Multi-Drugs Rapid Test Panel
Package Insert

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 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-Drugs Rapid Test Panel is a lateral flow chromatographic immunoassay for the qualitative detection of following drugs without the need of instruments.

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	1,000
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP 300)	d-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Benzodiazepines (BZO 200)	Oxazepam	200
Benzodiazepines (BZO 100)	Oxazepam	100
Cocaine (COC)	Benzoylecgonine	300
Cocaine (COC 150)	Benzoylecgonine	150
Clonazepam (CLO)	Clonazepam	300
Fentanyl (FYL)	Fentanyl	200
Ketamine (KET)	Ketamine	1000
SPC/K2	JWH-073/JWH-018	50
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	25
Tramadol (TML)	Tramadol	100
Tramadol (TML)	Tramadol	300
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	d-Methamphetamine	1,000
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET 300)	d-Methamphetamine	300
Methylenedioxymethamphetamine (MDMA)	d,l Methylenedioxymethamphetamine	500
Methylenedioxymethamphetamine (MDMA	d,l Methylenedioxymethamphetamine	300
Morphine (MOP 300)	Morphine	300
Methcathinone (MCAT)	Methcathinone	500
Opiate (OPI 2000)	Morphine	2,000
Phencyclidine (PCP)	Phencyclidine	25

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-Drugs Rapid Test Panel 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.

COMPOSITION

- Each test kit contains Multi-tests and package insert.
- Materials required but not provided: timer, Specimen collection container.

STORAGE AND HANDLING

- Store the test kit in a cool, dry place between 2-30°C. Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- **Do not freeze.** Use the test kit at temperatures between 15-30°C.
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

Note: *All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.*

WARNINGS, PRECAUTIONS AND LIMITATIONS

- 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.
- The Drug Rapid Test 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.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- The test does not distinguish between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

SPECIMEN COLLECTION AND PREPARATION

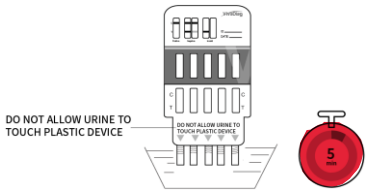
1) Urine Assay
The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

2) 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.

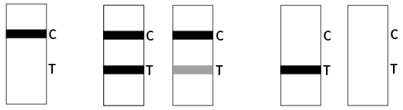
TEST PROCEDURE

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

1. Remove the test panel from the sealed pouch and use it as soon as possible.
2. Take off the cap outside of the test end. With arrows pointing toward the urine specimen and start the timer, **immerse the test panel vertically into the urine specimen for at least 10-15 seconds.** Immerse the test panel to at least the level of the wavy lines on the strip(s), do not pass the arrows on the test panel when immersing the panel. See the illustration below.
3. Place the test panel on a non-absorbent flat surface, wait for the colored line(s) to appear.
4. Read the results at 5 minutes. DO NOT INTERPRET RESULT AFTER 10 MINUTES.



INTERPRETATION OF TEST RESULTS



Positive **Negative** **Invalid**

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 specimen exceeds the designated cut-off for that specific drug.

Negative: **Two distinct colored lines appear**. 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 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.*

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.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. Control standards are not supplied with this kit; however, 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.

PERFORMANCE

1. Accuracy

The accuracy of the Drug Rapid Test were compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99% in agreement.

