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.

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)	Benzoylecgonine	300
Marijuana (THC)	11-nor-Δ^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
stip 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

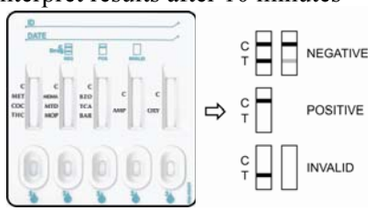
MATERIALS REQUIRED BUT NOT PROVIDED

- 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 µL 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 © 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 © 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 panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

Specimen	AMP	BAR	BZO	COC	THC	MTD	MET	MDMA	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%

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region © 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) is the preferred confirmatory method.[1,2,3]
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 300	OPI 2000	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 ± 50% cut-off and ± 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
Butabarbital 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
(±) Lorazepam 1,562
RS-Lorazepam glucuronide 156
Midazolam 12,500
Nitrazepam 98
Norchlordiazepoxide 195
Nordiazepam 390
Temazepam 98
Triazolam 2,500
COCAINE (COC)
Benzoylecgonine 300
Cocaine 760
Cocaethylene 12,500
Ecgonine 32,000
MARIJUANA (THC)
11-nor-Δ9-THC-9 COOH 50
Cannabinol 20,000
11-nor-Δ8-THC-9 COOH 30
Δ8-THC 15,000
Δ9-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-Methylenedioxymethamphetamine 2,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)
3,4-Methylenedioxymethamphetamine 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-β-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, Methylenedioxymethamphetamine, 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 µg/mL.

NON CROSS-REACTING COMPOUNDS

Acetaminophen	Cortisone	Ketoprofen	D-Propoxyphene
Acetophenetidin	L- Cotinine	Labetalol	D-
N-	Creatinine	Loperamide	Quinidine
Acetylsalicylic	Deoxycorticoster	Meprobamate	Quinine
Aminopyrine	Dextromethorpha	Methoxyphenami	Ranitidine
Amitryptyline	Diclofenac	Nalidixic acid	Salicylic acid
Amoxicillin	Diflunisal	Naloxone	Serotonin
Ampicillin	Digoxin	Naltrexone	Sulfamethazine
L-Ascorbic acid	Diphenhydramin	Naproxen	Sulindac
Apomorphine	L-Ψ-Ephedrine	Niacinamide	Hydrochloride
Aspartame	Ecgonine	Nifedipine	Tetracycline
Atropine	Ethyl-p-	Norethindrone	Tetrahydrocortis
Benzilic acid	ß-Estradiol	D-	3-acetate
Benzoic acid	Estrone-3-sulfate	Noscapine	Tetrahydrocortis
Benzphetamine	Erythromycin	DL-Octopamine	3-(ß-D-
Bilirubin	Fenoprofen	Oxalic acid	Tetrahydrozoline
D,L-	Furosemide	Oxolinic acid	Thiamine
Caffeine	Gentisic acid	Oxymetazoline	Thioridazine
Cannabidiol	Hemoglobin	Papaverine	D,L-Tyrosine
Chloralhydrate	Hydralazine	Penicillin-G	Tolbutamide
Chloramphenicol	Hydrochlorothiaz	Perphenazine	Triamterene
Chlorothiazide	Hydrocortisone	Phenelzine	Trifluoperazine
D,L-	O-	L-Phenylephrine	Trimethoprim
Chlorpromazine	3-	ß-	Tyramine
Chloroquine	D,L-	Phenylpropanola	D,L-Tryptophan
Cholesterol	Isoxsuprine	Prednisolone	Uric acid
Clonidine	Ketamine	Prednisone	Verapamil
		D,L-Propranolol	Zomepirac

BIBLIOGRAPHY

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4. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488

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