

#### INTENDED USE

**FastScreen™ Single Drug Test** is a rapid, competitive binding immunoassay for qualitative determination of different drugs and drug metabolites in human urine. It is intended for professional and laboratory use only. The assay should not be used without proper supervision and is not intended for over the counter sale to layperson.

The test provides only preliminary data which should be confirmed by other analytical methods, such as **gas chromatography/ mass spectrophotometry (GC/MS)**. The preliminary positive results should be justified with compelling clinical consideration and professional judgment.<sup>1-4</sup>

#### SUMMARY AND EXPLANATION OF THE TEST

**FastScreen™ Single Drug Test** is an easy, fast, and visually read screening method without the use of any instrument. The test system employs unique polyclonal antibodies to selectively identify specific drugs and drug metabolites in urine samples with a high degree of sensitivity.

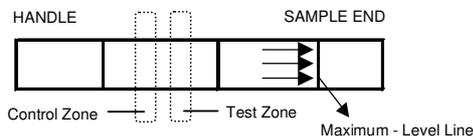
Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Erimin, Ketamine, Marijuana, Methamphetamine, and Morphine are of clinical importance to treat patients in various circumstances.<sup>1,4,6</sup> These drugs and their metabolites can be detected in urine as a result of drug abuse. Immunoassay testing has been developed for the determination of their concentration in urine at various cut-off values.<sup>7-10</sup> These values are in accordance with the United States Substance Abuse and Mental Health Services Administration (SAMHSA).<sup>11</sup> These drugs' respective use in clinical applications and their corresponding cut-off values can be referred in separate evaluation sheets. Please contact the manufacturer for detailed descriptions.

#### PRINCIPLE

The **FastScreen™ Single Drug Test** is a chromatographic absorbent device in which drug or drug metabolites in a sample compete with drug conjugate immobilized on a porous membrane support for limited antibody sites.

Labeled antibody-dye conjugate mixes with sample specimen and binds to the free drug or drug metabolites present to form an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the test zone preventing the formation of a purplish-pink color band when the drug is above the detection level. Unbound dye conjugate binds to the reagent in the control zone and produces a purplish-pink color band, demonstrating that the reagents and device are functioning correctly.

A negative specimen produces two distinct color bands, one in the test zone and one in the control zone. A positive specimen produces only one color band in the control zone.



#### REAGENTS AND MATERIALS SUPPLIED

1. **100 pieces of FastScreen™ Single Drug Test dipsticks:** Each test dipstick contains membrane-immobilized reagent specific to the drug of choice.
2. **1 copy of Product insert**

#### MATERIALS REQUIRED, BUT NOT PROVIDED

1. Urine container for sample collection and testing
2. Clock or timer

#### WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use kit beyond the expiration date.
3. The test device should remain in the sealed pouch until use.
4. Urine specimens may be infectious, properly handle and dispose of all used reaction devices into a biohazard container.

#### STORAGE

Store the test kits at 4-30°C, do not freeze. Refer to the expiration date for stability.

#### SAMPLE COLLECTION AND PREPARATION

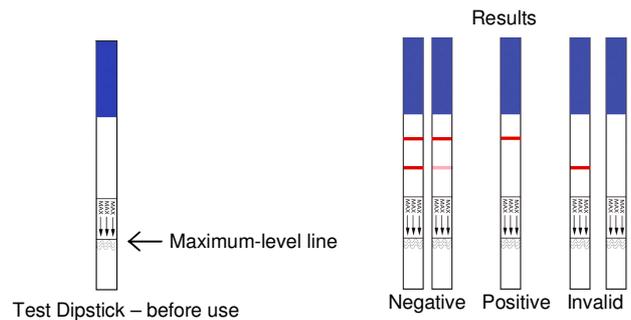
The urine specimen must be collected into a clean and dry container. Urine can be collected at any time of the day. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.

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.

#### ASSAY PROCEDURE

1. Bring the urine sample and the test components to room temperature (15-28°C).
2. Once ready, tear open the foil pouch at the notch and remove the test device.
3. With arrows pointing towards the urine sample, immerse the test dipstick into the urine sample for at least 6-10 seconds. When immersing, make sure that the urine sample do not exceed the maximum-level line indicated. See the illustration below.
4. Lay the test dipstick flatly on a non-absorptive clean surface.
5. Read the test result within five minutes.

\* **IMPORTANT:** The result must be interpreted within five (5) minutes. Waiting more than five (5) minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.



#### INTERPRETATION OF RESULTS

1. **Negative:** Two horizontal purplish-pink color bands appear, one in the control zone and one in the test zone. The color intensity of the control line and test line may not be equal. Any faint band appears at the test zone, visible within 5 minutes, should be interpreted as presence of the test line. This is a negative result and indicates that the drug concentration is below the detection sensitivity.
2. **Positive:** A purplish-pink color band appears in the control zone but not in the test zone. This is a positive result and indicates that the drug level is at or above the detection sensitivity. It is recommended that all positive results to be confirmed by using an appropriate analytical technique.
3. **Invalid:** If no band appears, or a test band appears without a control band, disregard the results and repeat with a new test. The presence of a control line is necessary to validate test performance.