2. 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		AMP 500		AMP 300		BAR		BZO		BZO 200		BZO100	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	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	30	0
-25% Cut-off	30	22	8	24	6	27	3	27	3	27	3	21	9	24	6
Cut-off	30	12	18	16	14	13	17	14	16	11	19	19	11	16	14
+25% Cut-off	30	2	28	4	26	4	26	7	23	5	25	9	21	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	COC		COC 150		CLO		FYL		KET		K2		TCA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	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	30	0
-25% Cut-off	30	27	3	24	6	25	5	23	7	25	5	24	6	22	8
Cut-off	30	15	15	14	16	10	20	13	17	17	13	21	9	17	13
+25% Cut-off	30	4	26	7	23	7	23	0	30	1	29	2	28	5	25
+50% Cut-off	30	0	30	0	30	0	30	30	0	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	THC		THC25		TML		TML300		MTD		MET		MET500	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	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	30	0
-25% Cut-off	30	22	8	24	6	24	6	25	5	24	6	25	5	23	7
Cut-off	30	14	16	13	17	14	16	14	16	12	18	18	12	13	17
+25% Cut-off	30	4	26	2	28	2	28	6	24	2	28	1	29	8	22
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MET 300		MDMA		MDMA 300		MOP 300		MCAT		OPI 2000		PCP	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	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	30	0
-25% Cut-off	30	25	5	26	4	25	5	25	5	25	5	30	0	19	11
Cut-off	30	14	16	17	13	16	14	17	13	13	17	13	17	16	14
+25% Cut-off	30	4	26	4	26	4	26	1	29	4	26	4	26	6	24
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

3. Analytical Specificity

Compounds	Con.ng/mL	Compounds	Con.ng/mL
AMPHETAMINE			
d-Amphetamine	1,000	d,l-Amphetamine	2,000
l-Amphetamine	>100,000	Phentermine	6,000
3,4- Methylendioxyamphetamine (MDA)	1,000	l-Methamphetamine	>100,000
d-Methamphetamine	>100,000	Tyramine	>100,000
3,4–Methylenedioxymethamphetamine (MDMA)			>100,000
3,4–Methylenedioxyethylamphetamine (MDEA)			>100,000
AMPHETAMINE 500			
d-Amphetamine	500	d,l-Amphetamine	1,500
l-Amphetamine	>100,000	Phentermine	5,000
3,4- Methylendioxyamphetamine (MDA)	1,500	Tyramine	40,000
d-Methamphetamine	>100,000	l-Methamphetamine	>100,000
β-phenylethylamine	100,000		
3,4–Methylenedioxyethylamphetamine (MDEA)			>100,000
3,4–Methylenedioxymethamphetamine (MDMA)			>100,000
AMPHETAMINE 300			
d-Amphetamine	300	d,l-Amphetamine	1,000
l-Amphetamine	>100,000	Phentermine	3,000
3,4- Methylendioxyamphetamine (MDA)	1,500	β-phenylethylamine	60,000
d-Methamphetamine	>100,000	l-Methamphetamine	>100,000
Tyramine	25,000		
3,4–Methylenedioxyethylamphetamine (MDEA)			>100,000
3,4–Methylenedioxymethamphetamine (MDMA)			>100,000
BARBITURATES			
Secobarbital	300	Butalbital	2,000
Allobarbital	5,000	Butabarbital	75
Alphenal	625	Hexobarbital	>100,000
Amobarbital	300	Pentobarbital	300
Aprobarbital	600	Phenobarbital	300
BENZODIAZEPINES			
Oxazepam	300	Alprazolam	190
α-Hydroxyalprazolam	300	Flunitrazepam	400
Bromazepam	500	d,l Lorazepam	75,000
Chlordiazepoxide	1,500	Midazolam	2,200
Clobazam	110	Nitrazepam	200
Clonazepam	100,000	Norchlordiazepoxide	800
Diazepam	190	Nordiazepam	150
Temazepam	100	(+) Lorazepam	75,000
Triazolam	6,000		
BENZODIAZEPINES 200			
Oxazepam	200	Alprazolam	130
α-Hydroxyalprazolam	200	Flunitrazepam	280
Bromazepam	350	d,l Lorazepam	50,000
Chlordiazepoxide	1,000	Midazolam	1,500
Clobazam	75	Nitrazepam	150
Clonazepam	70,000	Norchlordiazepoxide	550
Diazepam	130	Nordiazepam	100
Temazepam	100	(+) Lorazepam	50,000
Triazolam	4,000		
BENZODIAZEPINES 100			
Oxazepam	100	Alprazolam	65
α-Hydroxyalprazolam	100	Flunitrazepam	140
Bromazepam	175	d,l Lorazepam	25,000
Chlordiazepoxide	500	Midazolam	750
Clobazam	50	Nitrazepam	75
Clonazepam	35,000	Norchlordiazepoxide	225
Diazepam	65	Nordiazepam	50
Temazepam	50	(+) Lorazepam	25,000
Triazolam	2,000		
COCAINE			

