

XYL Rapid Test Strip (Powder)

Package Insert

REF: DPXYL-S91	EN
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For Forensic Use Only

[INTENDED USE]

The Xylazine (XYL) Rapid Test Strip (Powder) is a rapid chromatographic immunoassay for the detection of Xylazine at the following cut-off concentration:

Abbreviation	Drug	Calibrator	Concentration (ng/mL)
XYL	Xylazine	Xylazine	500

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography mass spectrometry (GC/MS) or Liquid Chromatography mass spectrometry (LC/MS) is the preferred confirmatory method.

[SUMMARY]

Xylazine is a medicine given to animals to sedate them for surgery or relieve pain. Xylazine, sometimes known as tranq, is not approved for human use. However, xylazine is now being used as a recreational drug. Xylazine can be smoked, snorted, swallowed or injected. And Xylazine can be smoked, snorted, swallowed or injected. Most of the time, people aren't aware of its presence in other drugs. Xylazine test strips may detect xylazine in liquid or powder form. However, these test strips are often only available to medical professionals.

The Xylazine (XYL) Rapid Test Strip (Powder) is a rapid powder screening test that can be performed without the use of an instrument. The test utilizes the antibody to selectively detect elevated levels of XYL in sample. The Xylazine (XYL) Rapid Test Strip (Powder) yields a positive result when concentration of Xylazine exceeds the cut-off level.

[PRINCIPLE]

The Xylazine (XYL) Rapid Test Strip (Powder) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the sample compete against the drug conjugate for binding sites on the antibody.

During testing, the sample migrates upward by capillary action. Xylazine, if present in the sample below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Xylazine-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Xylazine level exceeds the cut-off level, because it will saturate all the binding sites of anti-Xylazine antibody.

A drug-positive sample will not generate a colored line in the test line region because of drug competition, while a drug-negative sample or a sample containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[REAGENTS]

The test contains mouse monoclonal anti-Xylazine antibody coupled particles and Xylazine-protein conjugate. Goat antibody and rabbit antibody are employed in the control line system.

[PRECAUTIONS]

- For forensic use only. Do not use after the expiration date.
- For individually packed test, the test should remain in the sealed pouch until use.
- The used test should be discarded according to local regulations.
- If any serious incident that has occurred in relation to this test shall be reported to us and the competent authority of the Member State in which the user and/or the patient is established.
- Please read all the information in this package insert before performing the test.

[STORAGE AND STABILITY]

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed. **DO NOT FREEZE.** Do not use beyond the expiration date.

[MATERIALS]

Materials Provided

- Test Strip

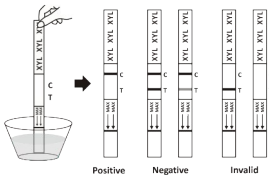
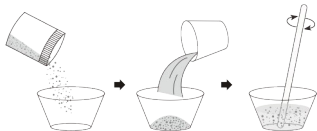
- Package insert

Materials Required but Not Provided

- Timer

[DIRECTIONS FOR USE]

- Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.
- Drop the powder into a container and mix with water until dissolved.
- With arrows pointing toward the sample, **immerse the test strip vertically in the sample for at least 10-15 seconds.** Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
- Place the test strips on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



[INTERPRETATION OF RESULTS]

(Please refer to the illustration above)

NEGATIVE: * Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Xylazine concentration is below the detectable cut-off level.

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Xylazine concentration exceeds the detectable cut-off level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The XYL Rapid Test Strip (Powder) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography mass spectrometry (GC/MS) or Liquid Chromatography mass spectrometry (LC/MS) is the preferred confirmatory method.^{3,4}
- It is possible that technical or procedural errors, as well as other interfering substances in the sample may cause erroneous results.

[EXPECTED VALUES]

This negative result indicates that the Xylazine concentration is below the detectable level. Positive result means the concentration of Xylazine is above the level.

[PERFORMANCE CHARACTERISTICS]

Analytical Sensitivity

Buffer was spiked with Xylazine at the following concentrations: 0% cutoff, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3X cutoff. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

XYL Concentration	n	Negative	Positive
0% cutoff	30	30	0
-50% cutoff	30	30	0
-25% cutoff	30	26	4
Cut-off	30	15	15
+25% cutoff	30	3	27
+50% cutoff	30	0	30
3X cutoff	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected by the XYL Rapid Test Strip (Powder) at 5 minutes.

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
Xylazine	500 (100%)	Clonidine	100,000 (0.5%)
Benztrapine	100,000 (0.5%)	3-hydroxy Xylazine	50 (1,000%)
4-hydroxy Xylazine	50 (1,000%)		

Cross-Reactivity

The following compounds show no cross-reactivity when tested with the XYL Rapid Test Strip (Powder) at a concentration of 100 mg/mL.

Non-Cross-Reacting Compounds

Acetaminophen	Dextromethorphan	Isoxsuprine	Procaine
Acetone	Diclofenac	Kanamycin	Promethazine
Acetophenetidin	Dicyclomine	Ketoprofen	Quinacrine
Aspirin	Diflunisal	Labetalol	Quinidine
Albumin	Digoxin	Lidocaine	Ranitidine
Amoxapine	4-Dimethylaminoantipyrine	Lindane	Riboflavin
Amoxicillin	Diphenhydramine	Loperamide	Sodium chloride
Ampicillin	5,5-Diphenylhydantoin	Methoxyphenamine	Sulfamethazine
Ascorbic acid	Disopyramide	Metoprolol	Sulindac
Aspartame	Doxylamine	Nalidixic acid	Temazepam
Atropine	Dopamine	(+)-Naproxen	Tetracycline
Benzoic acid	(1R, 2S) - (-)-Ephedrine	Nimesulide	Tetrahydrozoline
Bilirubin	Erythromycin	Norethindrone	Thebaine
(+/-) Brompheniramine	Ethanol (Ethyl alcohol)	Noscapine	Theophylline
Benzocaine	Etodolac	Niacinamide	Thiamine
Buspirone	Famprofazone	Norephedrine	Thioridazine
Caffeine	Fenoprofen	Orphenadrine	Tolbutamide
Chloramphenicol	Fluoxetine Hydrochloride	Oxalic acid	Trazodone
Chloroquine	Furosemide	Oxolinic acid	Triamterene
(+/-)-Chlorpheniramine	Gentisic acid	Oxymetazoline	Trifluoperazine
S- (+)-Chlorpheniramine maleate salt	D (+) Glucose	Papaverine	Trimethoprim
Chlorpromazine	Guaicol Glyceryl Ether	Pemoline	Trimipramine

Chlorprothixene	Hemoglobin	Penicillin-G	Tryptamine
Cimetidine	Hydralazine	Perphenazine	Tyramine
Clomipramine	Hydrochlorothiazide	Phenelzine	Uric acid
Clonidine	Hydroxyzine	Pheniramine	Verapamil
Creatine	Imipramine	Phenothiazine	Zomepirac
Cyclobenzaprine	Isoproterenol hydrochloride	β-Phenylethylamine	

[BIBLIOGRAPHY]

- Lane JC, Tennon MB, Lawless ST, et al.Movement disorder after withdrawal of fentanyl infusion.J Pediatr, 1991, 119 (4) : 649-651
- Dominguez KD, Lomako DM, Katz RW, et al. Opioid withdraw in critically ill neonates.Ann Pharmacotherm, 2003, 37 (4) : 473-477

Index of Symbols

	Consult		Tests per kit		Authorized Representative
	Do not use if package is damaged		Use by		Do not reuse
	Store between 2-30°C		Lot Number	REF	Catalog #

Number:

Effective date: