MD-U625

12 Panel Now
Drugs of Abuse Integrated Cup (Urine)

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)
6-MAM	6-Monoacetylmorphine	10
ACE	Acetaminophen	5,000
AMP	D-Amphetamine	300/500/1,000
APVP	α -Pyrrolidinovalerophenone	500
BAR	Secobarbital	300
BUP	Buprenorphine–3–β–D–Glucuronide	10
BZO	Oxazepam	300
COC	Benzoylecgonine	150/300
COT	Cotinine	200
CLO(CLON)	Clonazepam	150
EDDP	EDDP	100
ETG	Ethyl Glucuronide	500/300
FYL	Fentanyl	20/200
GAB	Gabapentin	1000
K2	JWH-018-5-Pentanoic acid	50
KET	Ketamine	1,000
KRA	Kratom	500
MDMA	Ecstasy	500
MET(MAMP)	D-Methamphetamine	300/500/1,000
MTD	Methadone	300
OPI(MOP)	Morphine	100/300/2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
PSY	Psilocybin	500
TCA	Nortriptyline	1,000
THC	11-nor-Δ9-THC-9-COOH	25/50/200
TIA（ZAZA）	Tianeptine	500
TRA(TML)	Tramadol	200/100
XYL	Xylazine	1000
LSD	9,10-Didehydro-N,N-diethyl-6-methylergoline-8beta-carboxamide	20
HCO	Hydrocodone	300
HCG	human chorionic gonadotropin	20 mIU/mL
ALC	Alcohol	0.02%
Adulteration（Strip A）	Oxidants / Specific Gravity / PH	
Adulteration（Strip B）	Nitrite / Glutaraldehyde / Creatinine	

The Drugs of Abuse Integrated Cup (Urine) is used to obtain visual qualitative result and is intended for health care professionals use including professionals at point of care sites to assist in the determination of drug compliance. It is not intended for over the counter sale to non-professionals.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC/MS) or Liquid Chromatography/ Mass Spectrometry (LC/MS) are the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

The Urine Adulteration Test Strips (Urine) are a semi-quantitative color comparison screen for the detection of Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants and Pyridinium Chlorochromate in human urine.

This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Abnormal results should be sent to a laboratory for confirmation.

The Drugs of Abuse Integrated Cup (Urine) also can be used to detect Human chorionic gonadotropin (hCG) in urine, is intended for using an aid in the early detection of pregnancy.

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.

The Adulteration Strips of the colors that appear on the pads can be compared with the printed color chart on the canister. The color comparison provides a semi-quantitative screen for Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants and Pyridinium Chlorochromate in human urine, which can help assess the integrity of the urine specimen.

The hCG Rapid Test Strip (Urine) detects human chorionic gonadotropin through visual interpretation of color development on the strip. Anti-hCG antibodies are immobilized on the test region of the membrane and anti-mouse antibodies on the control region. During testing, the specimen reacts with anti-hCG antibodies conjugated to colored particles and precoated on the sample pad of the strip. The mixture then migrates through the membraneby capillary action and interacts with reagents on the membrane. Ifthere is sufficient hCG in the specimen, a colored bandwill form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the controlregion serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed test cups with integrated drug of abuse test panels
- Adulteration Color Chart (when applicable)
- Alcohol Color Chart (when applicable)
- Caps
- Package insert

Materials Required but Not provided

- Timer
- Positive and negative controls
- Centrifuge

PRECAUTIONS

- For forensic use only.
- 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 assayed.
- 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.

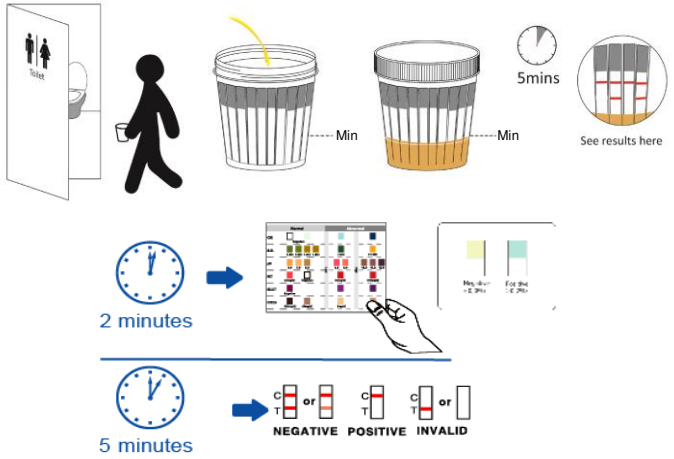
SPECIMEN COLLECTION AND STORAGE

- 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.

