

Drugs of Abuse Integrated

Cup (Urine)

MD-U621

For Forensic Use only

INTENDED USE

Quick test cup™ Multi-Drug Urine 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)
ACE	Acetaminophen	5,000
AMP	D-Amphetamine	300/500/1,000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC	Benzoylcegonine	150/300
COT	Cotinine	200
EDDP	EDDP	100
FYL	Fentanyl	200
KET	Ketamine	1,000
MDMA	Ecstasy	500
MET(MAMP)	D-Methamphetamine	300/500/1,000
MTD	Methadone	300
OPI/MOR	Morphine	100/300
OPI2000	Morphine	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1,000
THC	11-nor- Δ^9 -THC-9-COOH	50
HCG	human chorionic gonadotropin	20mIU/mL
ALC	Alcohol	0.02%
Adulteration (StripA)	Oxidants / Specific Gravity / PH	
Adulteration (StripB)	Nitrite / Glutaraldehyde / 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.

Quick test cup™ Multi-Drug Urine Cup 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

Quick test cup™ Multi-Drug Urine 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.

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 membrane by capillary action and interacts with reagents on the membrane. If there is sufficient hCG in the specimen, a colored band will 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 control region 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	Caps
Adulteration Color Chart (when applicable)	Package insert

Materials Required but Not provided

Timer	Centrifuge
Positive and negative controls	

PRECAUTIONS

- 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

- Quick test cup™ Multi-Drug Urine 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.

- Remove the cup from its sealed pouch and use it as soon as possible.
- Donor provides a urine specimen in the cup and screws the cap on to the cup. Start the timer.
- Donor dates and initials the security seal label. Operator checks the cap for tightness and attaches the security seal label over the cap.
- Remove the peel-off label.
- 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).
- 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.
- Positive test results may be confirmed by another test method. By sending the cup and urine specimen intact to a toxicology laboratory for confirmation.



INTERPRETATION OF RESULTS

(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 for DOA test:

- 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.
- 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

C **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).

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

C **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

Paramethoxyamphetamine	625	(-)-Ephedrine	2,000
Tyramine	>100,000	Morphine 300 related compounds	
Amphetamine 300 related compounds		Morphine	300
d-Amphetamine	300	Acetylcodeine	150
l-Amphetamine	50,000	Buprenorphine	3,125
Mephentermine hemisulfate salt	>100,000	Codeine	250
3,4-Methylenedioxyamphetamine (MDA)	625	Diacetyl Morphin	250
Phentermine	625	Dihydrocodeine	586
Paramethoxyamphetamine (PMA)	625	Ethylmorphine	200
Paramethoxymethamphetamine (PMMA)	>100,000	Hydrocodone	12,500
Tyramine	>100,000	Hydromorphone	12,500
Barbiturates 300 related compounds		6-Monoacetylmorphine	250
Secobarbital	300	Morphine-3-glucuronid	2,500
Allobarbitol	1,250	Nalorphine	25,000
Alphenal	625	Thebaine	25,000
Amobarbital	625	Methadone 300 related compounds	
Aprobarbital	188	Methadone	300
Butabarbital	94	(-)-alpha-methadol	2,000
Butalbital	2,500	Opiates 2000 related compounds	
Butethal	200	Morphine	2,000
Cyclopentobarbital	400	Acetylcodeine	1,563
Pentobarbital	1,000	Buprenorphine	25,000
Phenobarbital	300	Codeine	2000
Buprenorphine 10 related compounds		Diacetylmorphine (Heroin)	5,000
Buprenorphine	10	Dihydrocodeine	1,563
Buprenorphine-3-β-D-Glucuronide	10	Ethylmorphine	250
Norbuprenorphine	50	Hydromorphone	25,000
Norbuprenorphine-3-β-D-Glucuronide	100	Hydrocodone	50,000
Benzodiazepines 300 related compounds		Merperidine	>100,000
Oxazepam	300	6-Monoacetylmorphine (6-MAM)	4,000
Alprazolam	125	Morphine-3-β-d-glucuronide	12,500
Bromazepam	625	Nalorphine Hydrochloride	>100,000
Chlordiazepoxide	2500	Oxycodone	>100,000
Clobazam	63	Oxymorphone	>100,000
Clonazepam	250	Rifampicine	>100,000
Clorazepate	3330	Thebaine	50,000
Desalkflurazepam	250	Morphine 300 related compounds	
Diazepam	250	Morphine	300
Estazolam	5000	Acetylcodeine	150
Fentanyl	>100,000	Buprenorphine	3,125
Flunitrazepam	375	Codeine	250
Flurazepam	>100,000	Diacetyl Morphin	250
Lorazepam	1250	Dihydrocodeine	586
Lormetazepam	1250	Ethylmorphine	200
Medazepam	>100,000	Hydrocodone	12,500
Midazolam	>100,000	Hydromorphone	12,500
Nitrazepam	25000	6-Monoacetylmorphine	250
Norchlordiazepoxide	250	Morphine-3-glucuronid	2,500
Nordiazepam	500	Nalorphine	25,000
Prazepam	>100,000	Thebaine	25,000
Temazepam	63	Morphine 100 related compounds	
Triazolam	5000	Morphine	100
Cocaine 300 related compounds		Codeine	100
Benzoylcegonine	300	Diacetylmorphine (Heroin)	100
Cocaine	1,000	Ethylmorphine	100
Ecgonine	100,000	Hydromorphone	500
Ecgonine Methyl Ester	>100,000	Hydrocodone	500
Cocaine 150 related compounds		6-Monoacetylmorphine	100
Benzoylcegonine	150	Morphine-3-β-d-glucuronide	2,000
Cocaine HCl	500	Oxycodone	20,000