Benzoylecgonine	300	Cocaethylene	12,500
Cocaine	780	Ecgonine	32,000
COCAINE 150			
Benzoylecgonine	150	Cocaethylene	6,250
Cocaine	400	Ecgonine	12,500
Ecgonine methylester	50,000		
Clonazepam			
Clonazepam	300	Flunitrazepam	750
Alprazolam	500	Lorazepam	2,500
Bromazepam	1,250	Lormetazepam	2,500
Chlordiazepoxide	5,000	Nitrazepam	50,000
Clobazam	125	Norchlordiazepoxide	500
Oxazepam	60	Nordiazepam	1,000
Clorazepate	6,660	Temazepam	250
Delorazepam	5,000	Triazolam	10,000
Desalkflurazepam	500	Estazolam	10,000
Diazepam	500		
FENTANYL			
Fentanyl	200	Norfentanyl	>100,000
KETAMINE			
Ketamine	1,000	Norketamine	3,000
K2			
JWH 073 4-butanoic acid	50	JWH 018 5-pentanoic acid	50
JWH-073 4-Hydroxybutyl metabolite	200	JWH-018 5-Hydroxypentyl metabolite	250
JWH-018 N-(4-hydroxypentyl) metaboliteS-025	200	JWH-018 (Spice Cannabinoid)	80,000
TRICYCLIC ANTIDEPRESSANTS			
Nortriptyline	1,000	Amitriptyline	500
Chlorpromazine	2,000	Imipramine	200
Promethazine	>100,000	Diphenhydramine	>100,000
MARIJUANA			
11-nor-Δ^9-THC-9 COOH	50	Δ^8–THC	15,000
11-nor-Δ^9-THC-9 COOH	50	Δ^9–THC	15,000
Cannabinol	100,000		
MARIJUANA 25			
11-nor-Δ^9-THC-9 COOH	25	Δ^8–THC	7,500
11-nor-Δ^9-THC-9 COOH	25	Δ^9–THC	7,500
Cannabinol	50,000		
TRAMADOL			
Tramadol	200	Diphenhydramine	>100,000
(+)Chlorpheniramine	>100,000	Phencyclidine	>100,000
METHADONE			
Methadone	300	Doxylamine	100,000
METHAMPHETAMINE			
d-Methamphetamine	1,000	l-Methamphetamine	8,000
p-Hydroxymethamphetamine	30,000	Mephentermine	50,000
3,4–Methylenedioxyamphetamine (MDA)	>100,000	D-Amphetamine	>100,000
Phenylephrine	100,000	L-Amphetamine	>100,000
3,4–Methylenedioxymethamphetamine (MDMA)			8,000
3,4–Methylenedioxyethylamphetamine (MDEA)			25,000
METHAMPHETAMINE 500			
d-Methamphetamine	500	l-Methamphetamine	4,000
p-Hydroxymethamphetamine	15,000	Mephentermine	25,000
3,4–Methylenedioxyamphetamine (MDA)	>100,000	D-Amphetamine	>100,000
Phenylephrine	70,000	L-Amphetamine	>100,000
3,4–Methylenedioxymethamphetamine (MDMA)			1,000
3,4–Methylenedioxyethylamphetamine (MDEA)			12,500
METHAMPHETAMINE 300			
d-Methamphetamine	300	l-Methamphetamine	2,500
p-Hydroxymethamphetamine	15,000	Mephentermine	15,000
3,4–Methylenedioxyamphetamine (MDA)	>100,000	D-Amphetamine	>100,000
Phenylephrine	70,000	L-Amphetamine	>100,000
3,4–Methylenedioxymethamphetamine (MDMA)			600
3,4–Methylenedioxyethylamphetamine (MDEA)			10,000
METHYLENEDIOXYMETHAMPHETAMINE 500			
3,4–Methylenedioxymethamphetamine (MDMA)			500
3,4–Methylenedioxyamphetamine (MDA)			4,000
3,4–Methylenedioxyethylamphetamine (MDEA)			400
METHYLENEDIOXYMETHAMPHETAMINE 300			
3,4–Methylenedioxymethamphetamine (MDMA)			300
3,4–Methylenedioxyamphetamine (MDA)			60,000
3,4–Methylenedioxyethylamphetamine (MDEA)			3,000
MORPHINE 300			
Morphine	300	6-Monoacetylmorphine	300
Codeine	300	Morphine 3-β-D-glucuronide	1000
Ethylmorphine	200	Thebaine	20,000
Hydrocodone	>100,000	Nalorphine Hydrochloride	>100,000
Hydromorphone	700	Oxycodone	>100,000
Dihydroetorphine	4,000	Oxymorphone	>100,000
Methcathinone			
Methcathinone	500		
OPIATE 2000			
Morphine	2,000	Morphinie-3-β-d-glucuronide	2,000
Normorphine	50,000	Oxycodone	25,000
Codeine	2,000	Oxymorphone	25,000
Ethyl Morphine	1,500	Thebaine	50,000
Heroin	2,000	6-Monoacetylmorphine (6-MAM)	2,000
Hydrocodone	12,500	Procaine	100,000
Hydromorphone	3,500		
PHENCYCLIDINE			
Phencyclidine	25	4-Hydroxyphencyclidine	12,500
Hydrocodone	>100,000	Hydromorphone	>100,000

