

Xylazine (XYL) Liquid & Powder Drug Test Strip

Catalogue No.: WSPXYL-101

SAFElifeTM Xylazine (XYL) Liquid & Powder Drug Test Strip is an immunochromatographic assay for the qualitative determination of Xylazine in liquid, powder or pill samples at the cut-off concentration listed below:

Drug (Identifier)	Calibrator	Cut-off Level
Xylazine (XYL)	Xylazine	500 ng/mL

It is intended for forensic use only.

The SAFElife™ Xylazine (XYL) Liquid & Powder Drug Test Strip is not intended to distinguish between prescription use or abuse of this drug. Professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The SAFElife™ Xylazine (XYL) Liquid & Powder Drug Test Strip provides only preliminary test results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method.

WARNINGS AND PRECAUTIONS

- 1. This test kit is for external use only. Do not swallow.
- Discard after first use. The test kit cannot be used more than once.
- 3. Do not use the test kit beyond expiry date.
- Do not use the test kit if the pouch is punctured or not well sealed
- Keep out of the reach of children.
- Do not read after 5 minutes.
- The device cannot determine the purity, composition of liquid, powder or pill samples.
- 8. A negative or positive test result does NOT indicate that the test substance is safe to use. A positive result indicates the presence of Xylazine only and does not indicate quantity. A negative result does not at any time rule out the presence of Xylazine, as they may be present below the minimum detection level of the test. Many factors come into play when examining the samples, including but not limited to mixture of multiple substances, solubility, and pH of the sample.
- The kit is intended for harm reduction purposes. Follow the advice of your local harm reduction or public health agency.
- The test shall not encourage the use, supply, or production of illegal drugs or controlled substances in any way.
- The test is NOT to be used to test cocaine, methamphetamine, ketamine or any other non-opioid substances.

CONTENT OF THE KIT

- Test devices, one test in one pouch. One pouch containing a test strip and a desiccant.
 The desiccant is for storage purposes only, and is not used in the test procedures.
- Package Insert.

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer or clock
- Measuring scoop
- Measuring cup or testing cup

STORAGE AND STABILITY

Store at 2°C-30°C (36°F-86°F) in the sealed pouch up to the expiration date. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

HOW TO COLLECT SAMPLES?

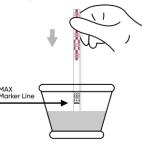
Crush the pill into powder or collect the liquid or powder directly. Dilute the drug to be tested in water. The Center for Forensic Science Research and Education (CFSRE) recommends adding one scoop (5-10mg) of drug sample to 5mL of water. Refer to the advice of your local health or harm reduction authority on how much water and drug sample you should use.

TEST PROCEDURE

Test should be performed at room temperature 18°C-30°C (65°F-86°F).

- . Remove the test strip from the foil pouch by tearing at the notch and use it as soon as possible. For best results, the test should be performed within one hour.
- Hold the end of the strip where the product name (XYL) is printed. Holding the strip vertically, dip the absorbent end into the liquid close to the MAX Marker Line for at least 15 seconds or until you start to see liquid migrating upwards.
- 3. Remove the strip from the sample and lay it flat on a clean, dry, non-absorbent surface.
- Read the result after 5 minutes. Do not read results after more than 5 minutes.

IMPORTANT: Do not allow the liquid level to exceed the MAX Marker Line, otherwise the test will not perform correctly.



Note: Results after more than 5 minutes may be not accurate and should not be read.

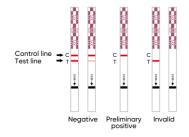
READING THE RESULTS

Preliminary positive (+)

A colored band is visible in the Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates a preliminary positive result for the Xylazine.

Negative (-

A colored band is visible in the Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of Xylazine is zero or below the detection limit of the test.



Invalid

If a colored band is not visible in the Control Region (C) or a colored band is only visible in the Test Region (T), the test is invalid. Another test should be run to re-evaluate the specimen. If the new test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number of the test.

Note: There is no meaning attributed to line color intensity or width.

The color intensity in the Test Region (T) may vary depending on the concentration of Xylazine present in the sample. Therefore, any chromaticity in the test region should be considered negative. Please note that this is only a qualitative test and cannot determine the concentration of Xylazine in the sample.

What Is the False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by SAFElife™ Xylazine Liquid & Powder Drug Test Strip. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is the False Negative Test?

The definition of a false negative test is that the initial Xylazine is present but isn't detected by SAFElife™ Xylazine Liquid & Powder Drug Test Strip. If the specimen is diluted, or the specimen is adulterated that may cause false negative result.

TEST LIMITATIONS

- 1. This test has been developed for testing liquid, powder or pill samples.
- The possibility exists that substances and factors not described in this directional insert
 may interfere with the test, causing false results (e.g. technical or procedural error).
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drug or the level of intoxication.

SUMMARY

Xylazine (XYL) is a potent $\alpha 2$ -adrenergic agonist that acts on $\alpha 2$ -receptors in the central nervous system. In central nervous system, the $\alpha 2$ stimulation reduces the release of dopamine and norepinephrine, thereby providing sedation and muscle relaxation. It widely used as analgesic, sedative, or muscle relaxant for animals. In humans, it may lead to nausea, emesis, dizziness, weakness or short-term mental disorders. Research has shown xylazine is often added to illicit opioids, including fentanyl, and people report using xylazine-containing fentanyl to lengthen its euphoric effects. Most overdose deaths linked to both xylazine and fentanyl also involved additional substances, including cocaine, heroin, benzodiazepines, alcohol, gabapentin, methadone, and prescription opioids.