Cocaethylene	7500	Oxymorphone	20,000
Ecgoinine	15000	Promethazine	>100,000
Norcocaine	50000	Rifampicine	8,400
Cotinine 200 related compounds		Thebaine	8,400
(-)-Cotinine	200	Trimipramine	20,000
(-)-Nicotine	6,250	Oxycodone 100 related compounds	
EDDP 100 related compounds		Oxycodone	100
EDDP	100	Hydrocodone	25,000
Meperidine	>100,000	Hydromorphone	50,000
Methadone	>100,000	Naloxone	50,000
Norfentanyl	>100,000	Oxymorphone	250
Phencyclidine	>100,000	Phencyclidine 25 related compounds	
Promazine	50,000	Phencyclidine	25
Promethazine	25,000	Hydrocodone	>100,000
Prothipendyl	50,000	Hydromorphone	>100,000
Prozine	12,500	4-hydroxyphencyclidine	75
Fentanyl 200 related compounds		Propoxyphene 300 related compounds	
Fentanyl and Fentanyl metabolites	200	D-Propoxyphene	300
Fentanyl	200	D-Norpropoxyphene	5,000
Norfentanyl	>10,000	Tricyclic Antidepressants related compounds	
Ketamine 1000 related compounds		Nortriptyline HCl	1,000
Ketamine	1000	Amitriptyline	1,500
Norketamine	1000	Clomipramine	>100,000
Dextromethorphan	> 100000	Cyclobenzaprine	12,500
Dextrorphan tartrate	>100000	Desipramine	188
D-Norpropoxyphene	31250	Doxepin	2,000
EDDP	> 100000	Imipramine	2,500
Meperidine	12500	Maprotiline	750
Mephentermine hemisulfate salt	50000	Nortriptyline	3,125
Methadone	12500	Nordoxepin	500
D-Methamphetamine	12500	Opipramol	1,563
3,4-Methylenedioxyethylamphetamine	25000	Promazine	1,000
Nordoxepin hydrochloride	25000	Promethazine	6,250
Phencyclidine	5000	Prothipendyl	25,000
Promazine	8000	Protryptiline	6,250
Promethazine	25000	Prozine	1,250
Ecstasy 500 related compounds		Trimipramine	>100,000
3,4-Methylenedioxy-methamphetamine	500	Marijuana 50 related compounds	
d-Amphetamine	>100,000	11-nor-Δ9-THC-9-COOH	50
l-Amphetamine	>100,000	11-nor-Δ8-THC-9-COOH	50
d-methamphetamine	>100,000	11-hydroxy-Δ9-Tetrahydrocannabinol	50
l-methamphetamine	>100,000	Δ8-Tetrahydrocannabinol	15,000
3,4-Methylenedioxyamphetamine	2,500	Δ9-Tetrahydrocannabinol	15,000
3,4-Methylenedioxyethylamphetamine	156	Cannabinol	20,000
Paramethoxyamphetamine	50,000	Cannabidiol	>100,000
Paramethoxymethamphetamine	>100,000		
Methamphetamine 1000 related compounds			
d-Methamphetamine	1,000		
Chloroquine	25,000		
Fenfluramine	12,500		
l-Methamphetamine	10,000		
Mephentermine hemisulfate salt	31,250		
3,4-Methylenedioxyethylamphetamine	50,000		
3,4-Methylenedioxy-methamphetamine	313		
Paramethoxymethamphetamine	625		
(-)-Ephedrine	4,000		

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 QuickCup 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-Dimethylaminoantipyrine	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)	Lidocaine
Chloroquine (Except MET)		

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	<i>In vitro</i> diagnostic medical cup		Use by
	Manufacturer		Do not reuse

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