

# DRUGSWAB™ Drug Screen Test

## Intended Use

The DRUGSWAB™ Drug Screen Test is a one-step lateral flow immunoassay device for the detection of drug residues on surfaces or drug solid. The DRUGSWAB™ device detects drugs listed below:

OPI	Heroin	10 ng/ml
COC	Cocaine	20 ng/ml
MET	d-Methamphetamine/MDMA	25 ng/ml
BUP	Buprenorphine	10 ng/ml
THC	Delta-9-Tetrahydrocannabinol	40 ng/ml
FEN	Fentanyl	20 ng/ml

This product is intended for forensic use only and is not for use in diagnostic procedures.

The DRUGSWAB™ Drug Screen Test provides only preliminary drug test results. For a quantitative result or for a confirmation of a presumptive positive result obtained by the DRUGSWAB™ Drug Screen Device, a more specific alternative method such as GC/MS or LC/MS must be used.

## Summary and Explanation

Illegal drug consumption contributes to many accidents, injuries and medical conditions.

DRUGSWAB™ Drug Screen Device is developed to detect drug residues on any surfaces, and drug solid. It is designed to integrate the collection of sample and lateral flow immunoassay screen testing in one single device.

## Test Principle

The DRUGSWAB™ Drug Screen Test is based on a competitive immunoassay procedure in which drug derivatives immobilized on the membrane compete with the drug(s) which may be present for limited antibody binding sites on the colored colloidal gold antibody conjugate. During testing, drug residue is collected by the collection pad, and migrates across the membrane when buffer is added. If no drug is present on the surface, the colored colloidal gold antibody conjugate will bind to the drug derivatives on the membrane to form visible bands at specific test regions. Therefore, the presence of a purple-red band at a specific test region indicates a negative result. If any drug(s) is (are) present on the surface, it competes with the immobilized drug conjugate for limited antibody binding sites of the colored colloidal gold conjugate. When sufficient amount of drug is present, the drug will saturate the antibodies, and the colored colloidal gold conjugate cannot bind to the drug derivative on the membrane. Therefore, the absence of a purple-red band at the test region indicates a presumptive positive result for that particular test.



Fig. a DRUGSWAB™ Drug Screen Test

A control band at the control region (C) indicates the test has performed properly. This control band should always appear regardless of the presence of drug or metabolite.

## Reagents

The DRUGSWAB™ Drug Screen Test contains two membrane strips and a collection pad. Each strip consists of a membrane immobilized with drug-protein conjugates and corresponding specific drug monoclonal antibody colloidal gold conjugate pad, a sample pad and an absorbent pad.

**Collection Pad:** The collection pad consists of an absorbent material.

**Buffer:** The buffer dissolves and/or extracts the drug from suspected residues.

## Materials Provided

Each DRUGSWAB™ Drug Screen Test kit contains:

- 1 Package Insert.
- 10 test devices kit. Each kit consists of an individually packaged test in a foil pouch with a desiccant, and a vial of 1.0 ml buffer.

## Warnings and Precautions

The DRUGSWAB™ Drug Screen Test is intended for *Forensic Use Only*. The test device should remain in its original sealed pouch until ready for use. Discard the test device if package is ripped or torn. Do not use the test device beyond the expiration date indicated on the kit.

## Product Storage

The DRUGSWAB™ Drug Screen Device pouch should be stored at room temperature (15°-30°C). Do not open pouch until ready to perform the assay.

## Test Procedure

1. Open the device kit and remove the test from the sealed pouch.
2. Carefully remove the blue cap by holding the sides and pull gently. This will expose the collection pad.

A. For drug residue on suspected surface:

Wipe the suspected surfaces with collection pad by pushing both side of pad flat on surface, and then add onto collection pad ~20 drops of buffer slowly or insert collection pad into buffer vial until fluid show up in the window.

B. For drug powder or tablet or plant:

Put small amount of suspected solid into the buffer vial, shake 15-30 seconds and then add ~20- drops of buffer onto collection pad or insert collection pad into buffer vial until fluid show up in the window area.

3. Lay the device on a flat surface and read results in approximately 3 minutes. Do not read results after 20 minutes.

## Interpreting Test Results

### Negative Results

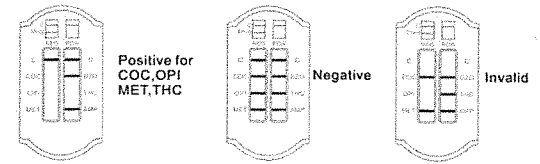
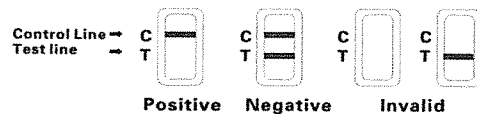
A red colored band should be observed in control region (C), and specific drug test region. The color and density of the test band may vary for control and drug test region.

### Presumptive Positive Results

When the control band is visible in the control region (C) and no band appears at the specific test region, the result is a **presumptive positive** for that particular drug.

### Invalid

When no band appears in the control (C) region, the test is invalid regardless of the results in the test region. If the test is invalid, check testing procedures. Repeat the test using a new device.



