ACESO Laboratories Inc. ™ Multi-Drug Test (Urine)

Package Insert

English

Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BZO/BUP/COC/THC/MTD/MET/MDMA/OPI/TML/K2/LSD/MDPV/α-PVP

INTENDED USE

The Multi-Drug Test is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	1,000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylecgonine	300
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	d-Methamphetamine	500
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxy-methamphetamine	500
Morphine/Opiate (MOP/OPI)	Morphine	300
Tramadol (TML)	Cis-Tramadol	200
Synthetic Marijuana (K2)	JWH-018、JWH-073	50
Lysergic Acid Diethylamide (LSD)	Lysergic Acid Diethylamide	50
3, 4-methylenedioxypyrovalerone (MDPV)	3, 4-methylenedioxypyrovalerone	1,000
Alpha-Pyrrolidinovalerophenone (α-PVP)	Alpha-Pyrrolidinovalerophenone	1,000

Configurations of the Multi-Drug Test come with any combination of the above listed drug analytes. This assay provides only a preliminary 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 indicated.

The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis. For laboratory professional *in vitro* diagnostic use only. The Multi-Drug Test should only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. The test 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 should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The Test 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 should 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 specimen 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

Materials Provided

- Test Dip cards
- Package Insert

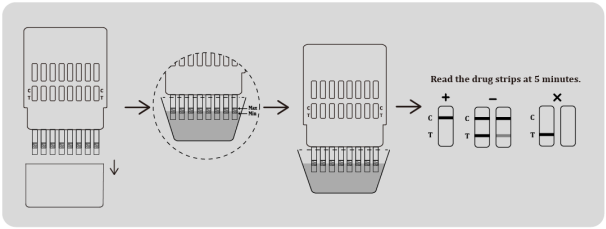
Materials Required But Not Provided

- Timer
- Specimen collection containers

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test dip card from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test dip card vertically in the urine specimen for at least 10 to 15 seconds. **Immerse the dipstick to at least the level of the wavy lines, but not above the arrow on the test dip card.**
4. Replace the cap and place the test dip card on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. The drug strip result should be read at **5 minutes**. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A colored line appears in the control region (C) and another colored line appears in the test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

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

POSITIVE: A colored line appears in the control region (C) and no line appears in the test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test. If the result is still invalid, contact your manufacturer.

PRINCIPLE

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 colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

QUALITY CONTROL

A procedural control is included in the test. A 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 Test provides only a qualitative, preliminary 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]
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. A positive result does not indicate level or intoxication, administration route or concentration in urine.
4. 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.
5. This test does not distinguish between drugs of abuse and certain medications.
6. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

% Agreement with GC/MS

	AMP 1,000	BAR 300	BZO 300	BUP 10	COC 300	THC 50	MTD 300	MET 500
Positive Agreement	98.1%	96.1%	98.4%	99.1%	98.2%	97.9%	98.9%	97.6%
Negative Agreement	97.9%	98.6%	99.2%	>99.9%	97.8%	98.1%	98.8%	97.0%
Total Results	98.0%	97.6%	98.8%	99.6%	98.0%	98.0%	98.8%	97.2%

	MDMA 500	MOP/ OPI	TML 200	K2 50	LSD 50	MDPV 1,000	α-PVP 1,000
Positive Agreement	98.1%	95.0%	88.2%	97.5%	94.1%	93.3%	92.1%
Negative Agreement	99.3%	95.3%	96.2%	98.2%	98.5%	98.6%	96.8%
Total Results	98.8%	95.2%	93.2%	98.0%	97.0%	97.0%	95.0%

% Agreement with Commercial Kit

	AMP 1,000	BAR 300	BZO 300	BUP 10	COC 300	THC 50	MTD 300	MDMA 500
Positive Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Negative Agreement	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%
Total Results	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%	>99.9%

	MOP/ OPI 300	MET 500	TRA 200	MDPV 1,000	K2-50	α-PVP 1,000	LSD 50
Positive Agreement	>99.9%	>99.9%	*	*	*	*	*
Negative Agreement	>99.9%	>99.9%	*	*	*	*	*
	>99.9%	>99.9%					

*Note: Based on GC/MS data instead of Commercial Kit.

Precision

A study was conducted at three hospitals using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of negative, 50% and 25% cut-off level, was labeled, blinded and tested at each site. **The results gained ≧75% accuracy in ±25% cut-off level specimen and 100% accuracy in negative and ±50% cut-off level specimen.**

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

Drug Concentration	AMP 1,000		BAR 300		BZO 300		BUP 10		COC 300		THC 50		MTD 300	
Cut-off Range	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	26	4	27	3	27	3	26	4	26	4	26	4	27	3

Cut-off	15	15	15	15	15	15	14	16	13	17	15	15	13	17	
+25% Cut-off	3	27	4	26	3	27	3	27	3	27	3	27	4	26	
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	
300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	

Drug Concentration Cut-off Range	MET 500		MDMA 500		MOP/ OPI 300		TML 200		K2 50		LSD 50		MDPV 1,000		α-PVP 1,000	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	27	3	25	5	26	4	27	3	26	4	27	3	26	4	26	4
Cut-off	15	15	14	16	15	15	15	15	15	15	14	16	14	16	15	15
+25% Cut-off	4	26	4	26	3	27	4	26	3	27	3	27	3	27	3	27
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the Multi-Drug Test at 5 minutes.