PRINCIPLE

SAFElifeTM Xylazine (XYL) Liquid & Powder Drug Test Strip is a competitive immunoassay that is used to screen for the presence of xylazine in sample. It is chromatographic absorbent device in which xylazine and its metabolites in a specimen competitively combined to a limited number of anti-xylazine monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end of the test device is immersed into the liquid samples, the liquid is absorbed into the device by capillary action, mixes with the xylazine monoclonal antibody conjugate, and flows across the pre-coated membrane. When specimen drug levels are zero or below the target cut off (the detection sensitivity of the test), anti-xylazine monoclonal antibody (mouse) conjugate binds to the xylazine-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored band that, regardless of its intensity, indicates a negative result.

When specimen drug levels are at or above the target cutoff, the free drug in the specimen binds to the xylazine monoclonal antibody conjugate preventing the xylazine monoclonal antibody conjugate from binding to the xylazine -protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored band will appear at the Control Region (C), where the goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials. Even though there is an internal procedural control line in the test device in the Control Region (C), the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment, each new operator and monthly to determine that tests are working properly.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the SAFElife™ Xylazine (XYL) Liquid & Powder Drug Test Strip was compared against LC/MS-MS with a threshold value at the same cut-off levels. The results were >96.9% in agreement.

Precision

Test precision was determined by blind tests with control solutions. The study was performed with 30 operators per concentration. Controls with Xylazine concentrations at 50% of the cut-off yielded negative results, and controls with Xylazine concentrations at 150% of the cut-off yielded positive results.

Specificity and Cross reactivity

To test the specificity of the test, the test device was used to test Xylazine, the concentration below also represents the limit of detection for the Xylazine,

Component	Concentration (ng/ml)
Xylazine (XYL)	500

Interfering Substances

All potential interferents were added at the concentration of 100 $\mu g/mL$. None of the samples showed any deviation from the expected results.

Acetaminophen	Duloxetine	Penfluidol
Acyclovir	Enalapril Maleate	Penicillin V Potassium
Amoxicillin	Estrogen	Phenytoin Sodium
Ampicillin	Fenofibrate	Pioglitazone Hydrochloride
Aspirin	Glipizide	Piracetam
Atorvastatin	Glucose	Pravastatin Sodium
Bupropion	Glyburide	Procaine Hydrochloride
Caffeine	Haloperidol	Promethazine
Captopril	Isoproterenol	Propranolol Hydrochloride
Carbamazepine	Ketoconazole	Propylthiouracil
Cefaclor	Lamotrigine	Quetiapine
Cefradine	Lidocaine Hydrochloride	Rifampicin

Cephalexin Lithium Carbonate Sertraline Hydrochloride Citalopram Loratadine Simvastatin Metoprolol Tartrate Clarithromycin Sodium Valproate Clopidogrel Mifepristone Tetracycline Clozapine Minocycline **Topiramate** Montelukast Sodium Cortisone Triamterene Dextromethorphan Mosapride Citrate Ursodeoxycholic Acid Hydrobromide Narcotine Vitamin B1 Digoxin Nimodipine Vitamin B2 Diltiazem Omeorazole Vitamin C

Paroxetine

Dirithromycin ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-888-444-3657 (9:30 a.m. to 5:00 p.m. CDT M-F).

BIBLIOGRAPHY OF SUGGESTED READING

- Chen L, Hu X, Sun Y, et al. An ultrasensitive monoclonal antibody-based lateral flow immunoassay for the rapid detection of xylazine in milk[J]. Food Chemistry, 2022(30):383.
- Kazandra Ruiz-Colón, Chavez-Arias C, José Eric Díaz-Alcalá,et al. Xylazine intoxication in humans and its importance as an emerging adulterant in abused drugs: A comprehensive review of the literature[J]. Forensic Science International, 2014, 240(240C):1-8.
- Friedman J, Montero F, Bourgois P, Wahbi R, Dye D, Goodman-Meza D, Shover C. Xylazine spreads across the US: A growing component of the increasingly synthetic and polysubstance overdose crisis. Drug Alcohol Depend. 2022(233):109380.
- Thangada S, Clinton HA, Ali S, Nunez J, Gill JR, Lawlor RF, Logan SB. Notes from the Field: Xylazine, a Veterinary Tranquilizer, Identified as an Emerging Novel Substance in Drug Overdose Deaths - Connecticut, 2019-2020. MMWR Morb Mortal Wkly Rep. 2021.70(37):1303-1304.

ADDITIONAL INFORMATION AND RESOURCES

- The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.
- National Clearinghouse for Alcohol and Drug Information www.health.org
- Center for Substance Abuse Treatment www.health.org 1-800-662-HELP
- The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL
- American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS



Keep away from sunlight



Store between 2°C~30°C (36°F~86°F)



Keep dry



Do not re-use



Consult instructions for use

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