RAPID SELF TEST™

RST Drug of Abuse Multi-Test Panel (Urine)

Package Insert

For in vitro diagnostic use. This device is intended for using at a point of care.

INTENDED USE

The RST Drug of Abuse Multi-Test Panel (Urine) is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of one to thirteen 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)
AMP	Amphetamine	300
AMP	Amphetamine	500
AMP	Amphetamine	1000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC	Benzoylecgonine	150
COC	Benzoylecgonine	300
COT	Cotinine	200
MDMA	3,4-Methylenedioxy- Methamphetamine	500
EDDP	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	100
FYL	Fentanyl	10
FYL	Fentanyl	20
KET	Ketamine	1000
THC	11-nor-Δ9-THC9-COOH	50
MET	Methamphetamine	300
MET	Methamphetamine	500
MET	Methamphetamine	1000
MTD	Methadone	300
OPI	Morphine	300
OPI	Morphine	2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	D-Propoxyphene	300
TCA	Nortriptyline	1000

This device is used at a point of care, such as a pharmacy, bedside, or healthcare Professional's office. This device 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.

PRINCIPLE

The RST Drug of Abuse Multi-Test Panel (Urine) 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

REAGENTSANDMATERIALS

Materials Provided

- RST Drug of Abuse Multi-Test Panel (Urine)
- Product Insert

Materials Required but Not provided

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

- For *in vitro diagnostic* use.
- 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

region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The pouched RST Drug of Abuse Multi-Test Panel (Urine) should be stored at normal humidity

and room temperature or refrigerated (2-30℃; 36-86℉) 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 RST Drug of Abuse Multi-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.

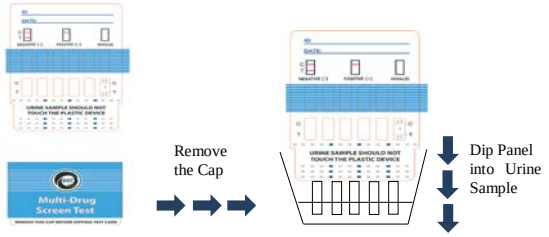
Urine Storage: It is recommended the collected fresh urine to be tested immediately. Fresh urine maybe stored at room temperature (25℃; 77℉) for up to 4 hours or to be refrigerated (2-8℃; 36-86℉) for up to 48 hours prior to performing the test. For prolonged storage, specimens may be frozen and stored below -20℃ (-4℉). 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℉) prior to testing. Do not open pouches until ready to perform the assay.

1. Bring the pouch to room temperature before opening it. 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, **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.
3. Place the test panel on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The results should be **read at 5 minutes**. Do not interpret results 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

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.

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 RST Drug of Abuse Multi-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 RST Drug of Abuse Multi-Test Panel (Urine) is for *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.
6. 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.
7. 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.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the RST Drug of Abuse Multi-Test Panel (Urine) was established by running urine sample against GC/MS specification. The following results were tabulated:

Specimen	MDMA 500	MET 300	MET 500	MET 1000	MTD 300	OPI 300	OPI 2000	OXY 100	PCP 25	PPX 300	THC 50	TCA 1000
Positive	100%	98.3%	98.7%	100%	96.3%	100%	100%	95.2%	98.0%	98.1%	100%	98.3%
Negative	99.6%	98.3%	98.9%	99.3%	93.1%	100%	100%	100.0%	95.5%	100%	99.5%	95.3%
Total	99.8%	98.3%	98.8%	99.7%	94.4%	100%	100%	97.9%	96.7%	99.2%	99.7%	96.7%

Specimen	AMP 300	AMP 500	AMP 1000	BAR 300	BUP 10	BZO 300	COC 150	COC 300	COT 200	EDDP 100	FYL 10	FYL 20
Positive	98.4%	97.0%	98.6%	99.0%	98.3%	97.0%	99.2%	100%	97.9%	98.0%	97.4%	98.0%
Negative	98.1%	97.8%	98.7%	99.1%	98.4%	99.4%	97.8%	98.3%	97.3%	96.8%	96.0%	94.4%
Total	98.2%	97.6%	98.7%	99.1 %	98.3%	98.5%	98.3%	99.0%	97.6%	97.3%	96.6%	96.1%

B. **Analytical Sensitivity**

The sensitivity of RST Drug of Abuse Multi-Test Panel (Urine) was determined by tested GC/MS confirmed controls to the concentration at negative, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3 times of cutoff. The results are summarized below:

