

For laboratory *in vitro* diagnostic use only.

INTENDED USE

The Rapid Response™ Multi-Drug Test Panel (Urine) is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of one to thirty 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:

Parameter	Calibrator	Cut-off(ng/mL)
ACE	Acetaminophen	5000
AMP	d-Amphetamine	1000/500/300
BAR	Secobarbital	300
BUP	BUP-3-D-Glucuronide	10/5
BZO	Oxazepam	500/300/200/100
COC	Benzoylecgonine	300/200/150/100
COT	(-)-Cotinine	600/300/200
EDDP	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	300/100
ETG	Ethyl Glucuronide	300
FYL	Norfentanyl/Fentanyl	200/10
HMO	Hydromorphone	250
K2	JWH-073/JWH-018	50
KET	Ketamine	1,000
LSD	9,10-Didehydro-N,N-diethyl-6-methylergoline-8beta-carboxamide	50
6-MAM	6-Monoacetylmorphine	10
MDMA	3,4-Methylenedioxy-MET	1000/500
MET	Methamphetamine	1000/500/300
MOP	Morphine	300/200/100
MPD	Methylphenidate	300
MQL	Methaqualone	300
MTD	Methadone	300
OPI	Morphine	2000/1000
OXY	Oxycodone	300/100
PCP	Phencyclidine	25
PPX	D-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor- Δ^9 -THC-9-COOH	200/150/50/25
TRA	Tramadol	300/100
ZOL	Zolpidem	50

Adulteration (Strip A) Oxidants / Specific Gravity / pH
 Adulteration (Strip B) Nitrite / Glutaraldehyde / Creatinine

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.

The Urine Adulteration Test Strips (Urine) are a semi-quantitative color comparison screen for the detection of Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants and Pyridinium Chlorochromate in human urine. This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Abnormal results should be sent to a laboratory for confirmation.

PRINCIPLE

The Rapid Response™ 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.

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 Creatinine, pH, and Specific Gravity and to detect the presence of Glutaraldehyde, Nitrite and Oxidants/Pyridinium Chlorochromate in urine.

Creatinine (CRE): Tests for specimen dilution. Creatinine is a waste product of Creatine, and is an amino-acid contained in muscle tissue and found in urine.¹ A person may attempt to foil a drug 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 to circumvent drug testing. Low Creatinine and Specific Gravity levels may indicate diluted urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with human urine.

Nitrite (NIT): Tests for specimen dilution. They work by oxidizing the major cannabinoid metabolite THC-COOH.² Normal urine should contain no trace of Nitrites. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde (GLUT): Tests for the presence of aldehydes. Adulterants can contain Glutaraldehyde and can cause false negative screening 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 generally indicates 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 that the specimen has been altered.

Specific Gravity (SG): Tests for specimen dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

Oxidants/Pyridinium Chlorochromate (OXI/PCC): Tests for the presence of oxidizing reagents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is commonly used adulterant.³ Normal human urine should not contain Oxidants or PCC.

REAGENTS AND MATERIALS

Materials Provided

- Rapid Response™ Multi-Drug Test Panel (Urine)
- Adulteration Color Chart (when applicable)
- Product Insert

Materials Required but Not provided

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

PRECAUTIONS

- For laboratory *in vitro* diagnostic use only.
- The pouch containing the test device should be sealed. Discard the test device if package is ripped or torn.
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container and specimen pipette for each urine sample.

STORAGE AND STABILITY

The pouched Rapid Response™ Multi-Drug Test Panel (Urine) should be stored at normal humidity and room temperature or refrigerated (2-30°C; 36-86°F) until the expiration date stated on the pouch. The product is humidity-sensitive and should be used immediately after being opened. Any test in an improperly sealed pouch should be discarded.

SPECIMEN COLLECTION AND STORAGE

Urine Collection: The Rapid Response™ 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°C; 77°F) for up to 4 hours or to be refrigerated (2-8°C; 36-86°F) for up to 48 hours prior to performing the test. For prolonged storage, specimens may be frozen and stored below -20°C (-4°F). 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.

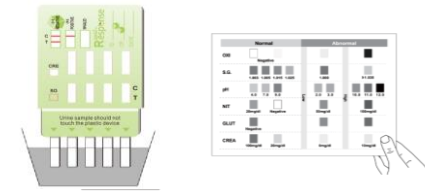
Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

PROCEDURE

IMPORTANT Test device, patient's sample, and controls should be brought to room temperature

(15-30°C; 59-86°F) 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. For the adulteration tests, visually compare the color of the reaction pad with the color card, and the results should be read at 2 minutes. Do not interpret the results after 5 minutes.



4. 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.

The Result of Adulteration Strips: For specific color please reference the Adulteration Color Chart.

NOTE: The Urine Adulteration Test Strips (Urine) 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.

Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine. **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. **Glutaraldehyde:** 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. **Specific Gravity:** Elevated levels of protein in urine may cause abnormally high Specific Gravity values. **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.

