptive detection of any combination of drugs of abuse in human urine specimens at the cut-off concentrations listed below:

Test	Calibrator	Cut-off (ng/mL
ACE	Acetaminophen	5000
AMP	d-Amphetamine	1000/500/300
BAR	Secobarbital	300/200
BUP	BUP-3-D-Glucuronide	10/5
BZO	Oxazepam	500/300/200/100
COC	Benzoylecgonine	300/200/150/100
COT	(-)-Cotinine	600/300/200/100
EDDP	-Ethylidine-1,5-dimethyl-3,3-diphenylpyrro	300/100
ETG	Ethyl Glucuronide	300
FYL	Fentanyl	20/10
HMO	Hydromorphone	250
K2	JWH-073/JWH-018	50
KET	Ketamine	1,000
LSD	,10-Didehydro-N,N-diethyl-6-methylergoli	50
6-MAM	6-Monoacetylmorphine	10
MDMA	3.4-Methylenediioxy-MET	1000/500
MDVP	Methylenedioxypyrovalerone	500
MET	Methamphetamine	1000/500/300
MOP	Morphine	300/200/100
MPD	Methylphenidate	300
MQL	Methagualone	300
MTD	Methadone	300/200
OPI	Morphine	2000/1000/100
OXY	Oxycodone	300/100
PCP	Phencyclidine	25
PPX	D-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor-∆ 9-THC-9-COOH	200/150/50/25
TRA	Tramadol	300/100
ZOL	Zolpidem Phenyl-4-carboxylic acid	50
7-ACL	7-Aminoclonazepam	300
ALC	Alcohol	0.02%
Adulteration (StripA)	Oxidants/ Specific Gravity / pH	
Adulteration (StripB)	Nitrite / Glutaraldehyde/Creatinine	

The Integrated Split Specimen Cup (Urine) can also come with adulteration strips listed below: Adulteration (StripA) Oxidants / Specific Gravity / PH Nitrite / Glutaraldehyde / Creatinine Adulteration (StripB)

PRINCIPLE

The Drugs of Abuse Integrated Cup (Urine) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will appear in the test line region of the corresponding drug strip. The presence of drug above the cut-off concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, no colored line will form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such asCreatinine. pH. and Specific Gravity and to detect the presence of Glutaraldehyde. Nitrite and Oxidants/Pyridinium Chlorochromate in urine

Creatinine (CRE): Tests for specimen dilution. Creatinine is a waste product of Creatine, and is an amino-acid contained in muscle tissue and found in urine.1 A person may attempt to foil a drug test by drinking excessive amounts of water or diuretics such as herbal teas to flush the system. Creatinine and Specific Gravity are two ways to check for dilution and flushing, which are the most common mechanisms used to circumvent drug testing. Low Creatinine and Specific Gravity levels may indicate diluted urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with human urine.

Nitrite (NIT): Tests for commonly used commercial adulterants. They work by oxidizing the major cannabinoid metabolite THC-COOH.2 Normal urine should contain no trace of Nitrites. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde (GLUT): Tests for the presence of aldehydes. Adulterants can contain Glutaraldehyde and can cause false negative screening results by disrupting the enzyme used in some immunoassay tests. 3Glutaraldehyde is not normally found in urine; therefore, detection of Glutaraldehyde in a urine specimen is generally indicates adulteration.

**pH:** Tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate that the specimen has been altered Specific Gravity (SG): Tests for specimen dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

Oxidants/Pyridinium Chlorochromate (OXI/PCC): Tests for the presence of oxidizing reagents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant. 3Normal human urine should not contain Oxidants or PCC.

## MATERIALS

Materials Provided

Individually packed test cups with integrated drug of abuse test panels, procedure card

# Materials Required but Not provided

Centrifuge

Positive and negative controls

# PRECAUTIONS

· For forensic use only.

Timer

- · Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- · This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- · Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assaved.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

## STORAGE AND STABILITY

- The kit should be stored at 2-30 °C until the expiry date printed on the sealed pouch.
- · The test must remain in the sealed pouch until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

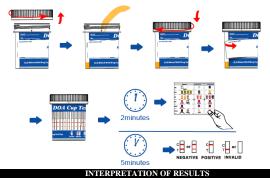
## SPECIMEN COLLECTION AND STORAGE

- The Drugs of Abuse Integrated Cup (Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers,
- · Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- · Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8 °C for up to 2 days. For long term storage, specimens should be kept below -20 °C.
- · Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- · If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

# PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30 °C) before use if stored at refrigerated temperatures. Remove the cup from sealed pouch and use it as soon as possible. Donor dates and initials body label.

