Multi-Drug 6 Drugs Rapid Test Key Cup with/without Adulteration (Urine)

Package Insert

Instruction Sheet for testing of any combination of the following drugs:
AMP/BZO/COC/THC/MET/OPI
Including Specimen Validity Tests (S.V.T.) for:
Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde, Creatinine and Bleach

A rapid test for the simultaneous, qualitative detection of multiple drugs 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 Cup 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	300
Benzodiazepines (BZO)	Oxazepam	200
Cocaine (COC)	Benzoylecgonine	300
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Methamphetamine (MET)	d-Methamphetamine	300
Morphine/Opiate (MOP/OPI)	Morphine	300

Configurations of the Multi-Drug Rapid Test Cup come with any combination of the above listed drug analytes with or without S.V.T. 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.

【SUMMARY OF ADULTERATION】

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, specific gravity and creatinine and to detect the presence of oxidants/PCC, nitrites or glutaraldehyde in urine.

【PRINCIPLE (FOR DOA TESTS EXCLUDING ALCOHOL)】

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.

【PRINCIPLE OF ADULTERATION】

Oxidants/PCC (Pyridiniumchlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridiniumchlorochromate (sold under the brand name Urine Luck) is a commonly used adulterant.[2] Normal human urine should not contain oxidants of PCC.
Specific gravity tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.
pH tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
Nitrite tests for commonly used commercial adulterants such as Klear and Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.[3] Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.
Glutaraldehyde tests for the presence of an aldehyde. Adulterants such as Urin Aid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests.[3] Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
Creatinine is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[1] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to " flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with human urine.
Bleach tests for the presence of bleach. Bleach refers to a number of chemicals which remove color, whiten or disinfect, often by oxidation, Bleaches are used as household chemicals to whiten clothes and remove stains and as disinfectants. Normal human urine should not contain bleach.

【PRINCIPLE (FOR ALCOHOL)】

The urine Alcohol Rapid Test Cup consists of a plastic strip with a reaction pad attached at the tip. On contact with alcohol, the reaction pad will change colors depending on the concentration of alcohol present. This is based on the high specificity of alcohol oxidase for ethyl alcohol in the presence of peroxidase and enzyme substrate such as TMB.

【REAGENTS (FOR DOA TESTS EXCLUDING ALCOHOL)】

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.

【REAGENTS (FOR ALCOHOL)】

Tetramethylbenzidine, Alcohol Oxidase, Peroxidase

【S.V.T REAGENTS】

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Creatinine	0.04%	99.96%
Nitrite	0.07%	99.93%
Bleach	0.39%	99.61%
Glutaraldehyde	0.02%	99.98%
pH	0.06%	99.94%
Specific Gravity	0.25%	99.75%
Oxidants / PCC	0.36%	99.64%

【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. When testing cards with S.V.T. or Alcohol storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing.

【MATERIALS】

Materials Provided

- Test Cups
- Package Insert
- Adulteration Color Chart (when applicable)

Materials Required But Not Provided

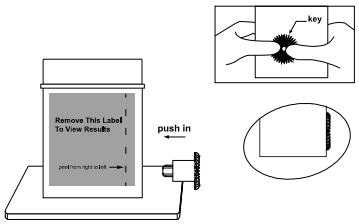
- Timer
- Specimen collection containers

【DIRECTIONS FOR USE】

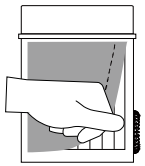
Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it within one hour.
2. Collect specimen in the cup and secure the cap tightly.
3. Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 32-38°C (90-100°F).
4. Check the cap for a tight seal, date and initial the security seal label, then place it over the cap.
5. Remove one key from the kit, place the cup on a flat surface, and push the key into the socket of the cup to begin the test. Start timer.
6. Remove the peel off label covering the test results and wait for the colored line(s) to appear.
7. **Read the adulteration strips and alcohol strip between 3-5 minutes with the help of color chart** provided separately. **Read drug strip results at 5 minutes.** Do not interpret results after 10 minutes.

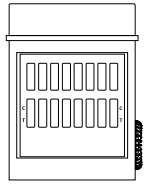
① **Place cup on a flat surface, insert key and push in.**



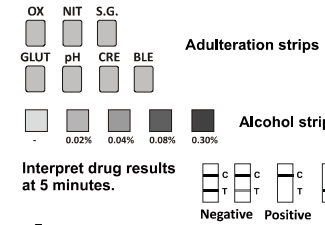
② **Peel off label to view results.**



③ **Wait 5 minutes to read drug results.**



Interpret adulteration strips and Alcohol strip between 3-5 minutes.See enclosed color chart for interpretation.



