



## DRG® Multi Drug Screening Test (\*\*with Timer\*\*) (RAP-3003)

Revised 29 July 2010 rm (Vers. 2.1)



*Please use only the valid version of the package insert provided with the kit.*

### 1 INTENDED USE

The QuickScreen™ Pro Multi Drug Screening Test is a rapid, self-timed, qualitative immunoassay for the detection of drugs of abuse in urine. The cutoff concentrations for this test are Methamphetamine at 500 ng/mL, Amphetamine at 1000 ng/mL, THC metabolite (THCA) at 50 ng/mL, Cocaine metabolite (Benzoylecgonine) at 300 ng/mL and Opiates at 300 ng/mL. This assay is intended for professional use.

**This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.**

### 2 SUMMARY & EXPLANATION OF THE TEST

**Methamphetamine (MET), Amphetamine (AMP)** and their metabolites are central nervous system stimulants whose pharmacological properties include alertness, wakefulness, increased energy, reduced hunger and an overall feeling of well being. Large doses and extended usage can result in higher tolerance levels and physiological dependency. Both *d* and *l* forms of Amphetamine and the (+) form of Methamphetamine are controlled substances. **Δ<sup>9</sup>-Tetrahydrocannabinol (THC)** is generally accepted to be the principle active component in marijuana and hashish, although other cannabinoids are likely to contribute to their physiological activity. THC is rapidly absorbed by inhalation and by the gastrointestinal tract, and is almost completely metabolized. Its predominant metabolite, 11-Nor-Δ<sup>9</sup>-THC-9-Carboxylic Acid, or **THCA**, is found in the plasma, feces and urine along with other compounds. Very low concentrations of THC may be detected in urine during the initial several hours, but THCA persists in urine at a detectable concentration for many days after smoking.

**Cocaine (COC)** is an alkaloid present in coca leaves (*Erythroxine coca*) whose pharmacological properties include alertness, wakefulness, increased energy and an overall feeling of euphoria. Cocaine has been used medicinally as a local anesthetic, however, its addictive properties have minimized its modern value as an anesthetic. Elimination of cocaine is predominantly controlled by its biotransformation. It is almost completely metabolized to Benzoylecgonine. Very low concentrations of Cocaine may be detected in urine during the initial several hours, but Benzoylecgonine persists in urine at detectable concentrations for 48 hrs.

**Opiates (OPI)** are addictive, narcotic pain-relieving drugs derived from the opium poppy (*Papaver somniferum*). An opiate is any natural or synthetic drug that has morphine-like pharmacological actions. Opiates include Morphine, Heroin, Codeine and Nalorphine.

Urine-based screening tests for drugs of abuse range from complex analytical procedures to simple immunoassay tests. The sensitivity and rapidity of the immunoassay have made them the most accepted method of preliminary screening for drugs of abuse in urine. This allows the laboratory to eliminate the large number of negative specimens and focus on the smaller number of initially positive samples.

### 3 PRINCIPLES OF THE PROCEDURE

The QuickScreen™ Pro Multi-Drug Screening Test is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is a chromatographic absorbent device in which drugs or drug metabolites in a

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sample compete with drug / protein conjugate immobilized on a porous membrane for a limited number of antibody / dye conjugate binding sites. The test device employs a unique combination of monoclonal and polyclonal antibodies to selectively identify drugs of abuse in urine with a high degree of confidence. The test device also contains a “self-timer” that indicates when results are ready to be interpreted.

In the procedure, the absorbent end of the test device is inserted into the urine sample. The urine is absorbed into the device by capillary action, mixes with the antibody / dye conjugate, and flows across the pre-coated membrane.

