

**Nova Century Scientific**  
**One Step Multi-Line Screen**  
**Test Device (Urine)**

(Cat. Number: DOA-1115, 25 Tests )

*Package insert for testing combinations of the following drugs: Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Oxycodone, and Tricyclic Antidepressants. A rapid one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. For medical and other professional in vitro diagnostic use only. For Laboratory Use Only*

**INTENDED USE AND SUMMARY**

Urine-based 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 Device (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1,000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoyllecgonine	300
Marijuana (THC)	11-nor- $\Delta^9$ -THC-9 COOH	50
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	D-Methamphetamine	1,000
Morphine (MOP 300)	Morphine	300
Methylenedioxymethamphetamine (MDMA)	DMethylenedioxymethamphetamine	500
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Oxycodone (OXY)	Oxycodone	100

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. 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 Device (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. The antibody will then react with the drug protein conjugate and a visible coloured line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the coloured line will not form in the test region. A drug-positive urine specimen will not generate a coloured 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 of the strip because of the absence of drug competition. To serve as a procedural control, a coloured line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**REAGENTS**

The test device contains mouse monoclonal antibody-coupled particles and drug-protein conjugates. A gold antibody is employed in the control line system.

**PRECAUTIONS**

For medical and other professional in vitro use only. Do not use after the expiration date. The test device 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 device should be discarded according to local regulations.

**STORAGE AND STABILITY**

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device 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 testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

**MATERIALS PROVIDED**

- Test devices
- Package insert

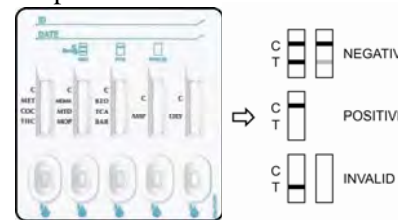
**MATERIALS REQUIRED BUT NOT PROVIDED**

- Specimen Container
- Timer

**DIRECTIONS FOR USE**

**Allow the test device, 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 test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approx. 100  $\mu$ L total volume) to each specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored lines(s) to appear. The results should be **read at 5 minutes**. Do not interpret results after 10 minutes



**INTERPRETATION OF RESULTS**

(Please refer to the illustration Below)

**NEGATIVE:**\* A colored line in the control region (C) and a colored line in the test region (T) for a specific drug indicates 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 region (C) but no line in the test 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

Specimen	AMP	BAR	BZ O	COC	THC	MTD	MET	MDM A	MOP 300	OPI 2000	PCP	TCA
Positive	>99 %	98%	99%	>99 %	>99%	87%	>99%	98%	95%	99%	>99%	92%
Negative	>99 %	>99 %	>99 %	99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%
Total	>99 %	99%	99%	99%	>99%	94%	>99%	99%	97%	99%	>99%	98%

panel. 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 red line appearing in the control 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 Device (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS)<sup>1,2,3</sup> is the preferred confirmatory method.
2. There is a possibility 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 does not indicate level or 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.

## PERFORMANCE CHARACTERISTICS

### Accuracy

A side-by-side comparison was conducted using the Multi-Drug One Step Multi-Line Screen Test Device (Urine) and a commercially available drug rapid test. Testing was performed on approximately 1,000 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. Negative urine specimens were screened initially by Predicate test, 10% negative specimens were confirmed by GC/MS. The following results were tabulated:

### % Agreement with Commercial Kit % Agreement with GC/MS

Specimen	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA	MOP	OPI	PCP	TCA*
Positive	94%	92%	99%	95%	95%	93%	90%	99%	98%	99%	90%	>99%
Negative	99%	99%	98%	>99%	96%	>99%	>99%	97%	97%	99%	99%	94%
Total	97%	96%	98%	98%	95%	97%	95%	98%	97%	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  $\pm 50\%$  cut-off and  $\pm 25\%$  cut-off. The results are summarized below.

Drug conc. (Cut-off)	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	30	0
-25% Cut-off	30	26	4	23	7	24	6	25	5	24	6	26	4
Cut-off	30	23	7	14	16	15	15	20	10	15	15	13	17
+25% Cut-off	30	7	23	7	23	6	24	5	25	6	24	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off)	n	MET		MOP		PCP		TCA	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	20	10	26	4	25	5
Cut-off	30	23	7	18	12	19	11	13	17
+25% Cut-off	30	6	24	7	23	5	25	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30

Eighty (80) specimens for each drug test were also run using the Multi-drug One Step Screen Test Device (Urine) by an untrained operator at a physician's office. Based on GC/MS data, the operator obtained a statistically similar positive agreement, negative agreement and overall agreement rate as the laboratory personnel.

### ANALYTICAL SPECIFICITY

The following list contains the concentration

of compounds (ng/mL) that are detected positive in urine by the Multi-Drug One Step Screen Test Device (Urine) at 5 minutes.