Interpret drug results at 5 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.

【INTERPRETATION OF RESULTS (S.V.T/ ADULTERATION)】

(Please refer to the color chart)

Semi-Quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

【INTERPRETATION OF RESULTS (ALCOHOL STRIP)】

Negative: Almost no color change by comparing with the background. The negative result indicates that the urine alcohol level is less than 0.02%.
Positive: A distinct color developed all over the pad. The positive result indicates that the urine alcohol concentration is 0.02% or higher.
Invalid: The test should be considered invalid if only the edge of the reactive pad turned color that might be ascribed to insufficient sampling. The subject should be re-tested. Besides, if the color pad has a blue color before applying urine sample, do not use the test.

【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 Cup 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.[4,5]
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.
7. A positive test result may be obtained from certain foods or food supplements.

【S.V.T/ ADULTERATION LIMITATIONS】

1. The adulteration tests included with the product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an "all-inclusive" representation of possible adulterants.
2. **Oxidants/PCC**: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. **Specific Gravity:** Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. **Nitrite**: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of >20 mg/dL may produce false positive glutaraldehyde results.
5. **Glutaraldehyde**: is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.
6. **Creatinine**: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.
7. **Bleach**: Normal human urine should not contain bleach. The presence of high levels of bleach in the specimen may result in false negative results for the bleach pad.
8. **pH:** Normal pH levels are between 4.0 and 9.0.

【PERFORMANCE CHARACTERISTICS】

Accuracy

% Agreement with GC/MS

	AMP 300	BZO 200	COC 300	THC 50	MET 300	MOP/ OPI 300
Positive Agreement	99.1%	99.2%	98.2%	97.9%	97.8%	95.0%
Negative Agreement	98.5%	98.4%	97.8%	98.1%	97.5%	95.3%
Total Results	98.8%	98.8%	98.0%	98.0%	97.6%	95.2%

% Agreement with Commercial Kit

	AMP 300	BZO 200	COC 300	THC 50	MET 300	MOP/ OPI 300
Positive Agreement	>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%
Total Results	>99.9%	>99.9%	>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 Cut-off Range	AMP 300		BZO 300		COC 300		THC 50		MET 300		MOP/ OPI 300	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	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
-25% Cut-off	27	3	27	3	26	4	26	4	27	3	26	4
Cut-off	15	15	15	15	13	17	14	16	16	14	15	15
+25% Cut-off	4	26	3	27	3	27	3	27	3	27	3	27
+50% Cut-off	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

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 at 5 minutes.

Analytes	conc. (ng/mL)	Analytes	conc. (ng/mL)
AMPHETAMINE (AMP 300)			
D,L-Amphetamine sulfate	75	Phentermine	300
L-Amphetamine	10,000	Maprotiline	15,000
(±) 3,4-Methylenedioxy amphetamine	150	Methoxyphenamine	2,000
		D-Amphetamine	300
BENZODIAZEPINES (BZO 200)			
Alprazolam	70	Bromazepam	600
a-hydroxyalprazolam	1,000	Chlordiazepoxide	600
Clobazam	120	Nitrazepam	120
Clonazepam	300	Norchlordiazepoxide	70
Clorazepatedipotassium	300	Nordiazepam	600
Delorazepam	600	Oxazepam	200
Desalkylflurazepam	120	Temazepam	70
Flunitrazepam	120	Diazepam	200
(±) Lorazepam	2,000	Estazolam	4,000
RS-Lorazepamglucuronide	120	Triazolam	2,000
Midazolam	4,000		
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		
METHAMPHETAMINE (MET 300)			
p-Hydroxymethamphetamine	7,500	(±)-3,4-Methylenedioxy-methamphetamine	3,750
D-Methamphetamine	300		
L-Methamphetamine	6,000	Mephentermine	15,000
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

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 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. 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 above related calibrator substances. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test at a concentration of 100 µg/mL.

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		

【ALCOHOL PERFORMANCE CHARACTERISTICS】

The detection limit on the **Urine Alcohol Rapid Test** is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the **Urine Alcohol Rapid Test** can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

【ALCOHOL ASSAY SPECIFICITY】

The **Urine Alcohol Rapid Test** will react with methyl, ethyl and allyl alcohols.

【ALCOHOL INTERFERING SUBSTANCES】

The following substances may interfere with the **Urine Alcohol Rapid Test** when using samples other than urine. The named substances do not normally appear in sufficient quantity in urine to interfere with the test.

A. Agents which enhance color development
- Peroxidases
- Strong oxidizers

B. Agents which inhibit color development
- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

【BIBLIOGRAPHY】

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Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
	Caution		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

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