Drugs of Abuse Integrated Cup (Urine)

Catologue No.: UDCS-0563A

INTENDED USE

The Turn-Key Split Cup 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)
AMP	d-Amphetamine	300
BZO	Oxazepam	200
COC	Benzoylecgonine	300
MET	Methamphetamine	300
OPI	Morphine	300
THC	11-nor-Δ ^{9}-THC-9-COOH	50
Adulterant	Oxidants / pH /Creatinine	

The DOA test 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.

PRINCIPLE

The Turn-Key Split Cup 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.[3] Glutaraldehyde 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.[3] Normal human urine should not contain Oxidants or PCC.

MATERIALS

Materials Provided

Individually packed test cups with integrated drug of abuse test panels

Caps	Keys
Package insert	Adulteration Color Chart (when applicable)

Materials Required but Not provided

Timer	Centrifuge
Positive and negative controls	

PRECAUTIONS

- For professional in vitro diagnostic 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.

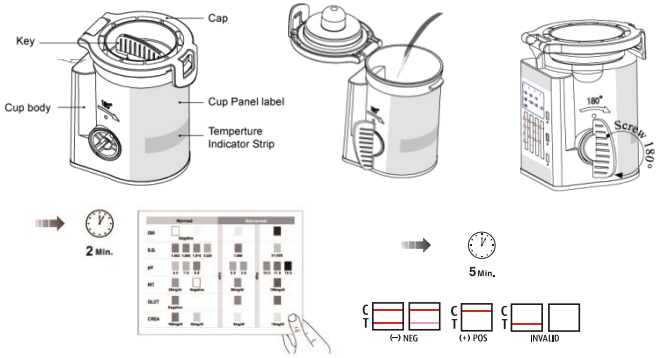
SPECIMEN COLLECTION AND STORAGE

- The Turn-Key Split Cup 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 with its key from sealed pouch and use it as soon as possible.
2. Donor provides a urine specimen in the cup and screws cap on to it.
3. Donor dates and initials body label.
4. Donor screws key deasil for 180°, and start timer immediately.
5. Operator checks the cap for tightness.
6. Remove the peel-off label.
7. 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).
8. 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.
9. Positive test results must be confirmed by another test method. Send the cup and urine specimen intact to a toxicology laboratory for confirmation.
10. 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.



INTERPRETATION OF RESULTS

The Result of DOA Strips: (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:

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.

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.

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

LIMITATIONS OF THE TEST

1. The Turn-Key Split Cup Drugs of Abuse Integrated Cup(Urine) is for professional in vitro diagnostic use, and 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.

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 Turn-Key Split Cup Drugs of Abuse Integrated Cup (Urine) was established by running urine samples against GC/MS.

Specimen	AMP300	BZO200	COC	MET300	OPI	THC
Positive	96.1%	97.4%	98.2%	96.8%	97.6%	96.8%
Negative	100%	98.2%	98.1%	100%	98.4%	98.3%
Total	98.1%	97.9%	98.2%	98.4%	98.1%	97.5%

B. Sensitivity

The sensitivity of The Turn-Key Split Cup 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	AMP		BZO		COC		MET		THC		OPI	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+
Negative	50	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
75% Cutoff	50	50	0	50	0	50	0	50	0	50	0	50	0
Cutoff	50	20	30	11	39	11	39	15	35	17	33	23	27
125%	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
3XCutoff	50	0	50	0	50	0	50	0	50	0	50	0	50

C. Specificity

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

Amphetamine 300 related compounds			
d-Amphetamine	300	Phentermine	625
l-Amphetamine	50,000	Paramethoxyamphetamine (PMA)	625
Mephenterminehemisul-fatesalt	>100,000	Paramethoxymethamphetamine-(PMMA)	>100,000
3,4-Methylenedioxy-amphetamine (MDA)	625	Tyramine	>100,000
Methamphetamine 300 related compounds			
d-Methamphetamine	300	Buprenorphine	3,125
Chloroquine	7,500	Codeine	250
Fenfluramine	12,500	DiacetylMorphin	250
l-Methamphetamine	10,000	Dihydrocodeine	586
Mephentermine hemisulfate salt	31,250	Ethylmorphine	200
MDEA	50,000	Hydrocodone	12,500
MDMA	313	Hydromorphone	12,500
PMMA	625	6-Monoacetylmorphine	250
(-)-Ephedrine	2,000	Morphine-3-glucuronid	2,500
Morphine	300	Nalorphine	25,000
Acetylcodeine	150	Thebaine	25,000
Cocaine 300 related compounds			
Benzoylecgonine	300	Ecgonine	100,000
Cocaine	1,000	Ecgonine Methyl Ester	>100,000
Benzodiazepines 200 related compounds			
Oxazepam	200	Lorazepam	5,000
Alprazolam	75	Lormetazepam	100
Bromazepam	200	Midazolam	10,000
Chlordiazepoxide	50	Nitrazepam	100
Clobazam	75	Norchlordiazepoxide	50
Clonazepam	250	Nordiazepam	100
Clorazepate	100	Prazepam	>100,000
Desalkflurazepam	250	Temazepam	50
Diazepam	250	Triazolam	600
Estazolam	250	Escitalopram	>100,000
Flunitrazepam	>50,000		
Flurazepam	>100,000		
Morphine 300 related compounds			
Morphine	300	Ethylmorphine	200
Acetylcodeine	150	Hydrocodone	12,500
Buprenorphine	3,125	Hydromorphone	12,500
Codeine	250	6-Monoacetylmorphine	250
DiacetylMorphin	250	Morphine-3-glucuronid	2,500
Dihydrocodeine	586		
Marijuana 50 related compounds			
11-nor-Δ9-THC-9-COOH	50	Δ9-Tetrahydrocannabinol	15,000
11-nor-Δ8-THC-9-COOH	50	Cannabinol	20,000
11-hydroxy-Δ9-Tetrahydrocannabinol	50	Cannabidiol	>100,000
Δ8-Tetrahydrocannabinol	15,000		

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 Multi-Drug Integrated Split Spec. 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 (Except ACE)	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.
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 device		Use by
	Manufacturer		Do not reuse

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