- 2. Donor provides a urine specimen in the cup and screws cap on to it. Start timer immediately.
- 3 Operator checks the cap for tightness.
- 4 Remove the peel-off label.
- 5. Check the temperature strip label at 2-4 minutes after specimen collection for the fresh urine specimen. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100  $\oplus$  (32-38 °C).
- 6. Drug test results are indicated by the presence or absence of colored band(s) in the result area of the test strips. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.
- 7 Positive test results must be confirmed by another test method. Send the cup and urine specimen intact to a toxicology laboratory for confirmation.
- 8. For the adulteration compared with the color card, and the results should be read at 2 minutes , do not interpret the result after 5 minutes.



#### (See previous illustration)

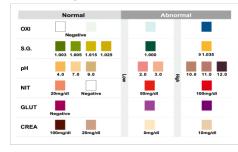
POSITIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T) for the drug in question. A positive result indicates that the drug concentration exceeds the detectable level.

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor. NOTE:

- 1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- 2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

### The Result Of Adulteration Strips:



NOTE:

The Urine Adulteration Test Strips (Urine) are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.

Nitrite: Nitrite is not a normal component of human urine. However, Nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of >20 mg/dL may produce false positive Glutaraldehyde results.

Glutaraldehvde: Glutaraldehvde is not normally found in urine. However, certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results

Specific Gravity: Elevated levels of protein in urine may cause abnormally high Specific Gravity values

Oxidants/PCC: Normal human urine should not contain Oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants/PCC nad

# QUALITY CONTROL

# The Quality Control Of DOA:

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- · External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

#### The Quality Control Of Adulteration Strips:

Control standards are not supplied with this kit. However, it is recommended that positive and negative

Package insert

specimens or controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS OF THE TEST

- The Drugs of Abuse Integrated Cup(Urine) is for forensic use, and should be only used for the qualitative detection of drugs of abuse.
   This assay provides a preliminary analytical test result only. A more specific alternative chemical
- 2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and forensic judgment should be applied to any test result, particularly when preliminary positive results are indicated.
- There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless
  of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to
  testing.
- A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
- 6. A negative result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.

7. This test does not distinguish between drugs of abuse and certain medications.

## The Limitations Of Adulteration Strips:

The Urine Adulteration Test Strips (Urine) are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

1.Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.

2.Nitrite: Nitrite is not a normal component of human urine. However, Nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of >20 mg/dL may produce false positive Glutaraldehyde results.

3.Glutaraldehyde: Glutaraldehyde is not normally found in urine. However, certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.

4.Specific Gravity: Elevated levels of protein in urine may cause abnormally high Specific Gravity values.

5.Oxidants/PCC: Normal human urine should not contain Oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants/PCC pad.

### PERFORMANCE CHARACTERISTICS

## A. Accuracy

The accuracy of the Drugs of Abuse Integrated Cup(Urine) was established by running urine samples against GC/MS.

Specimen	ACE	AMP	AMP500	AMP300	BAR	BUP10	BUP5	BZO
Positive	96.1%	95.8%	95.9%	96.1%	97.8%	100%	100%	95.3%
Negative	100%	100%	100%	100%	98.1%	100%	100%	92.9%
Total	98.1%	98.1%	98.1%	98.1%	98%	100%	100%	93.9%

Specimen	BZO200	BZO100	COC	COC150	COC100	COT600	COT300	COT
Positive	97.4%	95.9%	98.2%	96%	98.2%	96.5%	97.9%	97.7%
Negative	98.2%	98%	98.1%	94%	98.1%	98%	98.1%	97.9%
Total	97.9%	97% 98.2% 95%		95%	98.2% 97.2%		98%	98%

Specimen	EDDP	EDDP100	ETG300	FYL200	FYL100	HMO	K2	KET
Positive	98.6%	95.8%	100%	96.8%	94.4%	95.9%	98.9%	98%
Negative	100%	100%	100%	100%	100%	100%	100%	98.6%
Total	99.1%	98.1%	100%	98.3%	97.2%	98.0%	99%	98.3%

