On•Call™ Multi-Drug

One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key ™ Cup (Urine)
Package Insert

REF DOA-127	**REF DOA-157**	**REF DOA-187**	**REF DOA-1117**	**English**
REF DOA-137	**REF DOA-167**	**REF DOA-197**	**REF DOA-1127**	
REF DOA-147	**REF DOA-177**	**REF DOA-1107**		

Package insert for testing of any combination of the following drugs:
Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Phencyclidine and Tricyclic Antidepressants.

A rapid, one step screen test for the simultaneous, qualitative detection of multiple drugs and metabolites in human urine.

For professional in vitro diagnostic use only.

INTENDED USE & SUMMARY

Urine based screen tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key™ Cup (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of following drugs without the need of instruments:[1]

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1,000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	300
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	D-Methamphetamine	1,000
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxymethamphetamine	500
Morphine (MOP 300)	Morphine	300
Opiate (OPI 2000)	Morphine	2,000
Phencyclidine (PCP)	Phencyclidine	25
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is 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 used.

PRINCIPLE

The Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key™ Cup (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a 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 coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

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 or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. 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.

REAGENTS

Each test line in the test panel contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test panel should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test panel is stable through the expiration date printed on the sealed pouch. The test panel must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Cups with multi-drug panels
- Keys
- Security seal labels
- Package insert

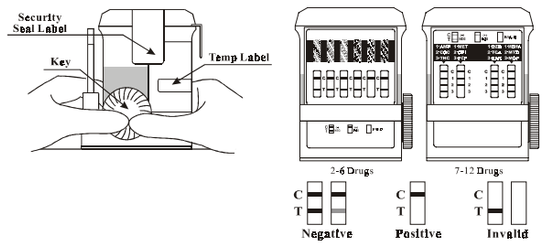
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

Allow the test panel, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. Pull tab to remove cap, **collect specimen in the cup** and secure cap by pressing down on all three corners.
3. **Check the temperature label** (Temp Label) up to 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).
4. Check the cap for a tight seal, date and initial the security seal label, then place it over the cap.
5. Remove one key from the kit, place the cup on a flat surface, and **push the key into the socket** of the cup to begin the test. Start timer.
6. Remove the peel off label covering the test results and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret results after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug.

***NOTE:** The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cup. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key™ Cup (Urine) provides only a preliminary analytical result. A more specific chemical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. [2, 3]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key™ Cup (Urine) and commercially available drug rapid tests. Testing was performed on approximately 300 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

Specimen	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA	MOP 300	OPI 2000	PCP	TCA
Positive	>99%	>99%	99%	>99%	>99%	87%	>99%	96%	95%	98%	99%	92%
Negative	>99%	99%	>99%	99%	99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%
Total	>99%	99%	99%	99%	99%	94%	>99%	98%	98%	99%	99%	98%

% Agreement with GC/MS

Specimen	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA	MOP 300	OPI 2000	PCP	TCA*
Positive	95%	92%	98%	95%	95%	99%	90%	97%	98%	99%	90%	>99%
Negative	99%	98%	98%	>99%	95%	>94%	>99%	99%	97%	99%	99%	94%
Total	97%	95%	98%	98%	95%	>96%	96%	98%	98%	99%	96%	95%

***Note:** TCA was based on HPLC data.

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

Drug Conc. (Cut-off range)	n	AMP		BAR		BZO		COC		THC		MTD	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	29	1
-25% Cut-off	30	24	6	27	3	26	4	25	5	27	3	24	6
Cut-off	30	17	13	22	8	12	18	19	11	14	16	21	9
+25% Cut-off	30	5	25	7	23	3	27	3	27	6	24	2	28
+50% Cut-off	30	0	30	2	28	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MET		MDMA		MOP 300		OPI 2000		PCP		TCA	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	26	4	25	5	25	5	26	4	22	8
Cut-off	30	18	12	17	13	17	13	17	13	14	16	12	18
+25% Cut-off	30	5	25	4	26	1	29	4	26	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following tables lists the concentration of compounds (ng/mL) that are detected positive in urine by the Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key™ Cup (Urine) at 5 minutes.