## QUALITY CONTROL

An internal procedural control has been incorporated into the test to ensure proper kit performance and reliability. A colored line appearing in the control line region (C) confirms that 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 OF THE TEST

1. This product is designed for use with human urine only.
2. Although the test is accurate, there is possibility that false results occur due to the presence of interfering substances in the urine sample.
3. The test is a qualitative screening assay and is not for determining quantitative concentration levels or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen and retest.

## PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The **FastScreen™ Single Drug Test** detects the specified drug and its metabolites in urine at concentrations equal to or greater than the specific cut-off values:

Drug Test	Cut-off ((ng/ml)
Amphetamine (AMP)	1000
Barbiturates (BAR)	300
Benzodiazepines (BZO)	300
Cocaine (COC)	300
Erimin (ER5)	300
Ketamine (KET)	1000
Marijuana (THC)	50
Methamphetamine (MET)	1000
Morphine (MOP)	300

2. **Specificity.** A study was conducted with the **FastScreen™ Single Drug Test** to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross-reactivity was detected with the substances listed in Table 1.

**Note: For a more comprehensive list for the cross-reactivity study for each type of drugs, please refer to separate sheets that can be obtained from the manufacturer.**

**Table 1:** Compounds tested and found not to cross-react with the test at a 100 µg/mL concentration in urine:

Acetophenetidin	Cortisone	Isoxsuprine	d-Pseudoephedrine
N-Acetylprocainamide	l-Cotinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Creatinine	Labetalol	Quinine
Aminopyrine	Deoxycorticosterone	Loperamide	Salicylic acid
Amoxicillin	Dextromethorphan	Meprobamate	Serotonin
Ampicillin	Diclofenac	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Diffunisal	Methylphenidate	Sulindac
Apomorphine	Digoxin	Nalidixic acid	Tetracycline
Aspartame	Diphenhydramine	Naproxen	Tetrahydrocortisone-3-acetate
Atropine	Ethyl-p-aminobenzoate	Niacinamide	Tetrahydrocortisone
Benzilic acid	b-Estradiol	Nifedipine	Tetrahydrozoline
Benzoic acid	Estrone-3-sulfate	Norethindrone	Thiamine
Bilirubin	Erythromycin	Noscapine	Thioridazine
d,l-Brompheniramine	Fenoprofen	d,l-Octopamine	d,l-Tryptophan
Caffeine	Furosemide	Oxalic acid	Tolbutamide
Cannabidiol	Genitic acid	Oxolinic acid	Triamterene
Chloral hydrate	Hemoglobin	Oxymetazoline	Trifluoperazine
Chloramphenicol	Hydralazine	Papaverine	Trimethoprim
Chlorothiazide	Hydrochlorothiazide	Penicillin-G	d,l-Tryptophan
d,l-Chlorpheniramine	Hydrocortisone	Perphenazine	Uric acid
Chlorpromazine	o-Hydroxyhippuric acid	Phenelzine	Verapamil
Cholesterol	3-Hydroxytyramine	Prednisone	Zomepirac
Clonidine	d,l-Isoproterenol	d,l-Propranolol	

3. **Accuracy.** Evaluation from the Doping Control Centre (DCC) is currently conducted. Please contact the manufacturer for full results.

4. **Precision.** The precision was determined by replicate assays of three different patient urine samples with kits from three different production lots. The resultant data indicated 100% precision for the duplicates within each lot and no appreciable inter-lot variation when testing both positive and negative spiked samples across three (3) different lots of devices.

## BIBLIOGRAPHY

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## ORDERING INFORMATION

Product Code	Description	Packing Size
DT-RD01-AMP	FastScreen™ Single Drug Test, Amphetamine (AMP)	100 tests/ kit
DT-RD01-BAR	FastScreen™ Single Drug Test, Barbiturates (BAR)	100 tests/ kit
DT-RD01-BZO	FastScreen™ Single Drug Test, Benzodiazepines (BZO)	100 tests/ kit
DT-RD01-COC	FastScreen™ Single Drug Test, Cocaine (COC)	100 tests/ kit
DT-RD01-ER5	FastScreen™ Single Drug Test, Erimin (ER5)	100 tests/ kit
DT-RD01-KET	FastScreen™ Single Drug Test, Ketamine (KET)	100 tests/ kit
DT-RD01-THC	FastScreen™ Single Drug Test, Marijuana (THC)	100 tests/ kit
DT-RD01-MET	FastScreen™ Single Drug Test, Methamphetamine (MET)	100 tests/ kit
DT-RD01-MOP	FastScreen™ Single Drug Test, Morphine (MOP)	100 tests/ kit

Bulk purchase is also available.

## DISTRIBUTED BY:

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