Specimen	LSD	6-MAM	MDMA	MDMA300	MET	MET500	MET300	MOP
Positive	100%	96.8%	98.5%	97.4%	96.8%	96.9%	96.8%	96.8%
Negative	100%	100%	98.2%	100%	100%	100%	100%	97.9%
Total	100%	98.2%	98.3%	98.4%	98.3%	98.3%	98.4%	97.3%

Specimen	MOP200	MOP100	MPD	MQL	MTD	OPI	OPI1000	OXY
Positive	96.1%	96.1%	97.7%	98.4%	96.1%	97.6%	96.5%	98%
Negative	100%	100%	98.4%	98%	100%	98.4%	96%	97%
Total	98.1%	98.1%	98.1%	98.2%	98.1%	98.1%	96.3%	97%

Specimen	OXY100	PCP25	PPX	TCA	THC200	THC150	THC	TRA100
Positive	96.1%	97.8%	97.8%	92.1%	96.1%	98.4%	96.8 %	98.4%
Negative	100%	100%	100%	100%	100%	98.3%	98.3%	100%
Total	98.1%	98.9%	99%	96.8%	98.1%	98.4%	97.5 %	99.1%

Specimen	THC25	ZOL	TRA	BAR200	MDPV500	MTD200
Positive	96.8%	96.3%	96.6%	96.6%	100%	96.1%
Negative	98.3%	98%	98.2%	97%	100%	100%
Total	97.5%	97.1%	97.4%	96.8%	100%	98.1%

Specimen	COT100	OPI100	7-ACL
Positive	99.9%	96.1%	100%
Negative	99.9%	100%	100%
Total	99.9%	98.1%	100%

\*NOTE: BUP was based on LC/MS data instead of GC/MS

# B. Sensitivity

The sensitivity of the Integrated Split Specimen Cup (Urine) was determined by testing GC/MS confirmed controls at negative, -50% cut-off, -25% cut-off, cut-off, +25% cut-off, +50% cut-off and 3 times cut-off concentrations. The results are summarized below:

Drug Conc.	n	A	CE	AN	мР	AM	AMP500		P300	BA	AR	BU	JP	BU	P5	BZO	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	19	31	16	34	14	36	20	30	11	39	25	25	21	29	17	33
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3×Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	BZO200		BZC	0100	CC	COC		2150	COC	2100	HMO		K2		LSD	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	11	39	12	39	11	39	24	26	23	27	25	25	14	36	22	28
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3×Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	6-M	AM	COI	600	COI	[300	CO	TC	ED	DP	EDD	P100	ETC	300	FYL	.200
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	25	25	15	35	17	33	13	37	24	26	25	25	25	25	22	28
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3×Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	FYL	.100	KI	ΞT	MD	MA	MDM	[A300	M	ET	ME	Г500	MET	Г300	M	OP
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	25	25	16	34	25	25	13	37	23	27	10	40	15	35	18	32
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3×Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	MOI	200	MOP	100	MF	D	MQ	L	MT	Ď	OF	Ы	OPI1	000	OX	Y
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0

75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	18	32	20	30	22	28	14	36	6	44	23	27	13	37	19	31
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3×Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

				·		·		·				·				·		·	
Drug Conc.	n	OXY	/100	PO	CP	PF	PX	TC	CA	THO	2200	THC	2150	TH	C50	MTI	D200	OPI	100
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	19	31	9	41	20	30	9	41	17	33	19	31	17	33	10	40	20	30
125%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150%	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3×Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	TH	C25	TF	RA	TRA	A100	TRA	A200	ZO	DL	COI	`100	BAI	R200	MD	PV
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	11	39	15	35	11	39	14	36	16	34	25	25	15	35	16	34
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3×Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

n	7-A	CL
	-	+
50	50	0
50	50	0
50	50	0
50	5	45
50	0	50
50	0	50
50	0	50
	50 50 50 50 50 50 50	-           50         50           50         50           50         50           50         50           50         5           50         0           50         0

## C. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the Integrated Split Specimen Cup (Urine) identified positive results at 5 minutes.

