Multi-Drug Rapid Test Panel (Urine) Package Insert

Instruction Sheet for testing of any combination of the following drugs:
THC25 / THC50 / THC150 / THC300

A rapid test for the simultaneous, qualitative detection of drug and drug metabolites in human urine. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

【INTENDED USE】

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

Test	Calibrator	Cut-off (ng/mL)
Marijuana (THC300)	11-nor-Δ9-THC-9 COOH	300
Marijuana (THC150)	11-nor-Δ9-THC-9 COOH	150
Marijuana (THC 50)	11-nor-Δ9-THC-9 COOH	50
Marijuana (THC 25)	11-nor-Δ9-THC-9 COOH	25

Configurations of the Multi-Drug Rapid Test Panel come with any combination of the above listed drug analytes. 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 indicated.

【SUMMARY】

The Multi-Drug Rapid Test Panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

THC (Δ9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure. The main metabolite excreted in the urine is 11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The Multi-Drug Rapid Test Panel yields a positive result when the concentration of THC-COOH in urine exceeds detection level.

【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 (FOR DOA TESTS EXCLUDING ALCOHOL)】

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

【PRECAUTIONS】

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. 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 federal, state and 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 Panel 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 Panels
- Package insert

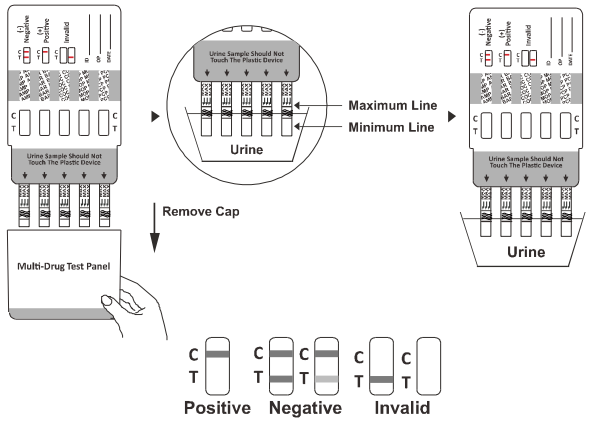
Materials Required But Not Provided

- Specimen collection containers
- Timer

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening it. Remove the test panel 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 panel 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 panel.**
4. Replace the cap and place the test panel 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 colored lines appear 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 card. If the result is still invalid, contact your manufacturer.

【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 Rapid Test Panel 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.[1,10]
2. There is a possibility that technical or procedural errors, as well as 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. This test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

The negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the Multi-Drug Rapid Test Panel and commercially available drug rapid tests. Testing was performed on approximately 250 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS.

Method		GC/MS		agreement with GC/MS
Multi-Drug Rapid Test Panel		Positive	Negative	
THC 300	Positive	85	3	95.5%
	Negative	4	158	98.1%
THC 150	Positive	86	4	94.5%
	Negative	5	155	97.5%
THC 50	Positive	92	3	97.9%
	Negative	2	153	98.1%
THC 25	Positive	95	4	96.9%
	Negative	3	148	97.4%

% Agreement with Commercial Kit

	THC300	THC150	THC50	THC25
Positive Agreement	*	>99.9%	>99.9%	>99.9%
Negative Agreement	*	>99.9%	>99.9%	>99.9%
Total Results	*	>99.9%	>99.9%	>99.9%

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

Precision

A study was conducted at three hospitals by laypersons 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 ± 50% and ± 25% cut-off level, was labeled, blinded **MARIJUANA (THC300)**

11-nor-Δ⁹-THC-9 COOH Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
150	10	10	0	10	0	10	0
225	10	8	2	9	1	9	1
375	10	2	8	3	7	1	9
450	10	0	10	0	10	0	10

MARIJUANA (THC150)

11-nor-Δ⁹-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
75	10	10	0	10	0	10	0
112.5	10	9	1	9	1	9	1
187.5	10	2	8	1	9	1	9
225	10	0	10	0	10	0	10

MARIJUANA (THC50)

11-nor-Δ⁹-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	8	2	9	1
62.5	10	1	9	1	9	2	8
75	10	0	10	0	10	0	10

MARIJUANA (THC25)

11-nor-Δ⁹-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	8	2	8	2	8	2
31.25	10	1	9	1	9	2	8
37.5	10	0	10	0	10	0	10
45	10	0	10	0	10	0	10

Analytical Sensitivity

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

Drug Concentration	THC300		THC150		THC50		THC25	
Cut-off Range	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0
-25% Cut-off	27	4	27	3	26	4	27	3
Cut-off	14	16	15	15	14	16	15	15
+25% Cut-off	4	26	4	26	3	27	4	26
+50% Cut-off	0	30	0	30	0	30	0	30
+300% Cut-off	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 Rapid Test Panel at 5 minutes.

Analytes	**Concentration (ng/mL)**	**Analytes**	**Concentration (ng/mL)**
MARIJUANA (THC300)			
Cannabinol	200,000	△8-THC	100,000
11-nor-△8-THC-9 COOH	200	△9-THC	100,000
11-nor-△9-THC-9 COOH	300		
MARIJUANA (THC150)			
Cannabinol	100,000	△8-THC	50,000
11-nor-△8-THC-9 COOH	100	△9-THC	50,000
11-nor-△9-THC-9 COOH	150		
MARIJUANA (THC50)			
Cannabinol	35,000	△8-THC	17,000
11-nor-△8-THC-9 COOH	30	△9-THC	17,000
11-nor-△9-THC-9 COOH	50		
MARIJUANA (THC25)			
Cannabinol	17,500	△8-THC	8,500
11-nor-△8-THC-9 COOH	15	△9-THC	8,500
11-nor-△9-THC-9 COOH	25		

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005-1.045) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Multi-Drug Rapid Test Panel was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

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 drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Multi-Drug Rapid Test Panel. The results demonstrate that varying ranges of pH do 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 drug positive urine containing Marijuana. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test Panel at a concentration of 100µg/mL.

Non Cross-Reacting Compounds

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

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Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

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