One Step 12 Panel DOA Cup (Urine)

INTENDED USE

The One Step 12 Panel DOA 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	1,000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC	Benzoylecgonine	300
MDMA	3,4-Methylenediioxy-MET	500
MET	d-Methamphetamine	1,000
MTD	Methadone	300
OPI2000	Morphine	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
THC	11-nor- Δ9-THC-9-carboxylic acid	50

PRINCIPLE

The One Step 12 Panel DOA 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.

MATERIALS

Materials Provided

Individually packed test cups with integrated drug of abuse test panels

Caps

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.

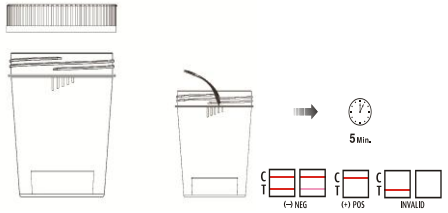
SPECIMEN COLLECTION AND STORAGE

- The One Step 12 Panel DOA Cup (Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

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

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



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:

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.

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.

LIMITATIONS OF THE TEST

1. The One Step 12 Panel DOA 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.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the One Step 12 Panel DOA Cup (Urine) was established by running urine samples against GC/MS.

Specimen	AMP	BAR	BUP10	BZO	COC	MDMA
Positive	95.8%	97.8%	100%	95.3%	98.2%	96.8%
Negative	100%	98.1%	98.1%	92.9%	98.1%	100%
Total	98.1%	98%	99.4%	93.9%	98.2%	98.3%

Specimen	MET	MTD	OPI	OXY	PCP	THC50
Positive	96.8%	96.1%	97.6%	96.1%	97.8%	96.8%
Negative	100%	100%	98.4%	100%	100%	98.3%
Total	98.3%	98.1%	98.1%	98.1%	98.9%	97.5%

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

B. Sensitivity

The sensitivity of The One Step 12 Panel DOA 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. (Cut-off Range)	n	AMP		BAR		BUP10		BZO		COC		MDMA	
		-	+	-	+	-	+	-	+	-	+	-	+
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% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	16	34	11	39	25	25	17	33	11	39	25	25
125% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50
3× Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off Range)	n	MET		MTD		OPI2000		OXY		PCP		THC50	
		-	+	-	+	-	+	-	+	-	+	-	+
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% Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	23	27	6	44	13	37	19	31	9	41	17	33
125% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50
150% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50
3× Cut-off	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 One Step 12 Panel DOA Cup (Urine) identified positive results at 5 minutes.

Amphetamine 1000 related compounds		d-Amphetamine	>100,000
d-Amphetamine	1,000	l-Amphetamine	>100,000
l-Amphetamine	>100,000	d-methamphetamine	>100,000
d-methamphetamine	>100,000	l-methamphetamine	>100,000
l-methamphetamine	>100,000	3,4-Methylenedioxyamphetamine	2,500
3,4-Methylenedioxyamphetamine	1,250	3,4-Methylenedioxyethylamphetamine	156
3,4-Methylenedioxy-methamphetamine	>100,000	Paramethoxyamphetamine	50,000
3,4-Methylenedioxyethylamphetamine	>100,000	Paramethoxymethamphetamine	>100,000
Paramethoxyamphetamine	625	**Methamphetamine 1000 related compounds**	
Phentermine	1,250	d-Methamphetamine	1,000
Tyramine	>100,000	Chloroquine	25,000
Barbiturates 300 related compounds		Fenfluramine	12,000
Secobarbital	300	l-Methamphetamine	10,000
Allobarbital	1,250	Mephentermine hemisulfate salt	31,250
Alphenal	625	3,4-Methylenedioxyethylamphetamine	50,000
Amobarbital	625	3,4-Methylenedioxy-methamphetamin	313
Aprobarbital	188	Paramethoxymethamphetamine	625
Butabarbital	94	(-)-Ephedrine	4,000
Butalbital	2,500	**Methadone 300 related compounds**	
Butethal	200	Methadone	300
Cyclopentobarbital	400	(-)-alpha-methadol	2,000
Pentobarbital	1,000	**Opiates 2000 related compounds**	
Phenobarbital	300	Morphine	2,000
Buprenorphine 10 related compounds		Acetylcodeine	1,563
Buprenorphine	10	Buprenorphine	25,000
Buprenorphine–3–β–D–Glucuronide	10	Codeine	500
Norbuprenorphine	50	Diacetylmorphine (Heroin)	1,250
Norbuprenorphine–3–β–D–Glucuronide	100	Dihydrocodeine	1,563

Benzodiazepines 300 related compounds		Ethylmorphine	800
Oxazepam	300	Hydromorphone	25,000
Alprazolam	125	Hydrocodone	50,000
Bromazepam	625	Merperidine	>100,000
Chlordiazepoxide	2500	6-Monoacetylmorphine	1,250
Clobazam	63	Morphine-3-β-d-glucuronide	12,500
Clonazepam	2500	Nalorphine Hydrochloride	>100,000
Clorazepate	3330	Oxycodone	>100,000
Desalkflurazepam	250	Oxymorphone	>100,000
Diazepam	250	Rifampicine	>100,000
Estazolam	5000	Thebaine	50,000
Fentanyl	>100,000	**Oxycodone 100 related compounds**	
Flunitrazepam	375	Oxycodone	100
Flurazepam	>100,000	Hydrocodone	25,000
Lorazepam	1250	Hydromorphone	50,000
Lormetazepam	1250	Naloxone	50,000
Medazepam	>100,000	Oxymorphone	250
Midazolam	>100,000	**Phencyclidine 25 related compounds**	
Nitrazepam	25000	Phencyclidine	25
Norchlordiazepoxide	250	Hydrocodone	12,500
Nordiazepam	500	Hydromorphone	6,250
Prazepam	>100,000	4-hydroxyphencyclidine	75
Temazepam	63	**Marijuana 50 related compounds**	
Triazolam	5000	11-nor-Δ9-THC-9-COOH	50
Cocaine 300 related compounds		11-nor-Δ8-THC-9-COOH	50
Benzoylecgonine	300	11-hydroxy-Δ9-Tetrahydrocannabinol	50
Cocaine	1,000	Δ8-Tetrahydrocannabinol	15,000
Ecgonine	100,000	Δ9-Tetrahydrocannabinol	15,000
Ecgonine Methyl Ester	>100,000	Cannabinol	20,000
Ecstasy 500 related compounds		Cannabidiol	>100,000
3,4-Methylenedioxy-methamphetamine	500		

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 One Step 12 Panel DOA Cup (Urine) when tested at concentrations up to 100 µg/mL.

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

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

Index of Symbols

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

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