Acetaminophen 5000 related compoun	ds	Dextrorphan tartrate	50
Acetaminophen	5,000	D-Norpropoxyphene	1.1
Acetophenetidine	7,500	EDDP	
Amphetamine 1000 related compound	s	Meperidine	1
d-Amphetamine	1,000	Mephentermine hemisulfate salt	4.
l-Amphetamine	>100,000	Methadone	1
d-methamphetamine	>100,000	D-Methamphetamine	
l-methamphetamine	>100,000	3,4-Methylenedioxyethylamphetamine	14
3,4-Methylenedioxyamphetamine	1,250	Nordoxepin hydrochloride	14
3,4-Methylenedioxy-methamphetamine	>100,000	Phencyclidine	4.
3,4-Methylenedioxyethylamphetamine	>100,000	Promazine	8
Paramethoxyamphetamine	625	Promethazine	14
Phentermine	1,250	LSD 50 related compounds	
Tyramine	>100,000	Lysergic acid diethylamide	4
Amphetamine 500 related compounds		6-MAM 10 related compounds	
d-Amphetamine	500	6-Monoacetylmorphine	1
l-Amphetamine	50,000	Acetylcodeine	$\sim$
3,4-Methylenedioxyamphetamine	625	Buprenorphine	$\sim$
Phentermine	1,250	Codeine	$\sim$
Paramethoxyamphetamine	625	Diacetylmorphine	1
Tyramine	>100,000	Dihydrocodeine	$\sim$
Amphetamine 300 related compounds		Ethylmorphine	$\sim$

