

AllSource Harm Reduction Harm6

Intended Use

The AllSource Harm Reduction Harm6 is a one-step lateral flow immunoassay device for the detection of drug residues on suspected surface, in powder or in liquid. The AllSource Harm Reduction Harm6 device detects drugs listed below:

OPI	Morphine	10ng/ml
coc	Cocaine	20ng/ml
MET	d-Methamphetamine	25ng/ml
OXY	Oxycodone	40ng/ml
тнс	Delta-9-Tetrahydrocannabinol	40ng/ml
FYL	Fentanyl	1 ng/ml

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

The AllSource Harm Reduction Harm6 provides only preliminary drug test results.For a quantitative result or for a confirmation of a presumptive positive result obtained by the Harm6 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.

The AllSource Harm Reduction Harm6 is developed to detect drug residues on suspected surface, in powder or in liquid. It is designed to integrate the collection of sample and lateral flow immunoassay screen testing in one single device.

Test Principle

The AllSource Harm Reduction Harm6 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 gresent on the surface, the colored colloidal gold antibody conjugate. 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 AllSource Harm Reduction Harm6

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 AllSource Harm Reduction Harm6 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 AllSource Harm Reduction Harm6 kit contains:

1. 1 Package Insert.

2. 10 test devices kit.Each kit consists of an individually packaged test in a foil pouch with a desiccant, and a vial of buffer.

Warnings and Precautions

The AllSource Harm Reduction Harm6 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 torm. Do not use the test device beyond the expiration date indicated on the kit.

Product Storage

The AllSource Harm Reduction Harm6 pouch should be stored at room temperature (2°C-30°C). Do not open pouch until ready to perform the assay.

Test Procedure

1.Remove the test from the sealed pouch.

2.Remove the blue cap to expose the collection pad.

A. For drug residue on suspected surface:

Wipe suspected surfaces with collection pad, then add15 drops of buffer onto collection pad.

B. For liquid, drug powder, tablet or plant:

Add 3 drops of liquid onto collection pad or Wipe suspected solid powder with collection pad(Crush the solid to be tested into powder), then add 15 drops of buffer onto collection pad.

3. Lay the device on a flat surface and read results in approximately 5 minutes. Do not read results after 15 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.





Invalid



Important: Do not compare color intensity of one test band to another. Read each test independently. Any dark or light red band is observed in the test region along with the presence of the control line (C), the sample should be considered negative. For confirmation of a presumptive positive result, a more specific quantitative method (GC/MS or LC/MS) must be used.

Quality Control

The AllSource Harm Reduction Harm6 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 H does not appear, the test device should be discarded.

Limitations of Procedure

- 1. The assay is designed for detection of nanoscale drug residues.
- 2. Positive results only indicate the presumptive presence of drugs.
- 3. 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 AllSource Harm Reduction Harm6 Tests are summarized below:

	Total # of Test	Concentration							
Drug Test		0%		50% cutoff		150% cutoff		300% cutoff	
		Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
OPI	20	20	0	20	0	0	20	0	20
MET	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
FYL	20	20	0	20	0	0	20	0	20
OXY	20	20	0	20	0	0	20	0	20

Specificity

The specificity was evaluated by adding structurally related analogs to negative buffer. The results are expressed as the lowest concentration of the compound, in ng/mL, that produced a positive result.Percent cross reactivity of a compound is calculated by dividing the cutoff concentration by the lowest concentration required to obtain a positive result and the multiplying by 100%.Each study device was tested in accordance with the instructions.

Compound Name	Concentration ng/mL	cross reactivity %	
coc			
Benzoylecgonine	20	100%	
Cocaine	20	100%	
Ecgonine HCI	800	2.5%	
Ecgonine methylester	200	10%	
OPI			
Morphine	10	100%	
Nalorphine	100	10%	
6-Acetylcodeine	20	50%	
6-Acetylmorphine	12	83%	
Codeine	10	100%	
Dihydrocodeine	10	100%	
Ethyl morphine	60	17%	
Heroin	15	67%	
Hydrocodone	60	17%	
Hydromophone	70	14%	
Morphine-3-beta-D- Glucuronide	25	40%	

