



SiteScreen Multi-5 Drug Screen Test

One-Step Multiple Test

For In Vitro Diagnostic Use

A visual one-step immunoassay for the simultaneous, qualitative detection of multiple drugs and metabolites in human urine. This product is used to obtain a visual, qualitative result and is intended for use by drug testing professionals in drug testing programs. The assay should not be used without proper supervision and is not intended for over the counter sale to lay persons.

INTENDED USE

The SiteScreen Drug Screen Test is a lateral flow, one-step panel immunoassay for the qualitative detection of amphetamine, benzodiazepines, benzoylecgonine (cocaine metabolite), methamphetamine, opiates, and 11-nor-⁹-THC-9-carboxylic acid in human urine.

This instruction sheet for use with the Drug Screen Test containing one or more of the following analytes at the concentrations listed below.

AMP	Amphetamine	1,000 ng/ml
BZO	Benzodiazepines	300 ng/ml
COC	Benzoylecgonine	300 ng/ml
M-AMP	Methamphetamine	1,000 ng/ml
OPI	Opiates (morphine)	300 ng/ml
THC	11-nor- ⁹ -THC-9-COOH	50 ng/ml

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) has been established as the preferred confirmatory method by the Substance Abuse and Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

Urine based screening tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method for screening urine for drugs of abuse.

The SiteScreen Drug Screen Test is based on the principle of the highly specific immunochemical reactions of antigens and antibodies which are used for the analysis of specific compounds in biological fluids. The SiteScreen Drug Screen Test is a rapid, visual, competitive panel immunoassay that can be used for the simultaneous, qualitative detection of amphetamine, benzodiazepines, benzoylecgonine (cocaine metabolite),

methamphetamine, opiates and 11-nor-⁹-THC-9-carboxylic acid in human urine. Characteristics of each drug are summarized as follows:

Amphetamine: Amphetamine and the structurally related "designer" drugs, are sympathomimetic amines whose biological effects include potent central nervous system (CNS) stimulation, anorectic, hyperthermic, and cardiovascular properties. They are usually taken orally, intravenously, or by smoking. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or excreted unchanged in the urine with a half life of about 12 hours. It can be detected in the urine for 1 to 2 days after use. Amphetamine is metabolized to deaminated (hippuric and benzoic acids) and hydroxylated metabolites. Methamphetamine is partially metabolized to amphetamine and its major active metabolite. Amphetamines increase the heart rate and blood pressure and suppress the appetite. Some studies indicate that heavy abuse may result in permanent damage to certain essential nerve structures in the brain.

Benzodiazepines: Benzodiazepines are the most widely used anxiolytic drugs. They are used extensively as anti-anxiety agents, hypnotics, muscle relaxants and anti-convulsants. They are taken orally or sometimes by injection and have a wide range of half-life from 2 to 40 hours. They can generally be detected for 1 to 2 days after Benzodiazepines use. Benzodiazepines are metabolized in the liver. Some metabolites of benzodiazepines also exhibit pharmacological activities. Benzodiazepines and metabolites are excreted in the urine. Their use can result in drowsiness and/or confusion. Benzodiazepines potentiate alcohol and other CNS depressants. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period.

Cocaine: Cocaine derived from leaves of cocoa plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in urine primarily as benzoylecgonine in a short period of time. Benzoylecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of cocaine (0.5 to 1.5 hour), and can be generally detected for 24 to 60 hours after cocaine use.

Methamphetamine: Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at high doses may be indistinguishable from schizophrenia. Methamphetamine has a half-life of about 15 hours and is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

Opiates: The opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. The principle metabolites of opiates are morphine, morphine-3-glucuronide, normorphine and codeine with a half-life of about 3 hours. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might both be found in the urine of a person who has taken only heroin. The body also changes codeine to morphine. Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the urine indicates heroin, morphine and/or codeine use.

Methodone: Methodone is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methodone are analgesia, sedation and respiratory depression. Overdose of methodone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver and excreted in urine as methodone, EDDP, EMDP and methadol. The kidneys are a major route of methodone excretion. Methodone has a biological half-life of 15 to 60 hours and can be detected in urine for up to 3 days after use.