d-Amphetamine	300	Hydrocodone	>10,000	Prazepam	>100,000	Diacetyl Morphin	250	Cocaine	1,000	Buprenorphine	25,000
l-Amphetamine	50,000	Hydromorphone	5,000	Temazepam	63	Dihydrocodeine	586	Ecgonine	100,000	Codeine	2000
Mephentermine hemisulfate salt	>100,000	Morphine	10,000	Triazolam	5000	Ethylmorphine	200	Ecgonine Methyl Ester	>100,000	Diacetylmorphine (Heroin)	5,000
3,4-Methylenedioxyamphetamine (MDA)	625	Morphine-3-glucuronide	>10,000	Benzodiazepines 200 related compound	ds	Hydrocodone	12,500	Cocaine 200 related compounds		Dihydrocodeine	1,563
Phentermine	625	Nalorphine	5,000	Oxazepam	200	Hydromorphone	12,500	Benzoylecgonine	200	Ethylmorphine	250
Paramethoxyamphetamine (PMA)	625	Thebaine	>20,000	Alprazolam	83	6-Monoacetylmorphine	250	Cocaine	125	Hydromorphone	25,000
Paramethoxymethamphetamine (PMMA)	>100,000	Ecstasy 500 related compounds	· · ·	Bromazepam	417	Morphine-3-glucuronid	2,500	Ecgonine	5,000	Hydrocodone	50,000
Tyramine	>100,000	3,4-Methylenedioxy-methamphetamine	500	Chlordiazepoxide	1,667	Nalorphine	25,000	Ecgonine Methyl Ester	>100,000	Merperidine	>100,000
Barbiturates 300 related compounds		d-Amphetamine	>100,000	Clobazam	42	Thebaine	25,000	Cocaine 150 related compounds		6-Monoacetylmorphine (6-MAM)	4,000
Secobarbital	300	l-Amphetamine	>100,000	Clonazepam	1,667	Morphine 200 related compounds		Benzoylecgonine	150	Morphine-3-β-d-glucuronide	12,500
Allobarbital	1,250	d-methamphetamine	>100,000	Clorazepate	2,220	Morphine	200	Cocaine	125	Nalorphine Hydrochloride	>100,000
Alphenal	625	l-methamphetamine	>100,000	Desalkflurazepam	167	Acetylcodeine	100	Ecgonine	10000	Oxycodone	>100,000
Amobarbital	625	3,4-Methylenedioxyamphetamine	2,500	Diazepam	167	Buprenorphine	2,000	Ecgonine Methyl Ester	>10000	Oxymorphone	>100,000
Aprobarbital	188	3,4-Methylenedioxyethylamphetamine	156	Estazolam	3,333	Codeine	170	Cocaine 100 related compounds		Rifampicine	>100,000
Butabarbital	94	Paramethoxyamphetamine	50,000	Fentanyl	>100,000	Diacetyl Morphin	168	Benzoylecgonine	100	Thebaine	50,000
Butalbital	2,500	Paramethoxymethamphetamine	>100,000	Flunitrazepam	250	Dihydrocodeine	395	Cotinine 600 related compounds		Opiates 1000 related compounds	
Butethal	200	Ecstasy 1000 related compounds		Flurazepam	>100,000	Ethylmorphine	135	(-)-Cotinine	600	Morphine	1,000
Cyclopentobarbital	400		1,000	Lorazepam	833	Hydrocodone	8,350	Cotinine 300 related compounds		Acetylcodeine	1,000
Pentobarbital	1.000	Methamphetamine 1000 related com		Lormetazepam	833	Hydromorphone	8,350	(-)-Cotinine	300	Buprenorphine	>10000
Phenobarbital	300	d-Methamphetamine	1.000	Medazepam	>100,000	6-Monoacetylmorphine	170	(-)-Nicotine	9,375	Codeine	1000
Buprenorphine 10 related compounds		Chloroquine	25,000	Midazolam	>100,000	Morphine-3-glucuronid	1,670	Cotinine 200 related compounds	,,	Diacetylmorphine (Heroin)	3,000
Buprenorphine	10	Fenfluramine	12,500	Nitrazepam	16,667	Nalorphine	16,666	(-)-Cotinine	200	Dihydrocodeine	1,000
Buprenorphine–3–β–D–Glucuronide	10	l-Methamphetamine	10.000	Norchlordiazepoxide	167	Thebaine	16,666	(-)-Nicotine	6,250	Ethylmorphine	200
Norbuprenorphine	50	Mephentermine hemisulfate salt	31,250	Nordiazepam	333	Morphine 100 related compounds	,	EDDP 100 related compounds	0,000	Hydromorphone	25,000
Norbuprenorphine–3–β–D–Glucuronide	100	3,4-Methylenedioxyethylamphetamine	50,000	Prazepam	>100,000	Morphine	100	EDDP	100	Hydrocodone	50,000
Buprenorphine 5 related compounds	100	· · · · ·	313	Temazepam	42	Codeine	100	Meperidine	>100,000	Merperidine	>100,000
Buprenorphine	5	Paramethoxymethamphetamine	625	Triazolam	3,333	Diacetylmorphine (Heroin)	100	Methadone	>100,000	6-Monoacetylmorphine (6-MAM)	3,000
Buprenorphine–3–β–D–Glucuronide	5	(-)-Ephedrine	4.000	Benzodiazepines 100 related compound		Ethylmorphine	100	Norfentanyl	>100,000	Morphine-3-β-d-glucuronide	10000
Norbuprenorphine	25	Methamphetamine 500 related comp		Oxazepam	100	Hydromorphone	500	Phencyclidine	>100,000	Nalorphine Hydrochloride	>100.000
Norbuprenorphine–3–β–D–Glucuronide	50	d-Methamphetamine	500	Alprazolam	42	Hydrocodone	500	Promazine	50,000	Oxycodone	>100,000
Benzodiazepines 500 related compound	50	Chloroquine	12,500	Bromazepam	208	6-Monoacetylmorphine	100	Promethazine	25,000	Oxymorphone	>100,000
Oxazepam	500	Fenfluramine	12,500	Chlordiazepoxide	833	Morphine-3-β-d-glucuronide	2.000	Prothipendyl	50,000	Rifampicine	>100,000
Benzodiazepines 300 related compound		l-Methamphetamine	3,125	Clobazam	21	Oxycodone	20,000	Prozine	12,500	Thebaine	50,000
Oxazepam	300	Mephentermine hemisulfate salt	25.000	Clonazepam	833	Oxymorphone	20,000	EDDP 300 related compounds	12,500	Oxycodone 300 related compounds	
Alprazolam	125	MDEA	12,500	Clorazepate	1,110	Promethazine	>100.000	EDDP 500 related compounds	300	Oxycodone	300
Bromazepam	625	MDHA	1,875	Desalkflurazepam	83	Rifampicine	8,400	Meperidine	>100,000	Hydrocodone	75,000
Chlordiazepoxide	2500	PMMA	625	Diazepam	83	Thebaine	8,400	Methadone	>100,000	Hydromorphone	>100,000
Clobazam	63	(-)-Ephedrine	2.000	Estazolam	1,667	Trimipramine	20,000	Norfentanyl	>100,000	Naloxone	>100,000
Clonazepam	2500	Methamphetamine 300 related comp		Fentanyl	>100,000	MPD 300 related compounds	20,000	Phencyclidine	>100,000	Oxymorphone	750
Clorazepate	3330	d-Methamphetamine	300	Flunitrazepam	125	Methylphenidate	300	Promazine	80.000	Oxycodone 100 related compounds	
Desalkflurazepam	250	Chloroquine	7.500	Flurazepam	>100.000	Methaqualone 300 related compoun		Promethazine	75.000	Oxycodone	100
Diazepam	250	Fenfluramine	12,500	Lorazepam	417	Methaqualone	300	Prothipendyl	80,000	Hydrocodone	6,250
Estazolam	5000	l-Methamphetamine	10.000	Lormetazepam	417	Amitriptyline	50.000	Prozine	37,500	Hydromorphone	50,000
Fentanyl	>100,000	Mephentermine hemisulfate salt	31,250	Medazepam	>100,000	Carbamazepine	20,000	ETG 500 related compounds	57,500	Naloxone	50,000
	375	MDEA	50,000	Midazolam	>100,000	· · · · · · · · · · · · · · · · · · ·	50,000		500		250
Flunitrazepam	>100,000		313		8,333	Nortriptyline	40,000	Ethyl Glucuronide Ethanol	>100,000	Oxymorphone Trionalia Antidopressanta related as	
Flurazepam	>100,000	MDMA PMMA	625	Nitrazepam Norchlordiazepoxide	8,333	Phenytoin	40,000	D-Glucuronic Acid	>100,000	Tricyclic Antidepressants related co Nortriptyline HCl	1.000
Lorazepam	1250	(-)-Ephedrine	625 2,000	Norchlordiazepoxide	83 167	Theophylline Methadone 300 related compounds	40,000	D-Glucuronic Acid Morphine-3-b-D-glucuronide	>100,000	Amitriptyline	1,000
Lormetazepam	>100,000	(-)-Ephedrine Morphine 300 related compounds	2,000		>100,000	· · · ·	300	×	>100,000	Clomipramine	>100,000
Medazepam		· · ·	300	Prazepam		Methadone	2,000	ETG 300 related compounds	300		>100,000
Midazolam	>100,000 25000	Morphine	300 150	Temazepam	21 1,667	(-)-alpha-methadol Opiates 2000 related compounds	2,000	Ethyl Glucuronide	500	Cyclobenzaprine	12,500
Nitrazepam		Acetylcodeine		Triazolam Consistence and an and a service and a	1,007		2.000	Fentanyl 10 related compounds	10	Desipramine	-
Norchlordiazepoxide	250	Buprenorphine	>10000	Cocaine 300 related compounds	200	Morphine	2,000	Fentanyl and Fentanyl metabolites	10	Doxepin	2,000
Nordiazepam	500	Codeine	250	Benzoylecgonine	300	Acetylcodeine	1,563	Fentanyl	100	Imipramine	2,500