Drug Conc.	n	AMP 300		AMP 500		AMP 1000		COC 150		COC 300		FYL 10		FYL 20	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0	25	0	25	0	25	0
50% Cut-off	25	25	0	25	0	25	0	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0	25	0	25	0	25	0
Cutoff	25	11	14	9	16	10	15	8	17	11	14	9	16	12	13
125%	25	0	25	0	25	0	25	0	25	0	25	0	25	0	25
150%	25	0	25	0	25	0	25	0	25	0	25	0	25	0	25
3×Cutoff	25	0	25	0	25	0	25	0	25	0	25	0	25	0	25

Drug Conc.	n	BAR 300		BUP 10		EDDP 100		KET 1000		MTD 300		OXY 100	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0	25	0	25	0
50% Cut-off	25	25	0	25	0	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0	25	0	25	0
Cutoff	25	8	17	9	16	8	17	11	14	8	17	5	20
125% Cutoff	25	0	25	0	25	0	25	0	25	0	25	0	25
150% Cutoff	25	0	25	0	25	0	25	0	25	0	25	0	25
3×Cutoff	25	0	25	0	25	0	25	0	25	0	25	0	25

Drug Conc.	n	BZO 300		MET 300		MET 500		MET 1000		OPI 300		OPI 2000	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+
Negative	25	25	0	25	0	25	0	25	0	25	0	25	0
50% Cut-off	25	25	0	25	0	25	0	25	0	25	0	25	0
75% Cutoff	25	25	0	25	0	25	0	25	0	25	0	25	0
Cutoff	25	9	16	8	17	11	14	9	16	6	19	8	17
125% Cutoff	25	0	25	0	25	0	25	0	25	0	25	0	25
150% Cutoff	25	0	25	0	25	0	25	0	25	0	25	0	25
3×Cutoff	25	0	25	0	25	0	25	0	25	0	25	0	25

Drug Conc.	n	MDMA 500		PCP 25		PPX 300		TCA 1000		THC 500			
(Cut-off)		-	+	-	+	-	+	-	+	-	+		
Negative	25	25	0	25	0	25	0	25	0	25	0		
50% Cut-off	25	25	0	25	0	25	0	25	0	25	0		
75% Cutoff	25	25	0	25	0	25	0	25	0	25	0		
utoff	25	10	15	9	16	5	20	6	19	11	14		
125% Cutoff	25	0	25	0	25	0	25	0	25	0	25		
150% Cutoff	25	0	25	0	25	0	25	0	25	0	25		
3×Cutoff	25	0	25	0	25	0	25	0	25	0	25		

C. **Specificity**

The specificity for the RST Drug of Abuse Multi-Test Panel (Urine) has been tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in drug-free normal human urine. The RST Drug of Abuse Multi-Test Panel (Urine) performance at cutoff point is not affected when pH range of urine specimens is at 3.0 to 8.5 and specific gravity range of urine specimens is at near 1.005 to 1.03.

The following compounds were found to produce positive results when tested at levels greater than the concentrations (in ng/ml) listed below, see the form in the final.