AMPHETAMINE	
D-Amphetamine	1,000
D,L-Amphetamine sulfate	3,000
L-Amphetamine	50,000
Phentermine	3,000
D,L-3,4-Methylenedioxy-amphetamine	2,000
BARBITURATES	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butethal	100
Butalbital	2,500
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES	
Oxazepam	300
Alprazolam	196
a-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clonazepam HCl	781
Clobazam	98
Clonazepam	781
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500

METHAMPHETAMINE	
D-Methamphetamine	1,000
ρ-Hydroxymethamphetamine	30,000
L-Methamphetamine	8,000
Mephentermine	50,000
D,L-3,4-Methylenedioxy-Methamphetamine	2,000
METHYLENEDIOXYMETHAMPHETAMINE	
3,4–Methylenedioxymethamphetamine HCl (MDMA)	500
3,4–Methylenedioxyamphetamine HCl (MDA)	3,000
3,4–Methylenedioxyethylamphetamine (MDE)	300
MORPHINE 300	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphone	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2000	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000

Flunitrazepam	390
D,L- Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
COCAINE	
Benzoylecgonine	300
Cocaine HCl	780
Cocaethylene	12,500
Ecgonine HCl	32,000
MARIJUANA	
11-nor-Δ^9 -THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8 –THC	15,000
Δ^9 –THC	15,000
METHADONE	
Methadone	300
Doxylamine	50,000

6-Monoacetylmorphine	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphone	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
PHENCYCLIDINE	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
TRICYCLIC ANTIDEPRESSANTS	
Notriptyline	1,000
Nordoxepine	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepine	2,000
Maprotiline	2,000
Promethazine	25,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Phencyclidine, Tricyclic Antidepressants positive urine. The following compounds show no cross-reactivity when tested with the Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key™ Cup (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Creatinine	Loperamide	Quinidine
N-Acetylprocainamide	Deoxycorticosterone	Meprobamate	Quinine
Acetylsalicylic acid	Dextromethorphan	Methoxyphenamine	Ranitidine
Aminopyrine	Diclofenac	Nalidixic acid	Salicylic acid
Amoxicillin	Diflunisal	Naloxone	Serotonin
Ampicillin	Digoxin	Naltrexone	Sulfamethazine
L-Ascorbic acid	Diphenhydramine	Naproxen	Sulindac
Apomorphine	L-Ψ-Ephedrine	Niacinamide	Tetracycline
Aspartame	Ecgonine methylester	Nifedipine	Tetrahydrocortisone,
Atropine	Ethyl-p-aminobenzoate	Norethindrone	3-Acetate
Benzilic acid	β-Estradiol	D-Norpropoxyphene	Tetrahydrocortisone
Benzoic acid	Estrone-3-sulfate	Noscapine	3-(β-D-glucuronide)
Benzphetamine	Erythromycin	D,L-Octopamine	Tetrahydrozoline
Bilirubin	Fenoprofen	Oxalic acid	Thiamine
D,L-Brompheniramine	Furosemide	Oxolinic acid	Thioridazine
Caffeine	Gentisic acid	Oxymetazoline	D,L-Tyrosine
Cannabidiol	Hemoglobin	Papaverine	Tolbutamide
Chloralhydrate	Hydralazine	Penicillin-G	Triamterene
Chloramphenicol	Hydrochlorothiazide	Perphenazine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Phenelzine	Trimethoprim
D,L-Chlorpheniramine	O-Hydroxyhippuric acid	L-Phenylephrine	Tyramine
Chlorpromazine	3-Hydroxytyramine	β-Phenylethylamine	D,L-Tryptophan
Chlorquine	D,L-Isoproterenol	Phenylpropanolamine	Uric acid
Cholesterol	Isoxsuprine	Prednisone	Verapamil
Clonidine	Ketamine	D,L-Propanolol	Zomepirac
Cortisone	Ketoprofen	D-Propoxyphene	
L-Cotinine	Labetalol	D-Pseudoephedrine	

BIBLIOGRAPHY

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2. Baselt RC. Disposition of Toxic Multi-Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

Manufacturer

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acc.to IVDD 98/79/EC
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