Norfentanyl	>10,000
Fentanyl 20 related compounds	
Fentanyl and Fentanyl metabolites	20
Fentanyl	200
Norfentanyl	>10,000
HMO 250 related compounds	
Hydromorphone	250
Acetylcodeine	10,000
Thebaine	25,000
Nalorphine	12,500
Morphine-3-glucuronid	2,500
Morphine	5,000
Hydrocodone	3,100
Ethylmorphine	5,000
Dihydrocodeine	25,000
Diacetyl Morphin	10,000
Codeine	50,000
Buprenorphine	10,000
6-Monoacetylmorphine	10,000
K2 50 related compounds	50
JWH-018-5-Pentanoic acid	50
JWH-073-4-Butanoic acid	50
Ketamine 1000 related compounds	1 000
Ketamine	1,000
Norketamine	1,000
Dextromethorphan	500
Tramadol 300 related compounds	-
Tramadol	300
Tramadol 100 related compounds	-
Tramadol	100
(+/-)Chlorpheniramine	50,000
Dimenhydrinate	50,000
Diphenhydramine	50,000
Phencyclidine	50,000
(+)-Chlorpheniramine	>100,000
OPI/MOR 100- related compounds	
Morphine	100
Codeine	100
Diacetylmorphine (Heroin)	100
Ethylmorphine	100
Hydromorphone	500
Hydrocodone	500
6-Monoacetylmorphine (6-MAM)	100
Morphine-3-β-d-glucuronide	2,000
Oxycodone	20,000
Oxymorphone	20,000
Promethazine	>100,000
Rifampicine	8,400
	8,400
Thebaine	0,400
Thebaine Trimipramine	20.000
Trimipramine	20,000
	20,000