### Compound ng/mL

#### AMPHETAMINE (AMP)

D-Amphetamine 1,000  
D,L-Amphetamine 3,000  
L-Amphetamine 50,000  
3,4-Methylenedioxyamphetamine 2,000  
Phentermine 3,000

#### BARBITURATES (BAR)

Secobarbital 300  
Amobarbital 300  
Alphenol 150  
Aprobarbital 200  
Butobarbital 75  
Butalbital 2,500  
Butethal 100  
Cyclopentobarbital 600  
Pentobarbital 300  
Phenobarbital 100

#### BENZODIAZEPINES (BZO)

Oxazepam 300  
Alprazolam 196  
a-Hydroxyalprazolam 1,262  
Bromazepam 1,562  
Chlordiazepoxide 1,562  
Clobazam 98  
Clonazepam 781  
Clorazepate 195  
Delorazepam 1,562  
Desalkylflurazepam 390  
Diazepam 195  
Estazolam 2,500  
Flunitrazepam 390  
( $\pm$ ) Lorazepam 1,562  
RS-Lorazepam glucuronide 156  
Midazolam 12,500  
Nitrazepam 98  
Norchlordiazepoxide 195  
Nordiazepam 390  
Temazepam 98  
Triazolam 2,500

#### COCAINE (COC)

Benzoyllecgonine 300  
Cocaine 760  
Cocaethylene 12,500  
Ecgonine 32,000  
**MARIJUANA (THC)**  
11-nor- $\Delta^9$ -THC-9 COOH 50  
Cannabinol 20,000  
11-nor- $\Delta^8$ -THC-9 COOH 30  
 $\Delta^8$ -THC 15,000  
 $\Delta^9$ -THC 15,000

#### METHADONE (MTD)

Methadone 300  
Doxylamine 50,000

#### METHAMPHETAMINE (MET)

d-Methamphetamine 1,000

p-Hydroxymethamphetamine 30,000

l-Methamphetamine 8,000

Mephentemine 50,000

3,4-Methylenedioxyamphetamine 2,000

#### METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

3,4-Methylenedioxyamphetamine 500  
3,4-Methylenedioxyamphetamine 3,000  
3,4-Methylenedioxyethylamphetamine 300

#### MORPHINE (MOP)

Morphine 300  
Codeine 300  
Ethylmorphine 6,250  
Hydrocodone 50,000  
Hydromorphone 3,125  
Levorphanol 1,500  
6-Monoacetylmorphine 400  
Morphine 3- $\beta$ -D-glucuronide 1,000  
Norcodeine 6,250  
Normorphine 100,000  
Oxycodone 30,000  
Oxymorphone 100,000  
Procaine 15,000  
Thebaine 6,250

#### TRICYCLIC ANTIDEPRESSANTS

Nortriptyline 1,000  
Nordoxepin 1,000  
Trimipramine 3,000  
Amitriptyline 1,500  
Promazine 1,500  
Desipramine 200  
Imipramine 400  
Clomipramine 12,500  
Doxepin 2,000  
Maprotiline 2,000  
Promethazine 25,000  
**OXYCODONE (OXY)**  
Oxycodone 100  
Naloxone 37,500  
Naltrexone 37,500  
Levorphanol 6,250  
Hydrocodone 6,250

### 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, Morphine 300, Opiates 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 Device at a concentration of 100  $\mu$ g/mL.

### NON CROSS-REACTING COMPOUNDS

Acetaminophen	Cortisone	Ketoprofen	D-Propoxyphene
Acetophenetidin	L-Cotinine	Labetalol	D-
N-	Creatinine	Loperamide	Ouinidine
Acetylsalicylic	Deoxycorticoster	Menrobamate	Ouinine
Aminonvrine	Dextromethorpha	Methoxyphenami	Ranitidine
Amitriptyline	Diclofenac	Nalidixic acid	Salicylic acid
Amoxicillin	Diflunisal	Naloxone	Serotonin
Amicillin	Digoxin	Naltrexone	Sulfamethazine
L-Ascorbic acid	Diphenhydramin	Naroxen	Sulindac
Anomorphine	L- $\Psi$ -Ephedrine	Niacinamide	Hydrochloride
Aspartame	Ecgonine	Nifedipine	Tracrycline
Atropine	Ethyl-r-	Norethindrone	Tetrahydrocortis
Benzilic acid	$\beta$ -Estradiol	D-	3-acetate
Benzoic acid	Estrone-3-sulfate	Noscapine	Tetrahydrocortis
Benzphetamine	Ervthromycin	DL-Octonamine	3-( $\beta$ -D-
Bilirubin	Fenoprofen	Oxalic acid	Tetrahydrozoline
D.L-	Furosemide	Oxolinic acid	Thiamine
Caffeine	Gentisic acid	Oxymetazoline	Thioridazine
Cannabidiol	Hemoglobin	Papaverine	D.L-Tvrosine
Chloralhydrate	Hydralazine	Penicillin-G	Tolbutamide
Chloramphenicol	Hydrochlorothiaz	Perphenazine	Triamterene
Chlorothiazide	Hydrocortisone	Phenelzine	Trifluoperazine
D.L-	O-	L-Phenylephrine	Trimethoprim
Chlorpromazine	$\beta$ -	Tvramine	
Chloroquine	D.L-	Phenylbronanola	D.L-Trvptohan
Cholesterol	Isoxsuprine	Prednisolone	Uric acid
Clonidine	Ketamine	Prednisone	Verapamil
		D.L-Propranolol	Zomepirac

### BIBLIOGRAPHY

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- Tietz NW. *Textbook of Clinical Chemistry*. W.B. Saunders Company, 1986; 1735
- Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*, 2<sup>nd</sup> Ed. Biomedical Publ., Davis, CA, 1982; 488



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