DrugScreen Cup
Catalogue No. See Box Label

INTENDED USE

The MD DrugScreen Cup 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	Amphetamine	1,000
AMP	Amphetamine	500
BAR	Barbiturate	300
BUP	Buprenorphine	10
BUP	Buprenorphine	5
BZO	Oxazepam	300
COC	Benzoylecgonine	300
COT	(-)-Cotinine	200
EDDP	EDDP	100
KET	Ketamine	1000
MDMA	MDMA	500
MET	Methamphetamine	1,000
MET	Methamphetamine	500
MTD	Methadone	300
OPI/MOP	Morphine	300
OPI2000	Morphine	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1,000
THC	11-nor- Δ9-THC-9-carboxylic acid	50
Adulteration(StripA)	Oxidants / Specific Gravity / PH	
Adulteration(StripB)	Nitrite / Glutaraldehyde / Creatinine	

PRINCIPLE

The MD DrugScreen Cup 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
Procedure cards
Package insert

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.

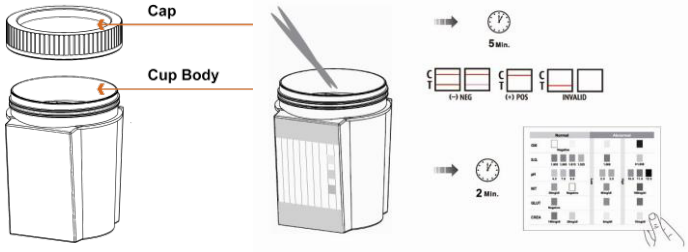
SPECIMEN COLLECTION AND STORAGE

- The MD DrugScreen Cup 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 body label. 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. 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 8 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.



INTERPRETATION OF RESULTS

The Result Of DOA:
(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.

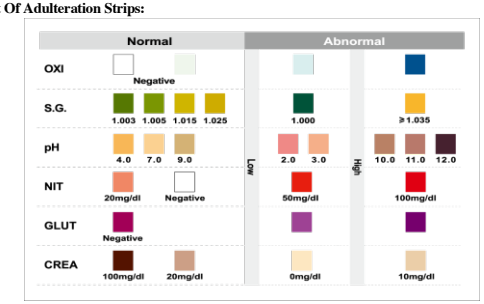
NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

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.

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

The Limitations Of DOA:

1. The MD DrugScreen Cup 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 MD DrugScreen Cup was established by running urine samples against GC/MS.

Specimen	AMP	AMP500	BAR	*BUP10	*BUP5	BZO	COC
Positive	95.8%	95.9%	97.8%	100%	100%	88.6%	98.2%
Negative	100%	100%	98.1%	100%	100%	98.2%	98.1%
Total	98.1%	98.1%	98%	100%	100%	94.9%	98.2%

Specimen	COT	EDDP100	KET	MDMA	MET	MET500	MTD
Positive	97.7%	98.6%	98%	100%	96.8%	96.9%	96.1%
Negative	97.9%	100%	98.6%	100%	100%	100%	100%
Total	98.0%	99.1%	98.3%	100%	98.3%	98.3%	98.1%

Specimen	MOP300	OPI	OXY	PCP	PPX	TCA	THC
Positive	96.8%	97.6%	98%	97.8%	97.8%	92.1%	96.8%
Negative	100%	98.4%	97%	100%	100%	100%	98.3%
Total	98.2%	98.1%	97%	98.9%	99.0%	96.8%	97.5%

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

B. Sensitivity

The sensitivity of the MD DrugScreen Cup 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		AMP500		BAR		BUP		BUP5		BZO	
(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	16	34	14	36	11	39	25	25	21	29	17	33
125% Cutoff	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
3X Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	COC		COT		EDDP100		KET		MDMA		MET	
(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	11	39	13	37	25	25	16	34	25	25	23	27
125% Cutoff	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
3X Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	MET500		MTD		MOP		OPI2000		OXY		PCP	
(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	10	40	6	44	18	32	13	37	19	31	9	41
125% Cutoff	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
3X Cutoff	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	PPX		TCA		THC	
(Cut-off)		-	+	-	+	-	+
Negative	50	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0
Cutoff	50	20	30	9	41	17	33
125% Cutoff	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50
3X Cutoff	50	0	50	0	50	0	50

C. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the MD Drug Screen Cup identified positive results at 5 minutes.

Amphetamine related compounds	
d-Amphetamine	1000
l-Amphetamine	100000
MDA	1250
Phentermine	1250
PMA	625

Nordoxepin hydrochloride	25000
Phencyclidine	5000
Promazine	8000
Promethazine	25000
Methamphetamine related compounds	
d-Methamphetamine	1000