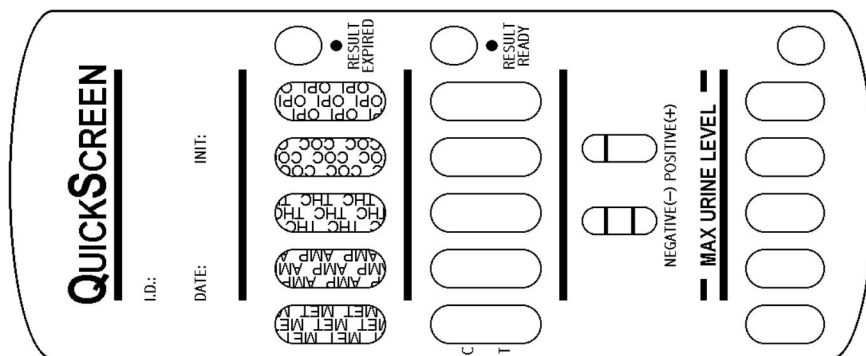
**When sample drug levels are below the target cutoff** (the detection sensitivity of the test), antibody / dye conjugate binds to the drug / protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test Band that, *regardless of its intensity*, indicates a negative result.

**When sample drug levels are at or above the target cutoff**, the free drug in the sample binds to the antibody / dye conjugate, preventing the antibody / dye conjugate from binding to the drug / protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band, indicating a potentially positive sample.

In either case, a colored Control Band is produced in the Control Region (C) by a non-specific antibody-dye / conjugate reaction. This band serves as a built-in quality control device, demonstrating antibody recognition and reactivity, as well as confirming that the test is complete.

### 4 REAGENTS & MATERIALS SUPPLIED

1. 5 Self-timed Test Devices. Separate panels for each target drug contain:
  - a. Monoclonal anti-drug antibody / colloidal gold conjugate in a protein matrix containing 0.1% sodium azide coated in the sample path
  - b. Drug derivative / protein conjugate immobilized as a line in the Test Region
  - c. Goat anti-mouse antibody immobilized as a line in the Control Region
2. Directional Insert
3. (Optional) Single Specimen Collection Kit (Cat. # 9501 or equivalent) – or –
4. (Optional) Split Specimen Collection Kit (Cat. # 9502 or equivalent)





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### **5 WARNINGS & PRECAUTIONS**

1. FOR *IN VITRO* DIAGNOSTIC USE ONLY.
2. For professional use only.
3. Urine samples have the potential to be infectious. Follow Universal Precautions for proper handling and disposal methods.
4. Do not use this kit beyond its expiration date.
5. This method has been established using urine only. Other fluids have not been evaluated.
6. Do not reuse the Test Device.

### **6 STORAGE & HANDLING REQUIREMENTS**

Store at room temperature (15 – 28 °C).

Do not freeze.

Refer to expiration date for stability.

### **7 SAMPLE COLLECTION & PREPARATION**

A fresh urine sample should be collected in one of the above-mentioned specimen collection kit or equivalent. Alternately, a clean, dry plastic or glass container, unused and without preservatives, may be used for specimen collection.

Testing requires at least ½ inch (50 to 60 mL) of urine in the sample container. If required by your procedure, aliquot a portion of urine into the split sample container for later confirmation of results. If not required, dispose of all but ½ inch of urine and save the remainder for the QuickScreen test.

Samples may be tested immediately or stored for up to 48 hours at 2 – 8 °C.

For longer storage, freeze samples at –20 °C or below.

### **8 ASSAY PROCEDURE**

#### **8.1 Preparation**

1. Confirm that all samples and test components are at room temperature (15 – 28 °C) before testing.
2. Do not break the seal on the foil pouch until you are ready to perform the test.

#### **8.2 Testing**

1. Open the foil pouch at the notch and remove the test device. Take care not to touch the exposed membranes.
2. Insert the reactive end of the test device into the urine sample. Make sure that the urine level is not above the “MAX URINE LEVEL” printed on the front of the device.
3. Leave the test device in the sample cup until you are read to interpret the test results.

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### 8.2.1 When to Read Test Results Using the “Timer”

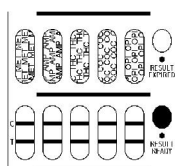


When the “RESULT READY” window is completely filled with red color, or is almost completely covered with red color that reaches the top of the window, the test results are ready to interpret.



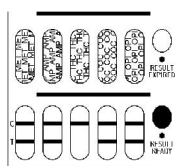
When red color becomes clearly visible at the bottom of the “RESULT EXPIRED” window, test results should no longer be interpreted and should not be considered as conclusive.