4. Effect of Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with -50% Cutoff and +50% Cutoff of drugs. The Drug Rapid Test was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

5. Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with -50% Cutoff and +50% Cutoff of drugs. The spiked, pH-adjusted urine was tested with the Amphetamine Rapid Test in duplicate. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

CROSS-REACTIVITY

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or positive urine. The following compounds show no cross-reactivity when tested with the Drug Rapid Test at a concentration of 100 µg/mL.

NON CROSS-REACTIVITY

Acetophenetidin	Cortisone	Isoxsuprine	d-Pseudoephedrine
N-Acetylprocainamide	l-Cotinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Creatinine	Labetalol	Quinine
Aminopyrine	Deoxycorticosterone	Loperamide	Salicylic acid
Amoxicillin	Dextromethorphan	Meprobamate	Serotonin
Ampicillin	Diclofenac	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Diflunisal	Methylphenidate	Sulindac
Apomorphine	Digoxin	Nalidixic acid	Tetracycline
Aspartame	Diphenhydramine	Naproxen	Tetrahydrocortisone,
Atropine	Ethyl-p-aminobenzoate	Niacinamide	3-Acetate
Benzilic acid	β-Estradiol	Nifedipine	Tetrahydrocortisone
Benzoic acid	Estrone-3-sulfate	Norethindrone	Tetrahydrozoline
Bilirubin	Erythromycin	Noscapine	Thiamine
d,l-Brompheniramine	Fenoprofen	d,l-Octopamine	Thioridazine
Caffeine	Furosemide	Oxalic acid	d,l-Tyrosine
Cannabidiol	Gentisic acid	Oxolinic acid	Tolbutamide
Chloral hydrate	Hemoglobin	Oxymetazoline	Triamterene
Chloramphenicol	Hydralazine	Papaverine	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	d,l-Propanolol	Zomepirac

REFERENCES

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735
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

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C 30°C	Storage temperature limitations		Manufacturer		Do not reuse
EC REP	Authorized Representative				

VivaChek

VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd.,
Yuhang Economy Development Zone,
Hangzhou, 311100, China
Email: info@vivachek.com
www.vivachek.com

EC REP

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.
Tel: +31644168999
Email: peter@lotusnl.com

CE IVD

Number: 1624043901
Effective date: 2023-02-20