MD-U59

Multi-Drug Test Panel (Urine)

For professional *in vitro* diagnostic use only.

INTENDED USE

The Multi-Drug Test Panel (Urine) is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of one to nine of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

Test	Calibrator	Cut-off (ng/mL)
AMP	d-Amphetamine	500
BZO	Oxazepam	300
COC	Benzoylecgonine	150
ETG	Ethyl Glucuronide	500
MET	D-Methamphetamine	500
MQL	Methaqualone	300
MTD	Methadone	300
OPI	Morphine	2000
THC	11-nor-△9-THC-9-COOH	50

The DOA test is used to obtain visual qualitative result and is intended to assist in the determination of drug compliance.

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.

PRINCIPLE

The Multi-Drug Test Panel (Urine) is one-step immunoassay in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs which may be present in urine. The test membrane strips are pre-coated with drug-protein conjugates on the test band(s). For each strip, the drug antibody-colloidal gold conjugate pad is placed at one end of the membrane. In the absence of drug in the urine, the solution of the colored antibody-colloidal gold conjugate move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugate then attach to the drug-protein conjugates to form visible lines as the antibody complex with the drug conjugate. Therefore, the formation of the visible precipitant in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugate on the test band region for the limited antibody. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

A control band with a different antigen/antibody reaction is added to the immune-chromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test strip should be discarded.

REAGENTS AND MATERIALS

Materials Provided

- Multi-Drug Test Panel (Urine)
- Product Insert

Materials Required but Not provided

- Specimen collection container
- Timer
- Positive and negative urine 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℃ 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

Urine Collection: The Multi-Drug Test Panel (Urine) is formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. 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 clear specimen for testing.

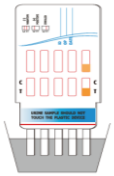
Urine Storage: It is recommended the collected fresh urine to be tested immediately. Fresh urine maybe stored at room temperature (25℃; 77℉) for up to 4 hours or to be refrigerated (2-8℃; 36-86℉) for up to 48 hours prior to performing the test. For prolonged storage, specimens may be frozen and stored below -20℃ (-4℉). Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

PROCEDURE

IMPORTANT Test device, patient's sample, and controls should be brought to room temperature (15-30℃; 59-86℉) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Dip the sample pad area of the dipstick strip or dipstick card in the urine specimen submerging only up to the "MAX" mark of the dipstick strip or the edge of the dipstick card.
3. The drug strip result(s) should be read at 5 minutes. However, negative results may be read and reported as early as 3 minutes but positive results must be reported at 5 minutes only. Do not interpret the drug strip result(s) after 10 minutes after the addition of sample.



INTERPRETATION OF RESULTS

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

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).

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 should be considered negative. 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 Multi-Drug Test Panel (Urine) is for laboratory in vitro diagnostic use, and should be only used for the qualitative detection of drugs of abuse.
2. The assay is designed for use with human urine only.
3. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
4. There is a possibility that technical or procedural error as well other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce either positive results, or that do not interfere with test performance.
5. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

PERFORMANCE CHARACTERISTICS

A. Accuracy

Accuracy of The Multi-Drug Test Panel (Urine) was established by running urine sample against GC/MS specification. The following results were tabulated:

Specimen	AMP500	BZO300	COC150	ETG500	MET500
Positive	95.9%	95.3%	96%	79.7%	96.9%
Negative	100%	92.9%	94%	84.7%	100%
Total	98.1%	93.9%	95%	82.2%	98.3%

Specimen	MQL300	MTD300	MTD200	OPI2000	THC50
Positive	98.4%	96.1%	97.3%	97.6%	96.8%
Negative	98%	100%	100%	98.4%	98.3%
Total	98.2%	98.1%	98.7%	98.1%	97.5%

B. Sensitivity

The sensitivity of The Multi-Drug Test Panel (Urine) was determined by tested GC/MS confirmed controls to the concentration at negative, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3 times of cutoff. The results are summarized below:

Drug Conc.	n	AMP500		BZO300		COC150		ETG500		MET500	
(Cut-off)		-	+	-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	47	3	50	0
75% Cutoff	50	50	0	50	0	50	0	42	8	50	0
Cutoff	50	14	36	17	33	24	26	18	32	10	40
125% Cutoff	50	0	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50	0	50
3✕Cutoff	50	0	50	0	50	0	50	0	50	0	50