### 8.2.2 Interpretation of Test Results



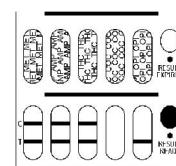
#### Negative Test Results for All Drugs Tested

**Negative** – If two (2) colored bands appear, one in the Control Region (C) and one in the Test Region (T), **at any time before** any red color appears at the bottom of the “RESULT EXPIRED” window, this is a Negative Result, indicating that the target drug is not present or its concentration is below the detection sensitivity of the test panel. Some negative results may appear in as little as 1 minute, and can be safely interpreted as soon as 2 colored bands are visible.



#### Positive Test Results for THC

**Positive** – If only one (1) colored band appears in the Control Region (C) and no band appears in the Test Region (T), **after** a red spot appears in the “RESULT READY” window but **before** any red color appears at the bottom of the timer’s “RESULT EXPIRED” window, this is a Positive Result, indicating that the target drug concentration is at or above the detection sensitivity of the panel. More than one panel may be positive. Potentially positive results can only be reported when a red spot appears in the timer’s “RESULT READY” window.



#### Invalid Test Results for Cocaine & Opiates

**Invalid** – A test must be considered invalid if, **after** a red spot appears in the “RESULT READY” window, no bands appear or if a band appears in the Test Region without a Control Band. The presence of a Control Band is necessary to confirm assay performance.



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### **9 QUALITY CONTROL**

An internal procedural control line has been incorporated into the test device to help ensure proper kit performance and reliability. However, the use of external controls is recommended. Positive and negative controls within 25% of the cutoff concentration should produce the expected results. For positive controls, only one (1) colored band will appear in the Control Region (C), and no band will appear in the Test Region (T). For negative controls, two (2) colored bands will appear, one in the Control Region (C) and one in the Test Region (T).

### **10 LIMITATIONS OF THE PROCEDURE**

1. The possibility exists that substances and factors not described in this directional insert may interfere with the test, causing false results (e.g., technical or procedural error).
2. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
3. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
4. All positive samples must be confirmed by another method. Gas chromatography / mass spectrometry (GC/MS) is the method of choice to confirm the presence and concentration of a drug in urine.
5. This test is a qualitative, competitive screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
6. Because the QuickScreen™ Test is a competitive assay, no prozone effect is present.
7. Occasionally, samples containing target drug concentrations below the cutoff sensitivity for the test may produce a positive result.

### **11 PERFORMANCE CHARACTERISTICS**

#### **11.1 Sensitivity**

The sensitivity of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared with a commercially available immunoassay at the cutoff concentrations. In addition, the combined studies of two independent clinical laboratories are reported for overall sensitivity, comparing QuickScreen to the Emit II instrument-based immunoassay.

#### **11.2 Specificity**

The specificity of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared with a commercially available immunoassay at the cutoff concentrations. In addition, the combined studies of two independent clinical laboratories are reported, comparing QuickScreen to the Emit II assay.

#### **11.3 Accuracy**

The accuracy of the QuickScreen™ Pro Multi Drug Screening Test was evaluated on clinical (urine) samples and compared with a commercially available immunoassay at the cutoff concentrations. In addition, the combined studies of two independent laboratories are reported, comparing QuickScreen to the Emit II assay.



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	In-House Study, % Agreement					Clinical Study, % Agreement				
Analyte	MET	AMP	THC	COC	OPI	MET	AMP	THC	COC	OPI
<i>n</i> =	189	189	143	164	176	125	124	102	143	151
Sensitivity	95.9	97.6	99	100	>99	97.7	98.8	98	100	>99
Specificity	100	100	99	95.9	>99	100	100	99	87.5 <sup>[1]</sup>	>99
Accuracy	97.3	99.4	98	98.1	>99	98.4	99.2	>98	96.5	>99

<sup>[1]</sup> Five discrepant results were observed in the Cocaine Clinical Study. The samples were from 3 to 10% below the assay cutoff concentration (271 to 293 ng/mL) and subsequently tested positive by GC/MS.