1. Remove the cup from its sealed pouch and use it as soon as possible.
2. Donor provides a urine specimen in the cup and screws the cap on to the cup. Start the timer.
3. Donor dates and initials the security seal label. Operator checks the cap for tightness and attaches the security seal label over the cap.
4. Remove the peel-off label.
5. Check the temperature strip label at 2-4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100°F (32-38°C).
6. Drug test results are indicated by the presence or absence of colored band(s) in the result area. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.
7. Positive test results may be confirmed by another test method. By sending the cup and urine specimen intact to a toxicology laboratory for confirmation.
8. For the adulteration, compare with the color card. The result should be read at 2 minutes. Do not interpret the result after 5 minutes.
9. For alcohol test, read results at 2 minutes by visually comparing the color of the reaction pad to the corresponding color blocks printed on the pouch to determine the alcohol concentration. Do not interpret the result after 3 minutes.
10. For HCG strip, the result should be read at 3 minutes. Do not interpret the result(s) after 5 minutes after sample application.



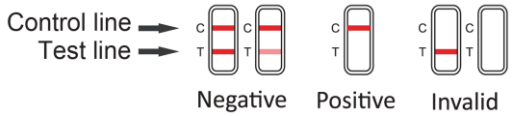
INTERPRETATION OF RESULTS

The Result for DOA test:

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.

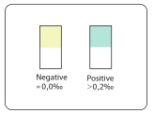
INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.



NOTE for DOA test:

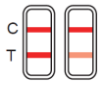
1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only, and cannot determine the concentration of 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 for Urine Alcohol Test ：



NEGATIVE: No color change appears on the reaction pad. The color should match the color block on the pouch corresponding to a negative (-) result. This indicates that alcohol has not been detected.
POSITIVE: A color change appears on the reaction pad. The color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks on the pouch.
INVALID: The outer edges of the reaction pad produce a slight color but the majority of the reaction pad remains colorless. Repeat the test with a new test strip, ensuring complete saturation of the reaction pad with the specimen. If the problem persists, do not continue the test and contact your local distributor.

The Result for Urine HCG Test
Important Notice!!
When reading the HCG strip on our 14 panel Cup， 2 lines are the positive results, 1 line is a negative result. This is the opposite of a regular drug test, a regular drug strip reads 1 line positive and 2 lines negative.



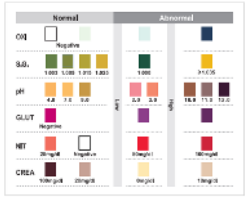
POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T).

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 of HCG:
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 should be considered positive. note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
Insufficient specimen volume, incorrect operating procedure or performing expired tests are the most likely reasons for control band failure.

The Result of Adulteration Strips: For specific colour please reference the Adulteration Color Chart.



QUALITY CONTROL

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

The Quality Control of Alcohol strips:

- The Urine Alcohol Test Strips may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 30 mL of water. This solution should produce a color change on the reaction pad corresponding to 0.02% or greater. The color reaction with alcohol in the human urine is somewhat slower and less intense than with alcohol in an aqueous solution.
- Do not perform the control test with undiluted alcohol, as pure alcohol solutions will not produce a positive result.

LIMITATIONSOF THE TEST

1. The Drugs of Abuse Integrated Cup (Urine) should be only used for the qualitative detection of drugs of abuse.
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 professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. 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.
4. 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.
5. 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.

Adulteration Limitations

The 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.
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.
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 pad.

The Limitations of Alcohol strip:

1. The Urine Alcohol Test Strip provides only a preliminary result for detection alcohol concentration in human urine. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography (GC) is the preferred confirmatory method.
2. Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Caution should be taken when interpreting test results due to the subjective nature of the test.
3. The Urine Alcohol Test Strip should not be used to determine the presence of alcohol in beverages, in undiluted alcohol, or in other liquid solutions.
4. Alcohol concentration in human body slowly increases after the alcohol ingestion. Generally, the maximum of alcohol concentration in human urine, appears in the range from 30 minutes to 60 minutes after the last alcohol ingestion. After the maximum appearance, the alcohol concentration in human body reduces. How long the alcohol concentration reduces to zero depends on how much alcohol ingested.
5. The Urine Alcohol Test Strip is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the test strip. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
6. Ingestion or general use of over-the-counter medications and products containing alcohol such as cold medicines, breath sprays and mouthwashes can produce positive results. Wait at least 20 minutes after ingesting any such products before using the test strip.