QUALITY CONTROL

- Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources and are recommended to be used daily. Use the same assay procedure as with a urine specimen. Controls should be challenging to the assay cutoff concentration. If control values do not fall within established limits, assay results are invalid. Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.
- The Rapid Response™ Multi-Drug Test Panel (Urine) provides built-in process control with a different antigen/antibody reaction at the control region (C) in each strip. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear, the test device should be discarded. The presence of this control band in the control region serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

LIMITATIONS OF THE TEST

1. The Rapid Response™ 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.

Midazolam	>100,000
Nitrazepam	25000
Norchlordiazepoxide	250
Nordiazepam	500
Prazepam	>100,000
Temazepam	63
Triazolam	5000
Benzodiazepines 200 related compounds	
Oxazepam	200
Alprazolam	83
Bromazepam	417
Chlordiazepoxide	1,667
Clobazam	42
Clonazepam	1,667
Clorazepate	2,220
Desalkflurazepam	167
Diazepam	167
Estazolam	3,333
Fentanyl	>100,000
Flunitrazepam	250
Flurazepam	>100,000
Lorazepam	833
Lormetazepam	833
Medazepam	>100,000
Midazolam	>100,000
Nitrazepam	16,667
Norchlordiazepoxide	167
Nordiazepam	333
Prazepam	>100,000
Temazepam	42
Triazolam	3,333
Benzodiazepines 100 related compounds	
Oxazepam	100
Alprazolam	42
Bromazepam	208
Chlordiazepoxide	833
Clobazam	21
Clonazepam	833
Clorazepate	1,110
Desalkflurazepam	83
Diazepam	83
Estazolam	1,667
Fentanyl	>100,000
Flunitrazepam	125
Flurazepam	>100,000
Lorazepam	417
Lormetazepam	417
Medazepam	>100,000
Midazolam	>100,000
Nitrazepam	8,333
Norchlordiazepoxide	83
Nordiazepam	167
Prazepam	>100,000
Temazepam	21
Triazolam	1,667
Cocaine 300 related compounds	
Benzoyllecgonine	300
Cocaine	1,000
Egonine	100,000
Egonine Methyl Ester	>100,000
Cocaine 200 related compounds	
Benzoyllecgonine	200
Cocaine	125
Egonine	5,000
Egonine Methyl Ester	>100,000

Morphine	200
Acetylcodeine	100
Buprenorphine	2,000
Codeine	170
Diacetyl Morphin	168
Dihydrocodeine	395
Ethylmorphine	135
Hydrocodone	8,350
Hydromorphone	8,350
6-Monoacetylmorphine	170
Morphine-3-glucuronid	1,670
Nalorphine	16,666
Thebaine	16,666
Morphine 100 related compounds	
Morphine	100
Codeine	100
Diacetylmorphine (Heroin)	100
Ethylmorphine	100
Hydromorphone	500
Hydrocodone	500
6-Monoacetylmorphine	100
Morphine-3-β-d-glucuronide	2,000
Oxycodone	20,000
Oxymorphone	20,000
Promethazine	>100,000
Rifampicine	8,400
Thebaine	8,400
Trimipramine	20,000
MPD 300 related compounds	
Methylphenidate	300
Methaqualone 300 related compounds	
Methaqualone	300
Amitriptyline	50,000
Carbamazepine	20,000
Nortriptyline	50,000
Phenytion	40,000
Theophylline	40,000
Methadone 300 related compounds	
Methadone	300
(-)-alpha-methadol	2,000
Opiates 2000 related compounds	
Morphine	2,000
Acetylcodeine	1,563
Buprenorphine	25,000
Codeine	500
Diacetylmorphine (Heroin)	1,250
Dihydrocodeine	1,563
Ethylmorphine	800
Hydromorphone	25,000
Hydrocodone	50,000
Merperidine	>100,000
6-Monoacetylmorphine (6-MAM)	1,250
Morphine-3-β-d-glucuronide	12,500
Nalorphine Hydrochloride	>100,000
Oxycodone	>100,000
Oxymorphone	>100,000
Rifampicine	>100,000
Thebaine	50,000
Opiates 1000 related compounds	
Morphine	1,000
Oxycodone 300 related compounds	
Oxycodone	300
Hydrocodone	75,000
Hydromorphone	>100,000
Naloxone	>100,000

