Harm Reduction

Cat#: Harm4

Intended Use

The AllSource Harm Reduction is a one-step lateral flow immunoassay device for the detection of drug residues on suspected surface, in powder or in liquid. The AllSource Harm4 detects drugs listed below:

FYL	*Fentanyl*	*1ng/ml*
BZO	*Benzodiazepines*	*20ng/ml*
XYL	*Xylazine*	*25ng/ml*
NTZ	*Nitazene*	*50ng/ml*

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

The AllSource Harm4 provides only preliminary drug test results. For a quantitative result or for a confirmation of a presumptive positive result obtained by the AllSource Harm4, 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 Harm4 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 Harm4 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.

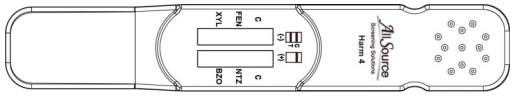


Fig. a AllSource Harm4

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 Harm4 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 Harm4 kit contains:

1. 25 test devices per kit. Each test device is individually packaged in a foil pouch with a desiccant.
2. 25 buffer vials.
3. 1 Package Insert.

Warnings and Precautions

The AllSource Harm4 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 AllSource Harm4 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 cap to expose the collection pad.

A. For drug residue on suspected surface:

Wipe suspected surfaces with collection pad, then add 10-15 drops of buffer onto collection pad.

B. For liquid,drug powder or tablet:

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 10-15 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

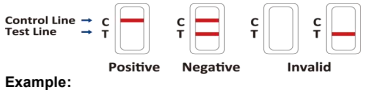
A red colored band should be observed in control region (C), and specific drug test region. The color and density of the test band may vary for control and drug test region.

Presumptive Positive Results

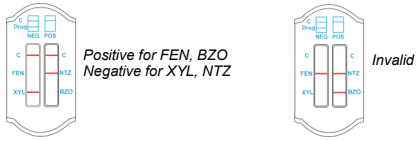
When the control band is visible in the control region (C) and no band appears at the specific test region, the result is a ***presumptive positive*** *for that particular drug.*

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.**



Example:



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 Harm4 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

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 Harm4 Tests are summarized below:

Drug Test	Total # of Test	Concentration							
		0%		50% cutoff		150% cutoff		300% cutoff	
		Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
FYL	*20*	*20*	*0*	*20*	*0*	*0*	*20*	*0*	*20*
BZO	*20*	*20*	*0*	*20*	*0*	*0*	*20*	*0*	*20*
XYL	*20*	*20*	*0*	*20*	*0*	*0*	*20*	*0*	*20*
NTZ	*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 %
FYL		
Fentanyl	*1ng/mL*	*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%*
BZO		
Oxazepam	*20ng/mL*	*100%*
Alprazolan	*40ng/mL*	*50%*
a-Hydroxyaprazolan	*200ng/mL*	*10%*
Bromazepam	*40ng/mL*	*50%*
Clobazam	*20ng/mL*	*100%*
Clonazepam	*800ng/mL*	*2.5%*
Delorazepam	*50ng/mL*	*40%*
Chlordiazepoxide	*1000ng/mL*	*2%*
XYL		
Xylazine	*25ng/ml*	*100%*
Clonidine	*100ng/ml*	*20%*
Dexmedetomidine	*200ng/ml*	*3%*
Tizanidine	*1000ng/ml*	*10%*
Guanfacine	*400ng/ml*	*20%*
NTZ		
Nitazene	*50ng/ml*	*100%*
Isotonitazene	*50ng/ml*	*100%*
Butonitazene	*100ng/ml*	*80%*
Etonitazene	*100ng/ml*	*100%*
Etodesnitazene	*200ng/ml*	*80%*
Metonitazene	*100ng/ml*	*90%*
Metodesnitazene	*100ng/ml*	*100%*
N-Pyrrolidino Etonitazene	*100ng/ml*	*100%*

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 Harm4.

6-Acetyl morphine	*Fluoxetine*
Amphetamine	*Heroin*
Allobarbital	*Hydromorphone*
Amoxicillin	*Ketamine*
Alprazolam	*Glucose*
Buprenorphine	*Levorphanol*
Buprenorphine glucuronide	*Meperidine*
Codeine	*Methadone*
Cannabinol	*Morphine*
Cholesterol	*Morphine-3-glucuronide*
Clobazam	*Naloxone*
Clomipramine	*Naltrexone*
Clonazepam	*Norbuprenorphine*
Cocaine	*Norcodeine*
Dextromethorphan	*Norketamine*
Dihydrocodeine	*Normeperidine*
Delorazepam	*Normorphine*
Desipramine	*Noroxycodone*
Deoxycortisone acetate	*Oxycodone*
EDDP	*Oxymorphone*
EMDP	*Pentazocine (Talwin)*
l-Epinephrine	*Pipamperone*
Erythromycin	*Risperidone*
Tapentadol	*Fentanyl(except FYL assay)*
Thioridazine	*Tramadol-N-Desmethyl*
Tilidine	*Trazodone*
Tramadol	*Verapamil*
Tramadol-O-Desmethyl	*Zomepirac*
Tetrahydrocannabinol	*Tricyclic antidepressants*
Methamphetamine	*Phencyclidine*
Pinaca	*AM2201*
Ur144	*Psilocybin, Psilocin*
Jwh-073	*Lysergic Acid Diethylamide*

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Made in China

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