MET		
d-Methamphetamine	25	100%
d,I-Ephedrine	1000	2.5%
1R, 2S I-Ephedrine	1000	2.5%
p-Hydroxymethamphetamine	1000	2.5%
MDEA	300	8.3%
MDMA	25	100%
d,I-Methamphetamine	30	83%
Desipramine	10000	0.25%
	500	5% 0.5%
0-Amphetamine	5000	0.5%
	2500	1%
Phenylephrine	5000	0.5%
d-Pseudoephedrine HCI	5000	0.5%
Trimethobenzamide	4000	0.6%
FYL		
Fentanyl	1	100%
Acetyl-α-methyl fentanyl	5ng/mL	20%
Acryl fentanyl	10ng/mL	10%
α-methyl fentanyl	1ng/mL	100%
Benzyl fentanyl	2.5ng/mL	40%
β-hydroxythio fentanyl	5ng/mL	20%
Cyclopropyl fentanyl	1ng/mL	100%
4-Fluoroisobutyryl Fentanyl	50ng/mL	2%
Methoxyacetyl fentanyl	12.5ng/mL	8%
4-methoxybutyryl fentanyl (para)	400ng/mL	0.25%
4-methyl Fentanyl	5ng/mL	20%
3'-methyl Fentanyl	10ng/mL	10%
N-methyl norfentanyl	1.5ng/mL	66.7%
o-Fluorofentanyl	2.5ng/mL	40%
p-Fluorobutyryl fentanyl	10ng/mL	10%
Tetrahydrofuran fentanyl	500ng/mL	0.2%
2-Thiofuranyl fentanyl	50ng/mL	2%
4-Piperidone	2500ng/mL	0.04%
meta-fluoro Acrylfentanyl	2.5ng/mL	40%
para-chloro Furanyl fentanyl 3-furancarboxamide	5ng/mL	20%
Acetyl norfentanyl	10ng/mL	10%
3'-Fluorofentanyl	2.5ng/mL	40%
ortho-fluoro Valeryl fentanyl	500ng/mL	0.2%
para-Chloroacetyl fentanyl	5ng/mL	20%
Cyclopropaneacetyl fentanyl	2.5ng/mL	40%

para-hydroxy Butyryl fentanyl	2.5ng/mL	40%
тнс		
Delta-9-Tetrahydrocannabinol	40	100%
Cannabinol	80	50%
Delta-8-Tetrahydrocannabinol	100	40%
11-nor-∆-8-THC-9-COOH	10	400%
11-nor-Δ-9-THC-9-COOH	10	400%
11-Hydroxy-∆9-THC	400	10%
OXY		
Oxycodone	40	100%
Hydrocodone	10,000	0.04%
Morphine	>100,000	<0.01%
Hydromorphone	>100,000	<0.01%

The following opioids compounds were tested at a concentration of 100ug/mL. Negative results were obtained for all these compounds. There is no cross-reactivity for these compounds using the AllSource Harm Reduction.

6-Acetyl morphine(except OPI assay)	Fluoxetine
Amphetamine	Heroin(<i>except OPI assay</i>)
Allobarbital	Hydromorphone
Amoxicillin	Ketamine
Alprazolam	Glucose
Buprenorphine	Levorphanol
Buprenorphineglucuronide	Meperidine
Codeine(except OPI assay)	Methadone
Cannabinol (except THC assay)	Morphine(except OPI assay)
Cholesterol	Morphine-3-glucuronide
Clobazam	Naloxone
Clomipramine	Naltrexone
Clonazepam	Norbuprenorphine
Cocaine <i>(except</i> <i>COC assay)</i>	Norcodeine
Dextromethorphan	Norketamine
Dihydrocodeine(except OPI assay)	Normeperidine
Delorazepam	Normorphine
Desipramine (except MET assay)	Noroxycodone
Deoxycortisone acetate	Oxycodone <i>(except OXY assay)</i>
EDDP	Oxymorphone
EMDP	Pentazocine (Talwin)
I-Epinephrine	Pipamperone
Erythromycin	Risperidone

Tapentadol	Fentanyl(except FYL assay)
Thioridazine	Tramadol-N-Desmethyl
Tilidine	Trazodone
Tramadol	Verapamil
Tramadol-O-Desmethyl	Zomepirac

Bibliography of Suggested Reading

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

Manufactured for:

AllSource Screening Solutions

1401 Pontiac Court

Export, PA 15632

website: www.allsourcescreening.com

email: peter@allsourcescreening.com

Made in China