Maprotiline Nortriptyline	750 3,125
	500
Nordoxepin	
Opipramol	1,563 1,000
Promazine Promethazine	
	6,250
Prothipendyl	25,000
Protryptyline	6,250
Prozine	1,250
Trimipramine	>100,000
Marijuana 200 related compounds	200
11-nor-Δ9-THC-9-COOH	200
Marijuana 150 related compounds	150
11-nor-Δ9-THC-9-COOH	150
11-nor-∆8-THC-9-COOH	90
∆8-Tetrahydrocannabinol	45,000
Δ9-Tetrahydrocannabinol	45,000
Cannabinol	60,000
Marijuana 50 related compounds	1
11-nor-Δ9-THC-9-COOH	50
11-nor-Δ8-THC-9-COOH	50
11-hydroxy-Δ9-Tetrahydrocannabinol	50
Δ8-Tetrahydrocannabinol	15,000
Δ9-Tetrahydrocannabinol	15,000
Cannabinol	20,000
Cannabidiol	>100,000
Marijuana 25 related compounds	
11-nor-∆9-THC-9-COOH	25
11-nor-∆8-THC-9-COOH	15
∆8-Tetrahydrocannabinol	7,500
Δ9-Tetrahydrocannabinol	7,500
Cannabinol	10,000
Zolpidem 50 related compounds	1
Zolpidem Phenyl-4-carboxylic	50
Zolpidem	>10,000
Propoxyphene 300 related compound	ls
D-Propoxyphene	300
D-Norpropoxyphene	5,000
Barbiturates 200 related compounds	
Secobarbital	200
Allobarbital	820
Alphenal	500
Amobarbital	500
Aprobarbital	130
Butabarbital	70
Butalbital	1,800
	150
Butethal	200
Butethal Cyclopentobarbital	300
	300 730
Cyclopentobarbital	
Cyclopentobarbital Pentobarbital	730

Phencyclidine 25 related compound	s
Phencyclidine	25
Hydrocodone	>100,000
Hydromorphone	>100,000
4-hydroxyphencyclidine	75
7-ACL 300 related compounds	
7-amine-clonazepam	300
Dxazepam	>10,000
Alprazolam	>10,000
Bromazepam	>10,000
Chlordiazepoxide	>10,000
Clobazam	>10,000
Clonazepam	10000
Clorazepate dipotassium	>10,000
Desalkylflurazepam	>10,000
Diazepam	>10,000
Estazolam	>10,000
Flunitrazepam	>50,000
±) Lorazepam	10000
Midazolam	>100,000
Vitrazepam	>10,000
Norchlordiazepoxide	>100,000
Nordiazepam	>100,000
Femazepam	>10,000

Methadone	200
(-)-alpha-methadol	1500
Doxylamine	3500
LAAM HCl	6500
Alpha Methadol	1500
EMDP	>100,000
EDDP	>100,000

ρ	Catalog number	8	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
Ι	In vitro diagnostic medical device	з	Use by
ш	Manufacturer	σ	Do not reuse

A study was conducted to determine the cross-reactivity of the test with compounds spiked into					
drug-free PBS stock. The following compounds demonstrated no false positive results on the Drugs of					
Abuse Integrated Cup (Urine) when tested at concentrations up to 100 µg/mL.					

Abuse Integrated Cup (Urine) when tested at concentrations up to 100 µg/mL.				
(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid		
(+)-Naproxen	Creatine	Penicillin-G		
(+/-)-Ephedrine (Except MET)	Dextromethorphan	Pheniramine		
4-Dimethyllaminoantiyrine	Dextrorphan tartrate	Phenothiazine		
Acetaminophen	Dopamine	Procaine		
Acetone	Erythromycin	Protonix		
Albumin	Ethanol	Pseudoephedrine		
Amitriptyline (Except TCA)	Furosemide	Quinidine		
Ampicillin	Glucose	Ranitidine		
Aspartame	Guaiacol Glyceryl Ether	Sertraline		
Aspirin	Hemoglobin	Tyramine		
Benzocaine	Ibuprofen	Vitamin C (Ascorbic Acid)		
Bilirubin	Imipramine (Except TCA)	Trimeprazine		
b-Phenylethyl-amine	Isoproterenol	Venlafaxine		
Caffeine	Lidocaine	Ibuprofen		
Chloroquine	Methadone (Except MTD)			

# LITERATURE REFERENCES

- 1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
- 2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
- 3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
- McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
- 5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

# GLOSSARY OF SYMBOLS