Analytes	**conc. (ng/mL)**	**Analytes**	**conc. (ng/mL)**
AMPHETAMINE (AMP 1,000)			
D,L-Amphetamine sulfate	300	Phentermine	1,000
L-Amphetamine	25,000	Maprotiline	50,000
(±) 3,4-Methylenedioxy amphetamine	500	Methoxyphenamine	6,000
		D-Amphetamine	1,000
BARBITURATES (BAR 300)			
Amobarbital	5,000	Alphenol	600
5,5-Diphenylhydantoin	8,000	Aprobarbital	500
Allobarbital	600	Butabarbital	200
Barbital	8,000	Butalbital	8,000
Talbutal	200	Butethal	500
Cyclopentobarbital	30,000	Phenobarbital	300
Pentobarbital	8,000	Secobarbital	300
BENZODIAZEPINES (BZO 300)			
Alprazolam	100	Bromazepam	900
a-hydroxyalprazolam	1,500	Chlordiazepoxide	900
Clobazam	200	Nitrazepam	200
Clonazepam	500	Norchlordiazepoxide	100
Clorazepatedipotassium	500	Nordiazepam	900
Delorazepam	900	Oxazepam	300
Desalkylflurazepam	200	Temazepam	100
Flunitrazepam	200	Diazepam	300
(±) Lorazepam	3,000	Estazolam	6,000
RS-Lorazepamglucuronide	200	Triazolam	3,000
Midazolam	6,000		
BUPRENORPHINE (BUP 10)			
Buprenorphine	10	Norbuprenorphine	50
Buprenorphine 3-D-Glucuronide	50	Norbuprenorphine 3-D-Glucuronide	100
COCAINE (COC 300)			
Benzoylecgonine	300	Cocaethylene	20,000
Cocaine HCl	200	Ecgonine	30,000
MARIJUANA (THC 50)			
Cannabinol	35,000	Δ^8-THC	17,000
11-nor-Δ^8-THC-9 COOH	30	Δ^9-THC	17,000
11-nor-Δ^9-THC-9 COOH	50		
METHADONE (MTD 300)			
Methadone	300	Doxylamine	100,000
METHAMPHETAMINE (MET 500)			
ρ-Hydroxymethamphetamine	12,500	(±)-3,4-Methylenedioxy-methamphetamine	6,250
D-Methamphetamine	500		
L-Methamphetamine	10,000	Mephentermine	25,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA 500) Ecstasy			
(±) 3,4-Methylenedioxy-methamphetamine HCl	500	3,4-Methylenedioxyethyl-amphetamine	300
(±) 3,4-Methylenedioxyam-phetamine HCl	3,000		
MORPHINE (MOP/OPI 300)			
Codeine	200	Norcodeine	6,000
Levorphanol	1,500	Normorphone	50,000
Morphine-3-β-D-Glucuronide	800	Oxycodone	30,000
Ethylmorphine	6,000	Oxymorphone	50,000
Hydrocodone	50,000	Procaine	15,000
Hydromorphone	3,000	Thebaine	6,000
6-Monoacethylmorphine	300	Morphine	300
TRAMADOL (TML 200)			
n-Desmethyl-cis-tramadol	400	o-Desmethyl-cis-tramadol	20,000
Cis-tramadol	200	Phencyclidine	200,000
Procyclidine	200,000	d,l-O-Desmethyl venlafaxine	100,000
SYNTHETIC MARIJUANA (K2-50)			
JWH-018 5-Pentanoic acid	50	JWH-073 4-butanoic acid	50
JWH-018 4-Hydroxypentyl	400	JWH-018 5-Hydroxypentyl	500
JWH-073 4-Hydroxybuty	500		
LYSERGIC ACID DIETHYLAMIDE (LSD 50)			
Lysergic Acid Diethylamide	50		
3, 4-METHYLENEDIOXYPYROVALERONE (MDPV 1,000)			
3, 4-methylenedioxy-pyrovalerone	1,000		
ALPHA-PYRROLIDINOVALEROPHENONE (α-PVP 1,000)			
Alpha-Pyrrolidinova-lerophenone	1,000		

Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Zomepirac	Quinidine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Salicylic acid
Aminopyrine	Dextromethorphan	Loperamide	Serotonin
Amoxicillin	Diclofenac	Meprobamate	Sulfamethazine
Ampicillin	Diflunisal	Isoxsuprine	Sulindac
l-Ascorbic acid	Digoxin	d,l-Propanolol	Tetracycline
Apomorphine	Diphenhydramine	Nalidixic acid	Tetrahydrocortisone,
Aspartame	Ethyl-p-aminobenzoate	Naproxen	3-acetate
Atropine	β-Estradiol	Niacinamide	Tetrahydrocortisone
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrozoline
Benzoic acid	Erythromycin	Norethindrone	Thiamine
Bilirubin	Fenoprofen	Noscapine	Thioridazine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	d,l-Tyrosine
Cannabidiol	Gentisic acid	Oxalic acid	Tolbutamide
Chloral hydrate	Hemoglobin	Oxolinic acid	Triamterene
Chloramphenicol	Hydralazine	Oxymetazoline	Trifluoperazine
Chlorothiazide	Hydrochlorothiazide	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	Hydrocortisone	Perphenazine	d,l-Tryptophan
Chlorpromazine	o-Hydroxyhippuric acid	Phenelzine	Uric acid
Cholesterol	3-Hydroxytyramine	Prednisone	Verapamil
Clonidine	d,l-Isoproterenol		

BIBLIOGRAPHY

1. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA),Research Monograph 73, 1986.
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City,CA 2002.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Contains sufficient for <*n*> test	REF	Catalogue number
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	EU REP	Authorized representative in the European Community/European Union
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

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