**Important:** Read each test independently. Do not compare color intensity of one test band to another. When a faint purple-red band for a specific test is obtained in the test region along with the presence of the control line (C), the sample should be considered negative. The DRUGSWAB™ Drug Screen Device only provides qualitative results for the presence of drug(s) at specified cut-off concentration(s). For confirmation of a presumptive positive result, a more specific quantitative method (GC/MS or LC/MS) must be used.

## Quality Control

The DRUGSWAB™ Drug Screen Test provides a built-in control band at the control region (C) to indicate that the test has performed properly. The control band should always appear regardless of the presence of drugs. The presence of the purple-red bands in the control region verifies that proper flow was obtained. If the control band does not appear, the test device should be discarded.

## Limitations of Procedure

The assay is designed for detection of nanoscale drug residues. Positive results only indicate the presumptive presence of drugs. Technical or procedural errors as well as substances in certain foods and certain medications may interfere with the test and cause false results.

## Performance Characteristics

### Precision

For each specific drug test, a drug standard was diluted into the buffer solution at various concentrations (0%, 50%, 150% and 300% cutoff). For each concentration, a total of 20 tests were performed to validate the test performance. The results for each drug of the DRUGSWAB™ Drug Screen Device Tests are summarized below:

Drug Test	Total # of Test/Concentration	Concentration							
		0%		50% cutoff		150% cutoff		300% cutoff	
		-	+	-	+	-	+	-	+
OPI	20	20	0	20	0	0	20	0	20
MET	20	20	0	20	0	0	20	0	20
MDMA	20	20	0	20	0	0	20	0	20
THC	20	20	0	20	0	0	20	0	20
COC	20	20	0	20	0	0	20	0	20
FEN	20	20	0	20	0	0	20	0	20
BUP	20	20	0	20	0	0	20	0	20

### Specificity

The specificity study for each drug test was evaluated by adding structurally related compounds into the buffer solution. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

Drug Test	Approximate Concentration(ng/ml)	Approximate % Cross Reactivity
<b>OPI</b>		
6-Acetylcodeine	20	50%
6-Acetylmorphine	12	83%
Codeine	10	100%
Dihydrocodeine	10	100%
Ethyl morphine	60	17%
Heroin	15	67%
Hydrocodone	60	17%
Hydromorphone	70	14%
Morphine	10	100%
Morphine-3-beta-D-Glucuronide	25	40%
Nalorphine	100	10%
<b>MET/MDMA</b>		
Desipramine	10000	0.25%
d,l-Ephedrine	1000	2.5%
1R, 2S l-Ephedrine	1000	2.5%
p-Hydroxymethamphetamine	1000	2.5%
MDEA	300	8.3%
MDMA	25	100%
d,l-Methamphetamine	30	83%
d-Methamphetamine	25	100%
l-Methamphetamine	500	5%
d-Amphetamine	5000	0.5%
Methoxyphenamine	2500	1%
Phenylephrine	5000	0.5%
d-Pseudoephedrine HCl	5000	0.5%
Trimethobenzamide	4000	0.6%
<b>THC</b>		
Cannabinol	80	50%
Δ-8-Tetrahydrocannabinol	100	40%
Δ-9-Tetrahydrocannabinol	40	100%
11-nor-Δ-8-THC-9-COOH	10	400%
11-nor-Δ-9-THC-9-COOH	10	400%
11-Hydroxy-Δ9-THC	400	10%
<b>COC</b>		
Benzoyllecgonine	20	100%
Cocaine	20	100%
<b>FEN</b>		
Fentanyl	10	100%
Norfentanyl	100	10%
<b>BUP</b>		
Buprenorphine	10	100%
Norbuprenorphine	5	200%

Acetaminophen  
 Acetoacetic acid lithium salt  
 Acetone  
 Acetylsalicylic acid  
 6-Acetylcodeine (except OPI assay)  
 6-Acetylmorphine (except OPI assay)  
 Albumin  
 Allobarbitol  
 Alphenal  
 Alprazolam  
 Amitriptyline  
 Amobarbital  
 Amoxapine  
 Amoxicillin  
 Bromazepam  
 d-Brompheniramine  
 Buprenorphine  
 Butalbital  
 Butethal  
 Caffeine  
 Cannabinol (except THC assay)  
 Cannabidiol  
 Chloral Hydrate  
 Chlordiazepoxide  
 Chloroquine  
 d-Chlorpheniramine  
 Chlorpromazine  
 Chloroamphetamine (DL-p-)  
 Cholesterol  
 Clobazam  
 Clonipramine  
 Clonazepam  
 Cocaine (except COC assay)  
 Codeine (except OPI assay)  
 Cortisone  
 l-Cotinine  
 Creatine  
 Creatinine  
 Cyclobenzaprine  
 Delorazepam  
 Deoxycortisone acetate  
 Desipramine (except MET/MDMA assay)  
 Dextromethorphan  
 Diazepam  
 Dihydrocodeine (except OPI assay)  
 4-Dimethylaminoantipyrine  
 Diphenhydramine  
 Dopamine (3-Hydroxytyramine)  
 Doxepin hydrochloride  
 Doxylamine  
 Ecgonine  
 Ecgonine Methyl Ester  
 l-Ephedrine  
 d,l-Ephedrine (except MET/MDMA assay)  
 1R, 2S l-Ephedrine (except MET/MDMA assay)  
 1S, 2R d-Ephedrine  
 l-Epinephrine  
 Erythromycin  
 Estazolam  
 -Estradiol  
 Estrone-3-sulfate potassium salt