Drug Conc.	n	MQL300		MTD300		OPI2000		THC50	
(Cut-off)		-	+	-	+	-	+	-	+
Negative	50	50	0	50	0	50	0	50	0
50% Cut-off	50	50	0	50	0	50	0	50	0
75% Cutoff	50	50	0	50	0	50	0	50	0
Cutoff	50	14	36	6	44	23	27	17	33
125% Cutoff	50	0	50	0	50	0	50	0	50
150% Cutoff	50	0	50	0	50	0	50	0	50
3✕Cutoff	50	0	50	0	50	0	50	0	50

C. Specificity

The following tables list the concentrations of compounds (ng/mL) above which The Multi-Drug Test Panel (Urine) identified positive results at 5 minutes.

AMP 500 related compounds	**Concentration (ng/mL)**
d-Amphetamine	500
l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine	625
Phentermine	1,250
Paramethoxyamphetamine	625
Tyramine	>100,000
BZO 300 related compounds	
Oxazepam	300

Alprazolam	125
Bromazepam	625
Chlordiazepoxide	2,500
Clobazam	63
Clonazepam	2,500
Clorazepate	3,330
Desalkflurazepam	250
Diazepam	250
Estazolam	5,000
Fentanyl	>100,000
Flunitrazepam	375
Flurazepam	>100,000
Lorazepam	1,250
Lormetazepam	1,250
Medazepam	>100,000
Midazolam	>100,000
Nitrazepam	25,000
Norchlordiazepoxide	250
Nordiazepam	500
Prazepam	>100,000
Temazepam	63
Triazolam	5,000
COC 150 related compounds	
Benzoylecgonine	150
Cocaine	125
Ecgonine	10,000
Ecgonine Methyl Ester	>10,000
ETG 500 related compounds	
Ethyl Glucuronide	500
Ethanol	>100,000
D-Glucuronic Acid	>100,000
Morphine-3-D-glucuronide	>100,000
MET 500 related compounds	
d-Methamphetamine	500
Chloroquine	12,500
Fenfluramine	12,500
l-Methamphetamine	3,125
Mephentermine hemisulfate salt	25,000
MDEA	12,500
MDMA	1,875
PMMA	625
(-)-Ephedrine	2,000
MQL 300 related compounds	
Methaqualone	300
Amitriptyline	50,000
Carbamazepine	20,000
Nortriptyline	50,000
Phenytoin	40,000
Theophylline	40,000
MTD 300 related compounds	
Methadone	300
(-)-alpha-methadol	2,000
OPI 2000 related compounds	
Morphine	2,000
Acetylcodeine	1,563
Buprenorphine	25,000
Codeine	2,000
Diacetylmorphine (Heroin)	5,000
Dihydrocodeine	1,563
Ethylmorphine	250
Hydromorphone	25,000
Hydrocodone	50,000
Merperidine	>100,000
6-Monoacetylmorphine (6-MAM)	4,000
Morphine-3-β-d-glucuronide	12,500
Nalorphine Hydrochloride	>100,000
Oxycodone	>100,000
Oxymorphone	>100,000
Rifampicine	>100,000
Thebaine	50,000
THC 50 related compounds	
11-nor-Δ^9-THC-9-COOH	50
11-nor-Δ^8-THC-9-COOH	50
11-hydroxy-Δ^9-Tetrahydrocannabinol	50
Δ^8-Tetrahydrocannabinol	15,000
Δ^9-Tetrahydrocannabinol	15,000
Cannabinol	20,000
Cannabidiol	>100,000

Non Cross-Reacting Compounds

The following compounds were found not to cross-react when tested at concentrations at 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	L-Phenylephrine
Acetone	Erythromycin	Procaine
Albumin	Ethanol	Protonix
Amitriptyline	Furosemide	Pseudoephedrine
Ampicillin	Glucose	Quinidine
Aspartame	Guaiacol Glyceryl Ether	Ranitidine
Aspirin	Hemoglobin	Sertraline
Atropine	Ibuprofen	Tyramine
Benzocaine	Imipramine	Vitamin C (Ascorbic Acid)
Bilirubin	(+/-)-Isoproterenol	Trimeprazine
b-Phenylethyl-amine	Lidocaine	Venlafaxine
Caffeine	Methadone (Except MTD)	Ibuprofen
Chloroquine	N-Methyl-Ephedrine	

LITERATURE **REFERENCES**

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

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