Compound	Conc. (ng/ml)	Compound	Conc. (ng/ml)
Amphetamine(300)			
D-Amphetamine	300	L-Amphetamine	15,000
D,L-Amphetamine sulfate	900	(+/-)3,4-	600
Phentermine	900		
Amphetamine(500)			
D-Amphetamine	500	L-Amphetamine	25,000
D,L-Amphetamine sulfate	1,500	(+/-)3,4-	1,000
Phentermine	1,500		
Amphetamine(1000)			
D-Amphetamine	1000	L-Amphetamine	50,000
D,L-Amphetamine sulfate	3000	(+/-)3,4-	2,000
Phentermine	3000		
Barbiturates			
Secobarbital	300	Butethal	100
Amobarbital	300	Butabarbital	75
Alphenol	150	Cyclopentobarbital	600
Aprobarbital	200	Pentobarbital	300
Butalbital	2,500	Phenobarbital	100
Benzodiazepines			
Alprazolam	196	Flunitrazepam	390
a-hydroxyalprazolam	1262	(+/-)Lorazepam	1562
Bromazepam	1562	RS-Lorazepam	156
Chlordiazepoxide	1562	Midazolam	12,500
Clobazam	98	Nitrazepam	98
Clonazepam	781	Norchlordiazepoxide	195
Clorazepate dipotassium	195	Nordiazepam	390
Delorazepam	1562	Oxazepam	300
Desalkylflurazepam	390	Temazepam	98
Diazepam	195	Triazolam	2,500
Estazolam	2500		
Buprenorphine			
Buprenorphine	10	Buprenorphine 3-D-Glucuronide	15
Norbuprenorphine	20	Norbuprenorphine 3-D-Glucuronide	200
Cocaine Metabolite(150)	>100,000		
Benzoylecgonine	150	Cocaine HCl	390
Cocaethylene	6,250	Ecgonine HCl	16,000
p-Hydroxymethamphetamine	15,000	(+/-)3,4-MDMA	1,000
D- Methamphetamine	500	Mephentermine	25,000
L-Methamphetamine	4,000		
Cocaine Metabolite(300)	>100,000		
Benzoylecgonine	300	Cocaine HCl	780
Cocaethylene	12,500	Ecgonine HCl	32,000
p-Hydroxymethamphetamine	30,000	(+/-)3,4-MDMA	2,000
D- Methamphetamine	1,000	Mephentermine	50,000
L-Methamphetamine	8,000		
Fentanyl(10)			
Fentanyl	10	Norfentanyl	18.75
Fentanyl(20)			
Fentanyl	20	Norfentanyl	37.50
Ketamine			
Ketamine	1,000	Secobarbital	100,000
Pentobarbital	50,000	Norketamine	50,000
Methamphetamine			
p-Hydroxymethamphetamine	9,000	(+/-)3,4-MDMA	900
D- Methamphetamine	300	Mephentermine	15,000
L-Methamphetamine	2,100		
Methamphetamine			
p-Hydroxymethamphetamine	15,000	(+/-)3,4-MDMA	1,000
D- Methamphetamine	500	Mephentermine	25,000
L-Methamphetamine	4,000		
Methamphetamine			
p-Hydroxymethamphetamine	30,000	(+/-)3,4-MDMA	2,000
D- Methamphetamine	1,000	Mephentermine	50,000
L-Methamphetamine	8,000		
MDMA			
(+/-)3,4-MDMA	500	(+/-)3,4-MDA	3,000
(+/-)3,4-MDEA	300		
Methadone			
Methadone	300	Doxylamine	50,000
Opiates (300)			
Codeine	300	Morphine	300
Ethylmorphine	6,250	Norcodeine	6,250
Hydrocodone	50,000	Normorphone	100,000
Hydromorphone	3,125	Oxycodone	30,000
Levorphanol	1,500	Oxymorphone	100,000
6-Monoacetylmorphine	400	Procaine	15,000
Morphine 3-β-D-glucuronide	1,000	Thebaine	6,250
Opiates (2000)			
Codeine	2,000	Morphine	2,000
Ethylmorphine	5,000	Norcodeine	12,500
Hydrocodone	12,500	Normorphone	50,000
Hydromorphone	5,000	Oxycodone	25,000
Levorphanol	75,000	Oxymorphone	25,000
6-Monoacetylmorphine	5,000	Procaine	150,000
Morphine 3-β-D-glucuronide	2,000	Thebaine	100,000
Oxycodone			
Oxycodone	100	Codeine	50,000
Dihydrocodeine	12,500	Ethylmorphine	25,000
Hydrocodone	1,562	Hydromorphone	12,500
Oxymorphone	1,562	Thebaine	50,000
PCP			
4-Hydroxyphencyclidine	12,500	Phencyclidine	25

PPX			
D-Propoxyphine	300	D-Norpropoxyphene	300
THC			
Cannabinol	20,000	Δ^8-THC	15,000
11-nor-Δ^8-THC-9 COOH	30	Δ^9-THC	15,000
11-nor-Δ^9-THC-9 COOH	50		
Tricyclic Antide- pressant			
Nortriptyline	1,000	Imipramine	400
Nordoxepin	1,000	Clomipramine	12,500
Trimipramine	3,000	Doxepine	2,000
Amitriptyline	1,500	Maprotiline	2,000

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

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

Index of Symbols

Consult instructions for use		Tests per kit		Authorized Representative	
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C		Lot Number	REF	Catalogue number

Rapid Self Test Inc.
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Mississauga, Ontario
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CE ISO 13485 CERTIFIED

CLIA Waived

Version 1.0
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