### 11.4 Precision

Eight urine pools, ranging in concentration from 0 to 200% of cutoff, were assayed twice a day for 20 days. The results were interpreted individually by two technicians. The inter- and intra-assay coefficients of variation were determined to be less than 2%.

### 11.5 Cross-Reactivity

The following structurally related compounds were spiked into normal human urine and found to cross-react in the QuickScreen™ Pro Multi Drug Screening Test. The results, in µg/mL, are expressed as that amount of compound capable of giving a result equivalent to the target drug at its cutoff concentration. Unless otherwise noted, a blank space indicates that no cross-reactivity was observed when the compound were tested to 100 µg/mL.

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Compound	AMP	MET	COC	THC	OPI
d-Amphetamine	1	20			
dl-Amphetamine	10	50			
l-Amphetamine • (R)-(+)- $\alpha$ -Phenylethylamine	100	100			
3-Hydroxytyramine • ( $\pm$ )- $\alpha$ -Phenylethylamine • $\beta$ -Phenylethylamine	10				
Mephentermine	100	10			
( $\pm$ )-3,4-Methylenedioxyamphetamine	4.5	100			
Tyramine	12.5	62.5			
N-Acetylprocainamide • (+) & ( $\pm$ )-Ephedrine • (+)- $\psi$ -Ephedrine		100			
(-)-Deoxyephedrine		1			
Fenfluramine		100			
( $\pm$ )-Isoproterenol		1.5			
(+)-Methamphetamine		0.5			
( $\pm$ )-3,4-Methylenedioxymethamphetamine		3.5			
Nylidrin		5			
Benzoylcegonine • Cocaine			0.3		
Metoclopramide			25		
Procaine • Pyrilamine			100		
11-Hydroxy- $\Delta^9$ -THC <sup>[A]</sup>				1	
11-Nor- $\Delta^9$ -THC-Carboxylic Acid <sup>[A]</sup> • $\Delta^9$ -Tetrahydrocannabinol				0.05	
11-Nor- $\Delta^8$ -THC-Carboxylic Acid <sup>[A]</sup>				0.1	
$\Delta^8$ -Tetrahydrocannabinol				100	
Codeine • Heroin <sup>[B]</sup> • Morphine • Morphine-3- $\beta$ -D-Glucuronide					0.3
Dextromethorphan					50
Ethylmorphine <sup>[B]</sup>					0.35
Hydrocodone • Hydromorphone • Naloxone					0.4
Levorphanol • Nalorphine • Norcodeine					0.5
Naltrexone					5
Normorphine <sup>[B]</sup>					10
Oxycodone • Thebaine					0.6

[A] A blank space indicates that no cross-reactivity was observed when the compound was tested to 5  $\mu$ g/mL.

[B] A blank space indicates that no cross-reactivity was observed when the compound was tested to 10  $\mu$ g/mL.



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### 11.6 Interfering Substances

The following compounds were spiked into normal human urine and tested for interference with the QuickScreen™ Pro Multi Drug Screening Test. Unless noted, these compounds were tested to 100 µg/mL with no interference observed.

Acetaminophen • Acetone • Acetylsalicylic Acid • Albumin • Alphenal • Alprazolam<sup>[Cl]</sup> • Amantadine • (+)-Amethopterin • Amikacin • *dl*-Aminoglutethimide • Aminopyrine • Amitriptyline • Amobarbital • Amoxicillin • Ampicillin • Apomorphine • Aprobarbital • (–)-Arterenol • *l*-Ascorbic Acid • Aspartame

