

Single Drug Test Strip (Urine) Product Insert

INTENDED USE

The Rapid Response™ Single Drug Test Strip is rapid chromatographic immunoassays for the qualitative and simultaneous detection of one 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	300/200
BUP	BUP-3-D-Glucuronide	10/5
BZO	Oxazepam	300/200/100
COC	Benzoylcegonine	300/200/100
COT	(-)-Cotinine	600/300/200
EDDP	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	300/100
ETG	Ethyl Glucuronide	300
FYL	Norfentanyl/Fentanyl	20/10
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	Metadone	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
ALC	Alcohol	-

The DOA test strip is used to obtain visual qualitative result and is intended for health care professionals use including professionals at point of care sites to assist in the determination of drug compliance. It is not intended for over the counter sale to non-professionals.

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.

PRINCIPLE

The Rapid Response™ Single Drug Test Strip 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 which are pre-coated with drug-protein conjugates on the test band(s). 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 (drug-protein conjugate)-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.

The alcohol strip is a chemical assay based on an alcohol-sensitive enzymatic reaction. Alcohol, if present in

the specimen, reacts with chemicals on the reaction pad and causes a color change.

REAGENTS AND MATERIALS

Materials Provided

- Test Panels Strip
- Alcohol Color Chart (when applicable)
- Product Insert

Materials Required but Not provided

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

PRECAUTIONS

- For professional *in vitro* diagnostic use only
- The pouch containing the test strip should be sealed. Discard the test strip 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™ Single Drug Test Strip 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™ Single Drug Test Strip 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 strip, 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 from its sealed pouch, or remove one strip from the canister, and use it as soon as possible. For best results, the assay should be performed within one hour. Canisters should be closed tightly after removing strips.
2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
3. Holding the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.
4. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

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 Alcohol Strip:

NEGATIVE: No color change appears on the reaction pad. The color should match the color block on the pouch corresponding to a negative (-) result. This indicates that alcohol has not been detected.

POSITIVE: A color change appears on the reaction pad. The color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks on the pouch.

INVALID: The outer edges of the reaction pad produce a slight color but the majority of the reaction pad remains colorless. Repeat the test with a new test strip, ensuring complete saturation of the reaction pad with the specimen. If the problem persists, do not continue the test and contact your local distributor.

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™ Single Drug Test Strip 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 strip 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™ Single Drug Test Strip (Urine) is for professional *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.
3. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
4. There is a possibility that technical or procedural error as well other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce either positive results, or that do not interfere with test performance.
5. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

PERFORMANCE CHARACTERISTICS

Accuracy Accuracy of the DOA Test was established by running urine sample against GC/MS specification. The following results were tabulated:

% Agreement with GC/MS

Specimen	ACE	AMP	AMP500	AMP300	BAR	BAR200	BUP10	BUP5
Positive	96.1%	95.8%	95.9%	96.1%	97.8%	96.6%	100%	100%
Negative	100%	100%	100%	100%	98.1%	97%	100%	100%
Total	98.1%	98.1%	98.1%	98.1%	98%	96.8%	100%	100%

Specimen	BZO	BZO200	BZO100	COC	COC200	COC100	COT	COT300
Positive	95.3%	97.4%	95.9%	98.2%	95.7%	98.2%	96.5%	97.9%
Negative	92.9%	98.2%	98%	98.1%	98.1%	98.1%	98%	98.1%
Total	93.9%	97.9%	97%	98.2%	97.0%	98.2%	97.2%	98%

Specimen	COT200	EDDP	EDDP100	FYL20	FYL10	HMO	K2	KET
Positive	97.7%	98.6%	95.8%	96.8%	94.4%	95.9%	98.9%	98%
Negative	97.9%	100%	100%	100%	100%	100%	100%	98.6%
Total	98%	99.1%	98.1%	98.3%	97.2%	98.0%	99%	98.3%

Specimen	6-MAM	MDMA	MDMA50	MET	MET500	MET300	MOP	MOP200
Positive	96.8%	98.5%	100%	96.8%	96.9%	96.8%	96.8%	96.1%
Negative	100%	98.2%	100%	100%	100%	100%	97.9%	100%
Total	98.2%	98.3%	100%	98.3%	98.3%	98.4%	97.3%	98.1%

Specimen	MOP100	MPD	MQL	MTD	OPI	OPI1000	OXY	OXY100
Positive	96.1%	97.7%	98.4%	96.1%	97.6%	96.5%	98%	96.1%
Negative	100%	98.4%	98%	100%	98.4%	96%	97%	100%
Total	98.1%	98.1%	98.2%	98.1%	98.1%	96.3%	97%	98.1%

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	
Benzoylcegonine	300
Cocaine	1,000
Ecgonine	100,000
Ecgonine Methyl Ester	>100,000
Cocaine 200 related compounds	
Benzoylcegonine	200
Cocaine	125
Ecgonine	5,000
Ecgonine Methyl Ester	>100,000
Cocaine 100 related compounds	
Benzoylcegonine	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

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
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

Prothipendyl	80,000
Prozine	37,500
ETG 300 related compounds	
Ethyl Glucuronide	300
Fentanyl 10 related compounds	
Fentanyl	10
Norfentanyl	50
Fentanyl 20 related compounds	
Fentanyl	20
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

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	
Zolpidem	50










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-Dimethylaminoantipyrine	Dextrorphan tartrate	Phenothiazine
Acetaminophen (Except ACE)	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline (Except TCA)	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	Vitamin C (Ascorbic Acid)
Bilirubin	Imipramine (Except TCA)	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	Ibuprofen
Chloroquine	Methadone (Except MTD)	

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

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

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