

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.**

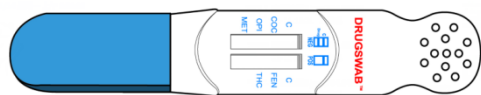


Fig. a DRUGSWAB™ Drug Screen Test

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

- Open the device kit and remove the test from the sealed pouch.
- Carefully remove the blue cap by holding the sides and pull gently. This will expose the collection pad.
 - For drug residue on suspected surface: Wipe the suspected surfaces with collection pad by pushing both sides 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.
 - For drug powder or tablet or plant: Put small amount of suspected solid into the buffer vial, shake 15-30 seconds and then add 10-20- drops of buffer onto collection pad or insert collection pad into buffer vial until fluid show up in the window area.
- 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.

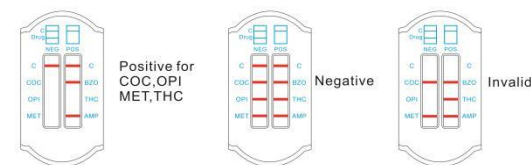
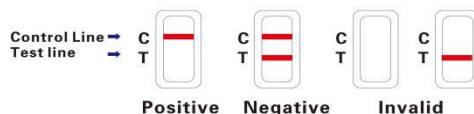
The color and density of the test band may vary for control and drug test region.

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
OPI		
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%
MET/MDMA		
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%
THC		
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%
COC		
Benzoyllecgonine	20	100%
Cocaine	20	100%
FEN		
Fentanyl	10	100%
Norfentanyl	100	10%
BUP		
Buprenorphine	10	100%
Norbuprenorphine	5	200%

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 10µg/ml (10,000ng/ml) unless specially noted after the compounds.

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
Barbital
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*)
Trimipramine Maleate
Tryptamine
d,l-Tryptophan
Tyramine
d,l-Tyrosine
Uric Acid
Verapamil
Zomepirac

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:
On-Site Testing Specialists
5308 Park Ave
Bethel Park, PA 15102
USA
1-866-833-2101

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