Cocaine 150 related compounds	
Benzoyllecgonine	150
Cocaine	125
Ecgonine	10000
Ecgonine Methyl Ester	>10000
Cocaine 100 related compounds	
Benzoyllecgonine	100
Cotinine 600 related compounds	
(-)-Cotinine	600
Cotinine 300 related compounds	
(-)-Cotinine	300
(-)-Nicotine	9,375
Cotinine 200 related compounds	
(-)-Cotinine	200
(-)-Nicotine	6,250
EDDP 100 related compounds	
EDDP	100
Meperidine	>100,000
Methadone	>100,000
Norfentanyl	>100,000
Phencyclidine	>100,000
Promazine	50,000
Promethazine	25,000
Prothipendyl	50,000
Prozine	12,500
EDDP 300 related compounds	
EDDP	300
Meperidine	>100,000
Methadone	>100,000
Norfentanyl	>100,000
Phencyclidine	>100,000
Promazine	80,000
Promethazine	75,000
Prothipendyl	80,000
Prozine	37,500
ETG 300 related compounds	
Ethyl Glucuronide	300
Fentanyl 10 related compounds	
Fentanyl	10
Norfentanyl	50
Fentanyl 200 related compounds	
Fentanyl	200
Norfentanyl	375
HMO 250 related compounds	
Hydromorphone	250
Acetylcodeine	10,000
Thebaine	25,000
Nalorphine	12,500
Morphine-3-glucuronid	2,500
Morphine	5,000
Hydrocodone	3,100
Ethylmorphine	5,000
Dihydrocodeine	25,000
Diacetyl Morphin	10,000
Codeine	50,000
Buprenorphine	10,000
6-Monoacetylmorphine	10,000
K2 50 related compounds	
JWH-018-5-Pentanoic acid	50
JWH-073-4-Butanoic acid	50
Ketamine 1000 related compounds	
Ketamine	1,000
Norketamine	1,000
Dextromethorphan	500
Dextrorphan tartrate	500

Oxymorphone	750
Oxycodone 100 related compounds	
Oxycodone	100
Hydrocodone	25,000
Hydromorphone	50,000
Naloxone	50,000
Oxymorphone	250
Phencyclidine 25 related compounds	
Phencyclidine	25
Hydrocodone	12,500
Hydromorphone	6,250
4-hydroxyphencyclidine	75
Propoxyphene 300 related compounds	
D-Propoxyphene	300
D-Norpropoxyphene	5,000
Tricyclic Antidepressants related compounds	
Nortriptyline HCl	1,000
Amitriptyline	1,500
Clomipramine	>100,000
Cyclobenzaprine	12,500
Desipramine	188
Doxepin	2,000
Imipramine	2,500
Maprotiline	750
Nortriptyline	3,125
Nordoxepin	500
Opipramol	1,563
Promazine	1,000
Promethazine	6,250
Prothipendyl	25,000
Protryptiline	6,250
Prozine	1,250
Trimipramine	>100,000
Marijuana 200 related compounds	
11-nor-Δ9-THC-9-COOH	200
Marijuana 150 related compounds	
11-nor-Δ9-THC-9-COOH	150
11-nor-Δ8-THC-9-COOH	90
Δ8-Tetrahydrocannabinol	45,000
Δ9-Tetrahydrocannabinol	45,000
Cannabinol	60,000
Marijuana 50 related compounds	
11-nor-Δ9-THC-9-COOH	50
11-nor-Δ8-THC-9-COOH	50
11-hydroxy-Δ9-Tetrahydrocannabinol	50
Δ8-Tetrahydrocannabinol	15,000
Δ9-Tetrahydrocannabinol	15,000
Cannabinol	20,000
Cannabidiol	>100,000
Marijuana 25 related compounds	
11-nor-Δ9-THC-9-COOH	25
11-nor-Δ8-THC-9-COOH	15
Δ8-Tetrahydrocannabinol	7,500
Δ9-Tetrahydrocannabinol	7,500
Cannabinol	10,000
Tramadol 300 related compounds	
Tramadol	300
Tramadol 100 related compounds	
Tramadol	100
(+/-)-Chlorpheniramine	50,000
Dimenhydrinate	50,000
Diphenhydramine	50,000
Phencyclidine	50,000
(+)-Chlorpheniramine	>100,000
Zolpidem 50 related compounds	

D-Norpropoxyphene	31,250
EDDP	800

Zolpidem	50
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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-Dimethylaminoantipyrene	Dextrorphan tartrate	Phenothiazine
Acetaminophen (Except ACE)	Dopamine	L-Phenylephrine
Acetone	Erythromycin	Procaine
Albumin	Ethanol	Protonix
Amitriptyline (Except TCA)	Furosemide	Pseudoephedrine
Ampicillin	Glucose	Quinidine
Aspartame	Guaiacol Glyceryl Ether	Ranitidine
Aspirin	Hemoglobin	Sertraline
Atropine	Ibuprofen	Tyramine
Benzocaine	Imipramine (Except TCA)	Vitamin C (Ascorbic Acid)
Bilirubin	(+/-)-Isoproterenol	Trimipramine
b-Phenylethyl-amine	Lidocaine	Venlafaxine
Caffeine	Methadone (Except MTD)	Ibuprofen
Chloroquine	N-Methyl-Ephedrine	

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GLOSSARY OF SYMBOLS

SVT/Adulterant Color Chart					
Abnormal	Abnormal	OX PCC	Oxidants/Pyridinium chlorochromate	NIT	Nitrite
Normal	Normal	S.G.	Specific gravity	GLUT	Glutaraldehyde
		pH	pH	CRE	Creatinine

Index of Symbols					
	Consult instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #

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