FastScreen™ Drug Combo Test

Product insert for testing of any combination of the following drugs:
AMP/ BAR/ BZO/ COC/ ER5/ KET/
MDMA/ MET/ MOP/ MTD/ PCP/ TCA/ THC

INTENDED USE

FastScreen™ Drug Combo Test is a rapid, competitive binding immunoassay for qualitative determination of multiple drugs and drug metabolites in human urine. These drugs can be custom-made in a minimum of any two-test combination to a maximum of ten-test combination. 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 methods, such as **gas chromatography/ mass spectrophotometry (GC/MS**). The preliminary positive results should be justified with compelling clinical consideration and professional judgment.[1-4]

SUMMARY AND EXPLANATION OF THE TEST

FastScreen™ Drug Combo 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.

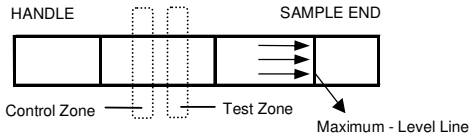
Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Nimetazepam, Ketamine, MDMA, Methamphetamine, Morphine, Methadone, Phencyclidine, Tricyclic Antidepressants and Marijuana are of clinical importance to treat patients in various circumstances.[1,4,6] These drugs and their metabolites can be detected 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.[7-10] These values are in accordance with the United States Substance Abuse and Mental Health Services Administration (SAMHSA).[11] 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™ Drug Combo 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. **25 pieces of FastScreen™ Drug Combo Test dipcards:** Each test dipcard consisting of a combination of dipsticks which contain membrane-immobilized reagents specific to the drugs 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. This product insert must be strictly adhered in order to produce accurate test results. Deviations from the procedure may lead to aberrant results.
3. The test device should remain in the sealed pouch until use.
4. Do not use cassette if the sealed pouch is visibly damaged.
5. Do not use kit beyond the expiration date.
6. Urine specimens may be infectious, properly handle and dispose of all used reaction devices into a biohazard container.
7. Wipe any spills of specimen promptly with disinfectant.
8. Do not reuse test device.

STORAGE

Store the test kits between 4-30℃, do not freeze. The test cassettes should be kept sealed until use. Refer to the expiration date for stability.

SAMPLE COLLECTION AND PREPARATION

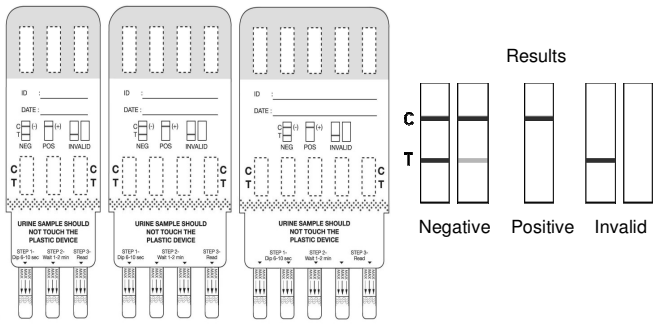
The urine specimen must be collected into a clean and dry container. Urine can be collected at any time of the day. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.

Urine specimens may be stored at 2-8℃ for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20℃. 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℃).
2. Once ready, open the foil pouch at the notch and remove the test device. Label the test dipcard with patient or control identifications.
3. Remove the cap from the test dipcard. With arrows pointing towards the urine sample, immerse the test dipcard 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 and urine sample should not touch the plastic device. See the illustration below.
4. Replace the cap and lay the test dipcard 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.



Test Dipcard – before use

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 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 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. 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. The FastScreen™ Drug Combo Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
3. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
4. The test is a qualitative screening assay and is not for determining quantitative concentration levels or the level of intoxication of the donor.
5. 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.
6. The test does not distinguish between drugs of abuse and certain medications. A positive test result may be obtained from certain foods or food supplements.
7. 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™ Drug Combo Test** detects the specified drug and its metabolites in urine at concentrations equal to or greater than the specific cut-off values:

Drug Test	*Calibrator*	*Cut-off (ng/ml)*
Amphetamine (AMP)	D-Amphetamine	1000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	300
Nimetazepam (Erimin, ER5)	Nimetazepam	300
Ketamine (KET)	Ketamine	1000
MDMA (Ecstasy, MDMA)	D,L Methylenedioxy-methamphetamine	1000
Methamphetamine (MET)	D-Methamphetamine	1000
Morphine (MOP)	Morphine	300
Methadone (MTD)	Methadone	300
Phencyclidine (PCP)	Phencyclidine	25
Tricyclic Antidepressants (TCA)	Nortriptyline	1000
Marijuana (THC)	11-nor-Δ9-THC-9	50

2. **Specificity.** A study was conducted with the **FastScreen™ 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 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	Diflunisal	Methylphenidate	Sulindac
Apomorphine	Digoxin	Nalidixic acid	Tetracycline
Aspartame	Diphenhydramine	Naproxen	Tetrahydrocortisone-3-acetate
Atropine	Ethyl-p-aminobenzoate	Niacinamide	Tetrahydrocortisone
Benzilic acid	β-Estradiol	Nifedipine	Tetrahydrozoline
Benzoic acid	Estrone-3-sulfate	Norethindrone	Thiamine
Bilirubin	Erythromycin	Noscapine	Thioridazine
d,l-Brompheniramine	Fenoprofen	d,l-Octopamine	d,l-Tyrosine
Caffeine	Furosemide	Oxalic acid	Tolbutamide
Cannabidiol	Gentisic 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-Propanolol	

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-RD02	FastScreen™ Drug Combo Test 2-in-1	25 tests/ kit
DT-RD03	FastScreen™ Drug Combo Test 3-in-1	25 tests/ kit
DT-RD04	FastScreen™ Drug Combo Test 4-in-1	25 tests/ kit
DT-RD05	FastScreen™ Drug Combo Test 5-in-1	25 tests/ kit
DT-RD06	FastScreen™ Drug Combo Test 6-in-1	25 tests/ kit
DT-RD07	FastScreen™ Drug Combo Test 7-in-1	25 tests/ kit
DT-RD08	FastScreen™ Drug Combo Test 8-in-1	25 tests/ kit
DT-RD09	FastScreen™ Drug Combo Test 9-in-1	25 tests/ kit
DT-RD10	FastScreen™ Drug Combo Test 10-in-1	25 tests/ kit

Please specify the combination of the Drug Combo Test when placing order. Bulk purchase is also available.

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