PERFORMANCE CHARACTERISTICS

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

Specimen	6-MAM10	ACE5000	AMP1000	AMP300	AMP500	APVP500	BAR300
Positive	96.80%	96.10%	95.80%	96.10%	95.90%	96.61%	97.80%
Negative	100.00%	100.00%	100.00%	100.00%	100.00%	96.67%	98.10%
Total	98.20%	98.10%	98.10%	98.10%	98.10%	96.64%	98.00%

Specimen	BUP10	BZO300	CLO150	COC150	COC300	COT200	EDDP100
Positive	100.00%	95.30%	100.00%	96.36%	98.20%	97.70%	95.80%
Negative	100.00%	92.90%	100.00%	96.61%	98.10%	97.90%	100.00%
Total	100.00%	93.90%	100.00%	96.49%	98.20%	98.00%	98.10%

Specimen	ETG300	ETG500	FYL20	FYL200	GAB1000	HCO300	K2 50
Positive	100.00%	98.21%	96.80%	96.80%	97.67%	100.00%	98.90%
Negative	100.00%	100.00%	100.00%	100.00%	97.62%	100.00%	100.00%
Total	100.00%	99.04%	98.30%	98.30%	97.65%	100.00%	99.00%

Specimen	KET1000	KRA500	LSD20	MDMA500	MET1000	MET300	MET500
Positive	98.00%	97.96%	100.00%	100.00%	96.80%	96.80%	96.90%
Negative	98.60%	96.23%	100.00%	100.00%	100.00%	100.00%	100.00%
Total	98.30%	97.06%	100.00%	100.00%	98.30%	98.40%	98.30%

Specimen	MTD300	OPI100	OPI2000	OPI300	OXY100	PCP25	PSY500
Positive	96.10%	96.10%	97.60%	96.80%	96.10%	97.80%	98.08%
Negative	100.00%	100.00%	98.40%	97.90%	100.00%	100.00%	98.15%
Total	98.10%	98.10%	98.10%	97.30%	98.10%	98.90%	98.11%

Specimen	PPX300	TCA1000	THC200	THC25	THC50	TIA500	TRA100
Positive	97.80%	92.10%	96.10%	96.80%	96.80%	97.30%	98.40%
Negative	100.00%	100.00%	100.00%	98.30%	98.30%	100.00%	100.00%
Total	99.00%	96.80%	98.10%	97.50%	97.50%	98.72%	99.10%

Specimen	TRA200	XYL1000	ALC0.02%
Positive	98.44%	97.44%	98.00%
Negative	100.00%	95.12%	97.90%
Total	99.13%	96.25%	98.00%

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

A method comparison study was performed comparing the HCG Rapid Test Strip to Elisa. Testing was conducted at 2 POC sites. 140-160 individuals per site were enrolled in the study. The samples were collected from women who fit the following categories: childbearing age, suspected pregnant women, (e.g. within days of missing the expected menses), women early in pregnancy, (e.g. within the first 30 days of pregnancy), and the first trimester of pregnancy.

		hCG Rapid Test		
		+	-	Total
EIA	+	130	0	130
	-	0	178	178
		130	178	308

Relative Sensitivity: >99.9% (97.2%-100.0%)*
Relative Specificity: >99.9% (98.0%-100.0%)*
Overall Agreement: >99.9% (98.8%-100.0%)*
*95% Confidence Interval

B. Sensitivity

The sensitivity of The Drugs of Abuse Integrated 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	6-MAM10		ACE5000		AMP1000		AMP300		AMP500		APVP500		BAR300	
Cut-off		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0%	50	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
-25%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	25	25	19	31	16	34	20	30	14	36	11	39	11	39
25%	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
3X	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	BUP10		BZO300		CLO150		COC150		COC300		COT200		EDDP100	
Cut-off		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0%	50	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
-25%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	25	25	17	33	12	38	24	26	11	39	13	37	25	25
25%	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
3X	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	ETG300		ETG500		FYL20		FYL200		GAB1000		HCO300		K2 50	
Cut-off		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0%	50	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
-25%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	25	25	16	34	17	33	22	28	12	38	16	34	14	36
25%	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
3X	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	KET1000		KRA500		LSD20		MDMA500		MET1000		MET300		MET500	
Cut-off		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0%	50	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
-25%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	16	34	38	37	22	28	13	37	23	27	15	35	10	40
25%	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
3X	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	MTD300		OPI100		OPI2000		OPI300		OXY100		PCP25		PSY500	
Cut-off		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0%	50	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
-25%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	6	44	20	30	23	27	18	32	19	31	9	41	14	36
25%	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
3X	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	PPX300		TCA1000		THC200		THC25		THC50		TIA500		TRA100	
Cut-off		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0%	50	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
-25%	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	20	30	9	41	17	33	11	39	17	33	13	37	11	39
25%	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
3X	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	TRA200	XYL1000