THC: Marijuana is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in marijuana, THC & Cannabinol can be metabolized and excreted as 11-nor-⁹-THC-9-COOH with a half-life of 24 hours. It can be detected for 1 to 5 days after infrequent use or up to 28 days following chronic use. Smoking is the primary method of use of marijuana/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

PRINCIPLE

The SiteScreen Drug Screen Test is a one-step immunoassay in which various chemically labeled drugs (drug-conjugates) compete with the drugs which may be present in urine for limited antibody binding sites. The test device contains a membrane strip which is pre-coated with various drug-conjugates on the test band. The colored antibody-colloidal gold conjugate pad is placed at the end of the membrane. In the absence of drug in the urine, the solution of colored antibody-colloidal gold conjugate and urine moves upward, chromatographically by capillary action, across the membrane. This solution then migrates to the immobilized drug-conjugate zone on the test band region. The colored antibody-colloidal gold conjugate attaches to various drug-conjugate to form visible lines as the antibody complexes with the drug conjugates. Therefore, the formation of a 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-conjugate on the test band region for limited antibody sites. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-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 that has a different antigen/antibody reaction is added to the immunochromatographic 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. This means that **negative** urine will produce colored bands next to the drug test names and **positive** urine to a particular drug will not produce colored band next to that drug test name.

STORAGE AND STABILITY

The test kit should be stored at room temperature 2-30°C (36-86°F). Each device should remain in its sealed pouch for the duration of the shelf-life.

PRECAUTIONS

- FOR *IN-VITRO* DIAGNOSTIC USE.

- 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.

REAGENTS AND MATERIALS SUPPLIED

- 25 individually wrapped test devices which include one disposable pipette each.
- One instruction sheet.

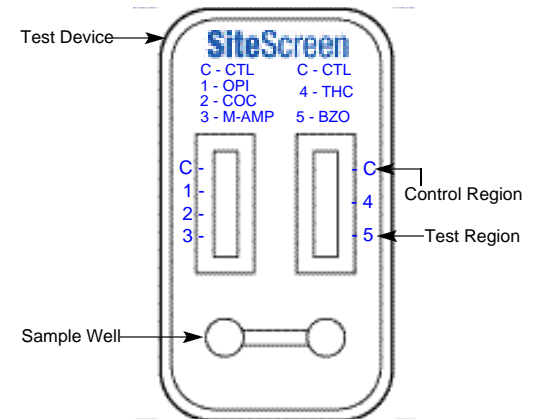
MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection container.
- Timer

SPECIMEN COLLECTION AND HANDLING

The SiteScreen Drug Screen Test is formulated for use with urine specimens. Fresh urine does not require any special handling or pretreatment. Urine samples should be collected such that testing can be performed as soon as possible after the specimen collection, preferably during the same day. The specimen may be refrigerated at 2-8°C for 2 days or frozen at -20°C for a longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed, equilibrated to room temperature, and mixed thoroughly prior to testing. Specimens freshly collected at 37°C can be tested immediately.

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.



TEST PROCEDURE

Review "Specimen Collection" instructions. Test device, patient's samples, and controls should be brought to room temperature (20-30°C) prior to testing. Do not open pouches until ready to perform the assay.

- Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identification.
- Draw the urine sample to the line marked on the pipette (approximately 0.2 mL). Dispense the entire contents into the sample well. Use a separate pipette and device for each sample or control.
- Read result between 3 and 8 minutes after the addition of the sample.** Do not read result after 8 minutes

INTERPRETATION OF RESULTS

Negative (-):

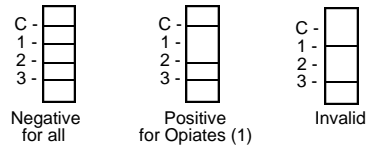
Colored lines should be observed next to the drug test names on the test region in the viewing window. The line on the control region (C) is the control line, and the other lines on test region are the test lines (drug probe lines).

Positive (+):

The appearance of control line and the absence of test line next to the drug test name on test region indicates a positive test result for that particular drug.

Invalid:

No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.



LIMITATIONS OF PROCEDURE

- The assay is designed for use with human urine only.
- A positive result with any of the tests indicates the presence of a drug/metabolite only and does not indicate or measure intoxication.
- There is a possibility that technical or procedural errors as well as other substances or factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.
- If it is suspected that the samples have been mislabeled or tampered with, a new specimen should be collected and the test should be repeated.

QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality control specimens are available from commercial sources. When testing the positive and negative controls, use the same assay procedure as with a urine specimen.

PERFORMANCE CHARACTERISTICS

A. Accuracy

For each individual drug screen assay, approximately 60 urine samples of specific drugs were obtained from clinical laboratories. The concentration of drug present in the samples was determined by either GC/MS or commercial kits. Each sample was then tested with a SiteScreen Drug Screen Test. Additionally, approximately one hundred urine samples collected from presumed non-user volunteers were tested with both methods. The results are as follows:

DRUG CONCENTRATION (ng/ml)	No. of Samples	SiteScreen Drug Screen Test Pos/Neg
AMP		
<1,000	113	0/113
>1,000	57	55/2
BZO		
<300	108	3/107
>300	49	49/0
COC		
<300	110	8/100
>300	58	56/2
M-AMP		
<1,000	109	0/109
>1,000	63	62/1
OPI		
<300	107	0/107
>300	67	67/0
THC		
<50	108	0/108
>50	64	64/0

B. Precision

The precision of the SiteScreen Drug Screen Test was determined by conducting the test with spiked controls. The control at the concentration of 200% of the cut-off gave a positive result. The control at the concentration of 50% below the cut-off gave a negative result.

