AllSource Harm Reduction

Fentanyl1/Xylazine25

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 Harm Reduction device detects Fentanyl at the cutoff of 1 ng/ml and xylazine at the cutoff of 25 ng/ml.

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

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

AllSource Harm Reduction 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 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.**

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 contains one membrane strip and a collection pad. The 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.

Fig. a AllSource Harm Reduction

Materials Provided

Each AllSource Harm Reduction kit contains:
1. 1 Package Insert.
2. 1 Test Device (individually packaged in a foil pouch with a desiccant).
3. 1 Buffer Vial (0.6ml per vial)

Warnings and Precautions

- The AllSource Harm Reduction is intended for Harm Reduction 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 Harm Reduction 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

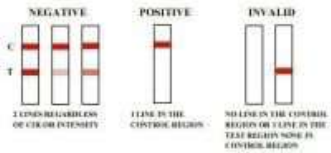
A red colored band should be observed in control region (C), and test region. The color and density of the test band may vary for control and drug test region.

Presumptive Positive Results

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

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.***



Any Indication of a line in the test region (T) should be considered a line, And therefore, a negative result.

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 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

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 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
XYL	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	1 ng/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%
XYL		
Xylazine	25 ng/mL	100%
3-hydroxy xylazine	25 ng/mL	100%
4-hydroxy xylazine	25 ng/mL	100%
4-hydroxy xylazine glucuronide	10 ng/mL	250%

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).

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Made in China

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