l-Amphetamine  
 Ampicillin  
 Apomorphine  
 Aprobarbital  
 l-Ascorbic Acid  
 Aspartame  
 Atropine  
 Barbitol  
 Benzillic acid  
 Benzocaine  
 Benzoyllecgonine hydrate (except COC assay)  
 Benzoic acid  
 Bilirubin  
 d,l-Methadone  
 d-Methamphetamine (except MET/MDMA assay)  
 d,l-Methamphetamine (except MET/MDMA assay)  
 l-Methamphetamine (except MET/MDMA assay)  
 Methaqualone  
 Methoxyphenamine (except MET/MDMA assay)  
 2-Methylamine-Propiophenone HCl  
 Methylphenidate  
 Morphine (except OPI assay)  
 Morphine-3-beta -D-Glucuronide (except OPI assay)  
 Nalidixic acid  
 Nalorphine (except OPI assay)  
 Naloxone  
 Naltrexone hydrochloride  
 d-Naproxen  
 Niacinamide  
 Nitrazepam  
 Nordiazepam  
 Nordoxepin hydrochloride  
 d,l-Norephedrine hydrochloride  
 Norethindrone  
 d-Norpropoxyphene  
 Nortriptyline hydrochloride  
 Oxalic Acid  
 Oxazepam  
 Oxolinic acid  
 Oxycodone  
 Papaverine  
 Penicillin-G (Benzylpenicillin)  
 Pentazocine  
 Pentobarbital  
 Perphenazine  
 Phencyclidine  
 Pheniramine  
 Phenobarbital  
 Phenothiazine  
 Phentermine  
 Phenylephrine (except MET/MDMA assay)  
 β-Phenylethylamine  
 d,l-Phenylpropanolamine hydrochloride  
 Prazepam  
 Prednisolone  
 Procaine  
 Promazine

Ethanol  
 Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrrolidine  
 Perchlorate salt  
 Ethyl Morphine (except OPI assay)  
 Flunitrazepam  
 Flurazepam  
 Furosemide  
 Gentisic acid  
 Glucose  
 Glutethimide  
 Guaiacol Glyceryl Ether  
 Hemoglobin  
 Heroin (except OPI assay)  
 Hippuric acid  
 Hydrochlorothizide  
 Hydrocodone (except OPI assay)  
 Hydrocortisone  
 Hydromorphone (except OPI assay)  
 11-Hydroxy-Δ-9-Tetrahydrocannabinol (except THC assay)  
 p-Hydroxymethamphetamine (Pholderin) (except MET/MDMA assay)  
 Ibuprofen  
 Imipramine  
 d,l-Isoproterenol  
 l-Isoproterenol HCl  
 Lidocaine  
 Lorazepam  
 Lormetazepam  
 MDMA (except MET/MDMA assay)  
 MDA  
 MDEA (except MET/MDMA assays)  
 Meperidine

Promethazine  
 d-Propoxyphene  
 Protriptyline  
 d-Pseudoephedrine HCl (except MET/MDMA assay)  
 Quinidine  
 Ranitidine  
 Riboflavin  
 Salicylic acid  
 Secobarbital  
 Serotonin  
 Sodium Chloride  
 Sulfamethazine  
 Sulindac  
 Starch (100ug/ml)  
 Sodium Chloride (100ug/ml)  
 Sodium Bicarbonate (100ug/ml)  
 Temazepam Tetracycline  
 Δ-8-Tetrahydrocannabinol (except THC assay)  
 Δ-9-Tetrahydrocannabinol (except THC assay)  
 11-nor-Δ-8-THC-9-COOH (except THC assay)  
 11-nor-Δ-9-THC-9-COOH (except THC assay)  
 Thiamine  
 Thioridazine  
 Triazolam  
 Trifluoperazine  
 Trimethobenzamide (except MET/MDMA assay)  
 Lorazepam  
 Lormetazepam  
 MDMA (except MET/MDMA assay)  
 MDA  
 MDEA (except MET/MDMA assays)  
 Meperidine

### Bibliography of Suggested Reading

1. Wong, R. The Current Status of Drug Testing in the US Workforce, American Clinical Laboratory, vol. 21(1), page 21-23, 2002.
2. Mandatory Guidelines for Federal Workplace Drug Testing Programs, April 13, 2004 (69 FR 19644).

Manufactured For:  
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### Interference

The following compounds were spiked into the buffer solution and found not to cross-react with the DRUGSWAB™ Drug Screen Device when tested at concentration of 10 μg/ml (10,000ng/ml) unless specially noted after the compounds.