C. Specificity

The specificity for the SiteScreen Drug Screen Test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

The following structurally related compounds produced positive results when tested at levels equal to or greater than the concentrations listed below.

Compound	Concentration(ng/ml)
Amphetamine	
d-Amphetamine	1,000
l-Amphetamine	10,000
(+/-)3,4-methylenedioxyamphetamine (MDA)	5,000
Phentermine	1,000
Tyramine	75,000

Benzodiazepines

Oxazepam	300
Alprazolam	600
Bromazepam	100
Chlordiazepoxide	300
Clobazam	300
Clonazepam	300
Chlorazepate	200
Delorazepam	3,000
Diazepam	300
Estazolam	300
Flunitrazepam	300
Flurazepam	150
Lorazepam	500
Lormetazepam	500
Medazepam	2,000
Nitrazepam	250
Nordiazepam	150
Prazepam	1,500
Temazepam	150
Triazolam	200

Cocaine

Benzoylcegonine	300
Cocaine	300

Methamphetamine

(+)-Methamphetamine	1,000
D-Amphetamine	50,000
Chloroquine	50,000
(+/-)-Ephedrine	50,000
(-)-Methamphetamine	25,000
Mephentermine	50,000
(+/-)3,4-methylenedioxyamphetamine (MDMA)	2,000
β-Phenylethylamine	50,000
Ranitidine	50,000
Trimethobenzamide	10,000

Opiates

Morphine	300
Codeine	300
Ethyl Morphine	300
Hydrocodone	5,000
Hydromorphone	5,000
Morphine-3-β-d-glucuronide	1,000
Thebaine	30,000

THC

11-nor- ⁹ -THC-9-COOH	50
11-nor- ⁸ -Tetrahydrocannabinol-9-carboxylic acid	50
11-hydroxy- ⁹ -Tetrahydrocannabinol	2,500
⁸ -Tetrahydrocannabinol	7,500
⁹ -Tetrahydrocannabinol	10,000
Cannabinol	10,000
Cannabidiol	100,000

The following compounds were found not to cross-react when tested at concentrations up to 100 µg/ml.

Acetaminophen	Aspartame
Acetone	Aspirin
Amoxapine	Atropine
Ampicillin	Baclofen
Albumin	Benzocaine

Benzafibrate	Ketamine
Bilirubin	Lidocaine
(+)Brompheniramine	Maprotiline
Caffeine	Methanol
Carbamate	2-IN-morpholinolathanesaltonic acid
Carbamazepine	Methaqualone
Carisoprodol	(1R,2S)-(-)-N-Methyl-Ephedrine
(+)-Chlorpheniramine	Methylphenidate
(+/-)-Chlorpheniramine	Naltrexone
Chlorpromazine	Naphthalene Acetic Acid
Chlorprothixene	(+)-Naproxen
Chlorthalidone	(-)-Nicotine
Clofibrate	Nicotinic Acid
Creatine	Noscapine Hydrochloride
Creatinine	(+/-)-Norephedrine
r-Cyclodextrin	Orphenadrine
Cyproheptadine	Oxalic Acid
Dantrolene	Pentazocine
Dexamethasone	Penicillin-G
Dexbrompheniramine	Phenothiazine
Dextromethorphan	Phenelzine
4-Dimethylaminoantipyrine	Pheniramine
Diphenhydramine	L-Phenylephrine
5,5-Diphenylhydantoin	Primidone
Dopamine	Procaine
Ecgonine	Promethazine
Ecgonine Methyl Ester	2-Propylantanoic acid
(-) - Ephedrine	Pseudoephedrine
(+) - Ephedrine	d-Propoxyphene
(+/-)-Epinephrine	Quinidine
Erythromycin	Quinine
Ethanol	Riboflavin
Fenofibrate	Salicylic Acid
Fentanyl	Sodium Chloride
Fluoxetine	Sulindac
Gemfibrozil	Tenocyclidine
Glucose	Theophylline
Guaicol Glyceryl Ether	Thioridazine
DL-Homatropine	cis-Thiothixene
Hemoglobin	D(+)-Trehalose
Hydrochlorothiazide	Trifluoperazine
Ibuprofen	VitaminC
(+/-)-Isoproterenol	

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