Cut-off		-	+	-	+
0%	50	50	0	50	0
-50%	50	50	0	50	0
-25%	50	50	0	50	0
Cut-off	50	22	28	13	37
25%	50	0	50	0	50
50%	50	0	50	0	50
3X	50	0	50	0	50

Drug Conc.	n	ALC 0.02%	
(Cut-off)		Correct	Incorrect
Alcohol free urine	75	75	0
0.02%(aqueous)	75	75	0
0.04%(aqueous)	75	75	0
0.08%(aqueous)	75	75	0
0.3% (aqueous)	75	75	0

C. Specificity

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

6-MAM10-related compounds			
6-Monoacetylmorphine	10	Hydrocodone	>10,000
Acetylcodeine	> 10,000	Hydromorphone	> 100,000
Buprenorphine	> 10,000	Morphine	100000
Codeine	5000	Morphine-3-glucuronide	> 10,000
Diacetylmorphine	1000	Nalorphine	5000
Dihydrocodeine	> 10,000	Thebaine	> 20,000
Ethylmorphine	> 10,000		
ACE5000-related compounds			
Acetaminophen	5000	Acetophenetidine	7500
AMP1000-related compounds			
d-Amphetamine	1000	3,4-Methylenedioxy-methamphetamine	> 100,000
l-Amphetamine	> 100,000	3,4-Methylenedioxyethylamphetamine	> 100,000
d-methamphetamine	> 100,000	Paramethoxyamphetamine	625
l-methamphetamine	> 100,000	Phentermine	1250
3,4-Methylenedioxyamphetamine	1250	Tyramine	> 100,000
AMP300-related compounds			
d-Amphetamine	300	Phentermine	625
l-Amphetamine	> 50,000	Paramethoxyamphetamine (PMA)	625
Mephentermine hemisulfate salt	> 100,000	Paramethoxymethamphetamine (PMMA)	> 100,000
3,4-Methylenedioxyamphetamine (MDA)	625	Tyramine	> 100,000
AMP500-related compounds			
d-Amphetamine	500	Phentermine	1250
l-Amphetamine	> 50,000	Paramethoxyamphetamine	625
3,4-Methylenedioxyamphetamine	625	Tyramine	> 100,000
APVP500-related compounds			
α-PVP	500	PVP	> 100,000
MDPV	40		
BAR300-related compounds			
Secobarbital	300	Butalbital	2500
Allobarbital	1250	Butethal	200
Alphenal	625	Cyclopentobarbital	400
Amobarbital	625	Pentobarbital	1000
Aprobarbital	188	Phenobarbital	300
Butabarbital	94		
BUP10-related compounds			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine–3–β–D–Glucuronide	10	Norbuprenorphine–3–β–D–Glucuronide	100
BZO300-related compounds			
Oxazepam	300	Flurazepam	>100,000
Alprazolam	125	Lorazepam	1250
Bromazepam	625	Lormetazepam	1250
Chlordiazepoxide	2500	Medazepam	>100,000
Clobazam	63	Midazolam	>100,000
Clonazepam	2500	Nitrazepam	25000
Clorazepate	3330	Norchlordiazepoxide	250
Desalkflurazepam	250	Nordiazepam	500
Diazepam	250	Prazepam	>100,000
Estazolam	5000	Temazepam	63
Fentanyl	>100,000	Triazolam	5000
Flunitrazepam	375		
CLO150-related compounds			
Clonazepam	150	Flunitrazepam	375
Alprazolam	250	Lorazepam	1250
Bromazepam	625	Lormetazepam	1250
Chlordiazepoxide	2500	Midazolam	100000
Clobazam	63	Nitrazepam	25000
Oxazepam	30	Norchlordiazepoxide	250
Clorazepate	3330	Nordiazepam	500
Delorazepam	2500	Sulindac	100000
Desalkflurazepam	250	Temazepam	125
Diazepam	250	Triazolam	5000
Estazolam	5000		
COC150-related compounds			
Benzoylecgonine	150	Ecgonine	10000
Cocaine	125	Ecgonine Methyl Ester	> 10,000
COC300-related compounds			
Benzoylecgonine	300	Ecgonine	100000
Cocaine	1000	Ecgonine Methyl Ester	> 100,000
COT200-related compounds			
(-)-Cotinine	200	(-)-Nicotine	6250
EDDP100-related compounds			
EDDP	100	Promazine	50000
Meperidine	> 100,000	Promethazine	25000
Methadone	> 100,000	Prothipendyl	50000
Norfentanyl	> 100,000	Prozine	12500
Phencyclidine	> 100,000	Quetiapine	10000
ETG300-related compounds			
Ethyl Glucuronide	300		
ETG500-related compounds			
Ethyl Glucuronide	500	D-Glucuronic Acid	> 100,000
Ethanol	> 100,000	Morphine-3-b-D-glucuronide	> 100,000
FYL20-related compounds			
Fentanyl metabolites	20	Norfentanyl	> 10,000
Fentanyl	200		
FYL200-related compounds			
Fentanyl	200	Norfentanyl	> 10,000
GAB1000-related compounds			
Gabapentin	1000	Pregbalin	10000
HCO300-related compounds			
Hydrocodone	300	Acetylcodeine	4000
Buprenorphine	>10,000	Δ9-Tetrahydrocannabinol	15000
Codeine	3000	Diacetyl Morphin	3000
Dihydrocodeine	4000	Ethylmorphine	4000
Hydromorphone	300	Morphine	2500
6-Monoacetylmorphine	3000	Morphine-3-glucuronid	2500
Nalorphine	12500	Thebaine	>20,000
Methadone	>100,000	Oxazepam	>100,000
Oxycodone	100000	EDDP	>100,000
K2 50-related compounds			
JWH-018-5-Pentanoic acid	50	JWH-073-4-Butanoic acid	50
KET1000-related compounds			
Ketamine	1000	Methadone	12500
Norketamine	1000	D-Methamphetamine	12500
Dextromethorphan	> 100,000	3,4-Methylenedioxyethylamphetamine	25000