*d*, *dl* & *l*-Aspartic Acid • Atropine • Barbital • Barbituric Acid • Benzoic Acid • Benzphetamine • Benztropine Methane Sulfonate • Bilirubin • Bromazepam • Bromocriptine Mesylate • (+)-Brompheniramine • Butabarbital • Butalbital • Butethal • Caffeine • Cannabidiol • Cannabinol • Carbamazepine • Cephalexin • Chloramphenicol • Chlordiazepoxide • Chloroquine • (+) & (±)-Chlorpheniramine • Chlorpromazine • Chlorpropamide • Chlorprothixene • Cimetidine • Clemastine • Clomipramine • Clonazepam • Clonidine • (–)-Cotinine • Creatinine • Cyclizine • Cyclobenzaprine • Cyclosporin A • Cyproheptadine • Desipramine • Desmethyldiazepam • 5,5-Diallylbarbituric Acid • Diazepam • Diflunisal • Digoxin • 4-Dimethylaminoantipyrine • Diphenhydramine • Diphenoxylate • 5,5-Diphenylhydantoin • Disopyramide • Doxepin • Doxylamine • (–)-Ephedrine • (–)-*ψ*-Ephedrine • (±) & (–)-Epinephrine • Erythromycin • Estriol • Estrone-3-Sulfate • Ethanol • Ethosuximide • Ethyl-*p*-Aminobenzoate • 2-Eth-ylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine • Fenoprofen • Fentanyl<sup>[DI]</sup>

Flunitrazepam • Flurazepam • Furosemide • Gentamicin • Gentisic Acid • Glucose • *dl*-Glutethimide • Griseofulvin • Guaiacol Glyceryl Ester • Hemoglobin • Hexobarbital • Hydrochlorothiazide • *o*-Hydroxyhippuric Acid • 5-Hydroxyindole-3-Acetic Acid • 5-Hydroxyindole-2-Carboxylic Acid • Hydroxyzine • Ibuprofen • Imipramine • Indole-3-Acetic Acid • Indole-3-Butyric Acid • Indomethacin

(+) & (–)-Isoproterenol • Isoxsuprine • Kanamycin • Ketamine • Ketoprofen • Labetalol • Lidocaine • Lithium Carbonate • (±)-Lorazepam • Lormetazepam • Lysergic Acid Diethylamide<sup>[El]</sup> • Medazepam • Melanin • Meperidine • Meprobamate • Mescaline • *dl*-Metanephine • (±)-Methadone • Methaqualone • (S)-6-Methoxy- $\alpha$ -Methyl-2-Naphthalene-acetic Acid • 2-Methyl-3-(3,4-Dihydroxyphenyl)- *dl* & *l*-Alanine • Methylphenidate • Methypylon • (±)-Metoprolol • Nafcillin • Naphazoline

$\alpha$  &  $\beta$ -Naphthaleneacetic Acid • Naproxen • Netilmicin • Niacinamide • Nialamide • Nicotinic Acid • Nifedipine • Nitrazepam • Nomifensine • Nordoxepin<sup>[DI]</sup> • Norethindrone • Nortriptyline • Noscapine • Orphenadrine • Oxalic Acid • Oxazepam • Oxymetazoline • Papaverine • Penicillin G • Pentazocine • Pentobarbital • Phencyclidine • Phenelzine • Pheniramine • Phenobarbital • Phenothiazine • Phentermine • Phenylacetone • *l*-Phenylalanine • Phenylbutazone • *trans*-2-Phenylcyclopropylamine • *l*-Phenylephrine • (±)-Phenylpropanolamine • Piroxicam • Potassium Chloride • Prazepam • Prednisolone • Primidone • Procainamide • Prochlorperazine • Promazine • Promethazine • (+)-Propoxyphene • 2-Propylpentanoic Acid • Protriptyline • Quinidine • Quinine • Ranitidine • Riboflavin • (–)-Scopolamine • Secobarbital • Sodium Chloride • Sulindac • Temazepam •





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Terbutaline • Tetracycline • Tetraethylthiuram Disulfide • Tetrahydrozoline • Theophylline • Thioridazine

• *cis*-Thiothixene • Tobramycin • Triamterene • Triazolam<sup>[D]</sup> • Trifluoperazine • Triflupromazine  
• *dl*-Trihexyphenidyl • Trimethobenzamide • Trimethoprim • Trimipramine • Triprolidine • Urea  
• Uric Acid • Vancomycin • (±)-Verapamil • Zomepirac

[C] No interference was observed when the compound was tested to 25 µg/mL.

[D] No interference was observed when the compound was tested to 10 µg/mL.

[E] No interference was observed when the compound was tested to 2.5 µg/mL.

### 12 BIBLIOGRAPHY & SUGGESTED REFERENCES

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