Tyramine	100000
Amphetamine related compounds	
d-Amphetamine	500
l-Amphetamine	50000
3,4-Methylenedioxyamphetamine	625
Phentermine	1250
Paramethoxyamphetamine (PMA)	625
Tyramine	100000
Barbiturates related compounds	
Secobarbital	300
Allobarbital	1250
Alphenal	625
Amobarbital	625
Aprobarbital	188
Butabarbital	94
Butalbital	2500
Butethal	200
Cyclopentobarbital	400
Pentobarbital	1000
Phenobarbital	300
Buprenorphine related compounds	
Buprenorphine	10
Buprenorphine Glucuronide	25
Buprenorphine–3–β–D–Glucuronide	10
Norbuprenorphine	50
Norbuprenorphine–3–β–D–Glucuronide	100
Buprenorphine related compounds	
Buprenorphine	5
Buprenorphine Glucuronide	10
Buprenorphine–3–β–D–Glucuronide	5
Norbuprenorphine	10
Norbuprenorphine–3–β–D–Glucuronide	50
Benzodiazepines related compounds	
Oxazepam	300
Alprazolam	125
Bromazepam	625
Chlordiazepoxide	2500
Clobazam	63
Clonazepam	2500
Clorazepate	3330
Delorazepam	2500
Desalkflurazepam	250
Diazepam	250
Estazolam	5000
Flunitrazepam	375
Lorazepam	1250
Lormetazepam	1250
Midazolam	100000
Nitrazepam	25000
Norchlordiazepoxide	250
Nordiazepam	500
Sulindac	100000
Temazepam	63
Triazolam	5000
Cocaine related compounds	
Benzoylecgonine	300
Cocaine	1000
Ecgonine	100000
Cotinine related compounds	
Cotinine	200
Buprenorphine	100000
EDDP related compounds	
EDDP	100

Chloroquine	25000
Fenfluramine	12500
l-Methamphetamine	10000
Mephentermine hemisulfate salt	31250
MDEA	50000
MDMA	313
PMMA	625
Methamphetamine related compounds	
d-Methamphetamine	500
Chloroquine	12500
Fenfluramine	25000
l-Methamphetamine	3125
Mephentermine hemisulfate salt	25000
3,4-Methylenedioxyethylamphetamine	12500
3,4-Methylenedioxy-methamphetamine	300
Procaine	50000
PMMA	625
Morphine 300 related compounds	
Morphine	300
Acetylcodeine	150
Buprenorphine	3125
Codeine	250
Diacetyl Morphin	250
Dihydrocodeine	586
Ethylmorphine	200
Hydrocodone	12500
Hydromorphone	12500
6-Monoacetylmorphine	250
Morphine-3-glucuronid	2500
Nalorphine	25000
Thebaine	25000
Methadone related compounds	
Methadone	300
(-)-alpha-methadol	2000
Opiates 2000 related compounds	
Morphine	2000
Acetylcodeine	1563
Buprenorphine	25000
Codeine	500
Diacetyl Morphin (Heroin)	1250
Dihydrocodeine	1563
Ethylmorphine	800
Hydrocodone	50000
Hydromorphone	25000
6-Monoacetylmorphine	1250
Morphine-3-β-d-glucuronid	12500
Nalorphine	100000
Thebaine	50000
Oxycodone related compounds	
Oxycodone	100
Codeine	50000
Dihydrocodeine	12500
Ethylmorphine	25000
Hydrocodone	1562
Hydromorphone	12500
Oxymorphone	1562
Thebaine	50000
Phencyclidine related compounds	
Phencyclidine	25
Hydrocodone	12500
Hydromorphone	6250
Propoxyphen related compounds	
D-Propoxyphene	300

Meperidine	100000
Methadone	100000
Norfentanyl	100000
Phencyclidine	100000
Promazine	50000
Promethazine	25000
Prothipendyl	50000
Prozine	12500
Ecstasy related compounds	
3,4-Methylenedioxy-methamphetamine	500
3,4-Methylenedioxyamphetamine	2500
3,4-Methylenedioxyethylamphetamine	156
Paramethoxyamphetamine, Result 1	50000
Paramethoxymethamphetamine	10000
Ketamine related compounds	
Ketamine	1000
Norketamine	1000
Dextromethorphan	500
Dextrorphan tartrate	500
D-Norpropoxyphene	31250
EDDP	800
Meperidine	12500
Mephentermine hemisulfate salt	15625
Methadone	50000
D-Methamphetamine	12500
3,4-Methylenedioxyethylamphetamine	25000

D-Norpropoxyphene	5000
Tricyclic Antidepressants related compounds	
Nortriptyline HCl	1000
Amitriptyline	1500
Clomipramine	100000
Cyclobenzaprine	12500
Desipramine	188
Doxepin	2000
Imipramine	2500
Maprotiline	750
Nortriptyline	3125
Nordoxepin	500
Opipramol	1563
Promazine	1000
Promethazine	6250
Prothipendyl	25000
Protryptyline	6250
Prozine	1250
Trimipramine	100000
Marijuana related compounds	
11-nor-Δ9-THC-9-COOH	50
11-nor-Δ8-THC-9-COOH	50
Δ9-tetrahydrocannabinol	15000
Δ8-tetrahydrocannabinol	15000
Cannabinol	>20000

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 MD Drug Screen Cup when tested at concentrations up to 100 μg/mL.

- Acetaminophen
- Acetone
- Albumin
- Ampicillin
- Aspartame
- Aspirin
- Atropine
- Benzocaine
- Bilirubin
- Caffeine
- Chlorpheniramine
- Creatine
- Dextrorphan tartrate
- 4-Dimethylaminoantipyrine
- Dopamine
- (±)-Ephedrine
- Erythromycin
- Ethanol
- Furosemide
- Guaiacol glyceryl ether
- Hemoglobin
- Ibuprofen
- (±)-Isoproterenol
- Lidocaine
- N-Methyl-ephedrine
- (+)-Naproxen
- Oxalic acid
- Penicillin-G
- Pheniramine
- Phenothiazine
- L-Phenylephrine
- β-Phenylethylamine
- Quinidine
- Ranitidine

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GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

Number: 1110005421
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