Dextrorphan tartrate	> 100,000	Nordoxepin hydrochloride	25000
D-Norpropoxyphene	31250	Phencyclidine	5000
EDDP	> 100,000	Promazine	8000
Meperidine	12500	Promethazine	25000
Mephentermine hemisulfate salt	50000		
KRA500-related compounds			
7-hydroxymitragynine	500	Mitragynine	6000
LSD20-related compounds			
Lysergic acid diethylamide	20		
MDMA500-related compounds			
3,4-Methylenedioxy-methamphetamine	500	3,4-Methylenedioxyamphetamine	2500
d-Amphetamine	> 100,000	3,4-Methylenedioxyethylamphetamine	156
l-Amphetamine	> 100,000	Paramethoxyamphetamine	50000
d-methamphetamine	> 100,000	Paramethoxymethamphetamine	> 100,000
l-methamphetamine	> 100,000		
MET1000-related compounds			
d-Methamphetamine	1000	3,4-Methylenedioxyethylamphetamine	50000
Chloroquine	25000	3,4-Methylenedioxy-methamphetamine	313
Fenfluramine	12500	Paramethoxymethamphetamine	625
l-Methamphetamine	10000	(-)-Ephedrine	4000
Mephentermine hemisulfate salt	31250		
MET300-related compounds			
d-Methamphetamine	300	MDEA	50000
Chloroquine	7500	MDMA	313
Fenfluramine	12500	PMMA	625
l-Methamphetamine	10000	(-)-Ephedrine	2000
Mephentermine hemisulfate salt	31250		
MET500-related compounds			
d-Methamphetamine	500	MDEA	12500
Chloroquine	12500	MDMA	1875
Fenfluramine	12500	PMMA	625
l-Methamphetamine	3125	(-)-Ephedrine	2000
Mephentermine hemisulfate salt	25000		
MTD300-related compounds			
Methadone	300	(-)-alpha-methadol	2000
OPI100-related compounds			
Morphine	100	Morphine-3-β-d-glucuronide	2000
Codeine	100	Oxycodone	20000
Diacetylmorphine (Heroin)	100	Oxymorphone	20000
Ethylmorphine	100	Promethazine	> 100,000
Hydromorphone	500	Rifampicine	8400
Hydrocodone	500	Thebaine	8400
6-Monoacetylmorphine	100	Trimipramine	20000
OPI2000-related compounds			
Morphine	2000	Merperidine	> 100,000
Acetylcodeine	1563	6-Monoacetylmorphine (6-MAM)	4000
Buprenorphine	25000	Morphine-3-β-d-glucuronide	12500
Codeine	2000	Nalorphine Hydrochloride	> 100,000
Diacetylmorphine (Heroin)	5000	Oxycodone	> 100,000
Dihydrocodeine	1563	Oxymorphone	> 100,000
Ethylmorphine	250	Rifampicine	> 100,000
Hydromorphone	25000	Thebaine	50000
Hydrocodone	50000		
OPI300-related compounds			
Morphine	300	Hydrocodone	12500
Acetylcodeine	150	Hydromorphone	12500
Buprenorphine	> 10,000	6-Monoacetylmorphine	250
Codeine	250	Morphine-3-glucuronid	2500
Diacetyl Morphin	250	Nalorphine	25000
Dihydrocodeine	586	Thebaine	25000
Ethylmorphine	200		
OXY100-related compounds			
Oxycodone	100	Naloxone	50000
Hydrocodone	6250	Oxymorphone	250
Hydromorphone	50000		
PCP25-related compounds			
Phencyclidine	25	Hydromorphone	> 100,000
Hydrocodone	> 100,000	4-hydroxyphencyclidine	75
PSY500-related compounds			
Psilocybin	500	5-MeO-DMT	10000
Tryptamine	100000		
PPX300-related compounds			
D-Propoxyphene	300	D-Norpropoxyphene	5000
TCA1000-related compounds			
Nortriptyline HCl	1000	Nordoxepin	500
Amitriptyline	1500	Opipramol	1563
Clomipramine	> 100,000	Promazine	1000
Cyclobenzaprine	12500	Promethazine	6250
Desipramine	188	Prothipendyl	25000
Doxepin	2000	Protryptyline	6250
Imipramine	2500	Prozine	1250
Maprotiline	750	Trimipramine	> 100,000
THC200-related compounds			
11-nor-Δ8-THC-9-COOH	200	Δ9-Tetrahydrocannabinol	> 10,000
11-nor-Δ9-THC-9-COOH	200	Cannabinol	> 20,000
Δ8-Tetrahydrocannabinol	> 10,000		
THC25-related compounds			
11-nor-Δ9-THC-9-COOH	25	Δ9-Tetrahydrocannabinol	7500
11-nor-Δ8-THC-9-COOH	15	Cannabinol	> 10,000
Δ8-Tetrahydrocannabinol	7500		
THC50-related compounds			
11-nor-Δ9-THC-9-COOH	50	Δ9-Tetrahydrocannabinol	15000
11-nor-Δ8-THC-9-COOH	50	Cannabinol	> 20,000
11-hydroxy-Δ9-Tetrahydrocannabinol	50	Cannabidiol	> 100,000
Δ8-Tetrahydrocannabinol	15000		
TIA500-related compounds			
Tianeptine	500	Ketorolac trometamol	20000
Tianeptine metabolite MC5	500		
TRA100-related compounds			
Tramadol	100	(+/-)Chlorpheniramine	50000
Dimenhydrinate	50000	Phencyclidine	50000
(+)-Chlorpheniramine	> 100,000		
TRA200-related compounds			
Tramadol	200		
XYL1000-related compounds			
Xylazine	1000	Lidocaine	10000
ALC0.02%-related compounds			
Acetone	0.25%	Glycerol	1.00%
2-Butanol	0.50%	Isopropanol	1.00%
1-Butanol	0.025%	Methanol	0.0001%

The specificity of the hCG Rapid Test (Urine) was determined from cross reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH) and Thyroid Stimulating Hormone (hTSH). 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 µIU/mL hTSH all produced negative results.

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 when tested at concentrations up to 100 µg/mL.

(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine (Except MET)	Dextromethorphan(Except KET)	Pheniramine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate(Except KET)	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	Imipramine (Except TCA)	Trimeprazine
Bilirubin	(+/-)-Isoproterenol	Venlafaxine
b-Phenylethyl-amine	Methadone (Except MTD)	Ibuprofen
Caffeine	Vitamin C (Ascorbic Acid)	
Chloroquine (Except MET)		

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.
4. 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

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical cup		Use by
	Manufacturer		Do not reuse