One Step Xylazine Drug of Abuse Test

(Strip)

For Forensic Use Only

INTENDED USE

The One Step Xylazine Drug of Abuse Test is a lateral flow chromatographic immunoassay for the qualitative detection of Xylazine in substances or urine at the following cut-off concentration:

TEST	CALIBRATOR	CUT-OFF
Xylazine (XYL500)	Xylazine	500ng/mL

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/mass spectrometry (LC/MS) is the preferred confirmatory method.[1] Apply clinical and professional judgment to Xylazine test result, particularly when a preliminary positive result is obtained.

SUMMARY AND EXPLANATION OF THE TEST

The One Step Xylazine Drug of Abuse Test is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of Xylazine in substances or urine without the use of an instrument.

XYLAZINE (XYL500)

Xylazine is not a controlled substance; it is marketed as a veterinary drug and used as a sedative, analgesic and muscle relaxant. In humans, it could cause central nervous system depression, respiratory depression, bradycardia, hypotension, and even death. Most of the non-fatal cases required medical intervention. Over recent years xylazine has emerged as an adulterant in recreational drugs, such as heroin or speedball (a cocaine and heroin mixture). Its chronic use is reported to be associated with physical deterioration and skin ulceration. Literature shows some similar pharmacologic effects between xylazine and heroin in humans. These similar pharmacologic effects may create synergistic toxic effects in humans. Therefore, fatalities among drug users may increase due to the use of xylazine as an adulterant. Xylazine alone has proven harmful to humans and even more when it is combined with drugs of abuse.

The XYL500 assay contained within the One Step Xylazine Drug of Abuse Test yields a positive result when the concentration of Xylazine in substances or urine exceeds 500 ng/mL.

PRINCIPLE

The One Step Xylazine Test is an immunoassay based on the principle of competitive binding. Drugs which may be present in the substances or urine specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a substance or urine specimen migrates upward by capillary action. A drug, if present in the substances or urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive substances or urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug - negative substances or urine specimen will generate a line in the test line region because of the absence of drug competition. 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 a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to individual drug on the list in the Intended Use section.

PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use. The test is for single use .
- While urine is not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood , the use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test device and substances or urine specimen should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30° C (39-86° F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Substances Assay

If the substance you are testing is in liquid form, or if you are testing substances, proceed to the respective Step 1 (see directions below) which corresponds to your device. If the substance you are testing is in powder form, place substance in a container and add water to the substance and mix well. Proceed to the respective Step 1 (see directions below) which corresponds to your device. If the substance you are testing is in pill format, crush or scrape some of the pill into a container. Add water to the substance and mix well. Proceed to the respective Step 1 (see directions below) which corresponds to your device.

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.

MATERIALS

Materials Provided

· Test device · Desiccants · Package insert

Materials Required But Not Provided

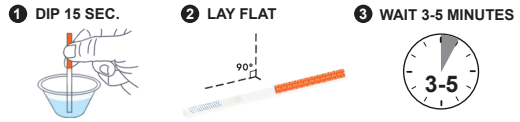
· Timer · Disposable gloves

DIRECTIONS FOR USE

Allow the test device substance, or urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

[For Strip]

1) Remove the strip from the foil wrapper or the desiccated container (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the strip with patient or control identifications.
2) Immerse the strip into the substances or urine with the arrow end pointing toward the substances or urine. Do not cover the substances or urine over the MAX (maximum) line. You may leave the strip in the substances or urine or you may take the strip out after a minimum of 15 seconds in the substances or urine and lay the strip flatly on a non - absorptive clean surface.
3) Read result at 3 to 5 minutes. **DO NOT READ RESULT AFTER 5 MINUTES.**



INTERPRETATION OF RESULTS

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

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

POSITIVE: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable 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 using a new test cup. If the problem persists, discontinue using the lot immediately and contact your supplier.

QUALITY CONTROL

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

LIMITATIONS

1. The One Step Xylazine Drug of Abuse Test provides only a qualitative, preliminary analytical result. A secondary analytical be used to obtain a confirmed result. Gaschromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.
3. A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine or the route of drug administration.
4. A Negative result may not necessarily indicate drug - free substances or urine. Negative results can be obtained when drug is present but below the cut - off level of the test.
5. Test does not distinguish between drugs of abuse and certain medications.
6. A positive test result may be obtained from certain foods or food supplements.
7. The test device is NOT intended to determine the purity, composition, or if the substance being examined is safe to use.
8. A positive or negative test result is NOT an indication that the substance being examined is safe to use. Many factors come into play when examining the samples, including but not limited to mixture of multiple substances, solubility, and pH of the sample.
9. The test shall not encourage the use, supply, or production of illegal drugs or controlled substances in any way. The test is intended for harm reduction purposes. Follow the advice of your local harm reduction or public health agency.
10. Not for testing Cocaine.
11. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test strip (Liquid / Powder) and cause false results.
12. A positive result indicates the presence of drugs only and does not indicate quantity.
13. A negative result does not at any time rule out the presence of drugs, as they may be present below the minimum detection level of the test.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

DRUG CONCENTRATION CUT-OFF RANGE	n	XYL500	
		-	+
0% Cut-Off	30	30	0
-50% Cut-Off	30	30	0
-25% Cut-Off	30	30	0
Cut-Off	30	2	28
+25% Cut-Off	30	0	30
+50% Cut-Off	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the One step Xylazine Test at a read time of 3-5 minutes.

Drug	Concentration
Xylazine	Positive at 500ng/ml
Clonidine hydrochloride	Positive at 100μg/ml
Doxylamine	Positive at 50μg/ml
Diclofenac Sodium Salt	Positive at 2000μg/ml
Levamisole	Positive at 500μg/ml
Caffeine	Negative at ≤10mg/mL
Diphenhydramine	Negative at ≤30mg/ml
4-Dimethylaminoantipyrine	Negative at ≤10mg/mL
Cocaine	Negative at ≤10mg/mL
Methamphetamine	Negative at ≤50mg/ml
MDMA	Negative at ≤50mg/ml
Fentanyl	Negative at ≤10mg/mL
Phenacetin	Negative at ≤10mg/ml
Phenelzine sulfate salt	Negative at ≤10mg/mL

Lidocaine	Negative at ≤10mg/mL
Quinine	Negative at ≤100µg/ml
Oxalic Acid	Negative at ≤10mg/mL
Oxymetazoline	Negative at ≤10mg/mL
Heroin	Negative at ≤10mg/mL
21-Hydroxy progesterone	Negative at ≤10mg/mL
Ketoprofen	Negative at ≤10mg/mL
Acetaminophen	Negative at ≤10mg/mL
Benzocaine	Negative at ≤10mg/mL
Procaine	Negative at ≤10mg/mL
Theophylline	Negative at ≤10mg/mL

Reproducibility
Reproducibility studies were carried out using commercially available stock solutions of the drug analytes listed. The results are listed in the following tables.

Xylazine CONCENTRATION (ng/mL)	TOTAL NUMBER OF DETERMINATIONS	RESULT	PRECISION
No Drug Present	60	60 negative	>99%
250	60	60 negative	>99%
750	60	60 positive	>99%

EFFECT OF URINARY SPECIFIC GRAVITY

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH - adjusted urine was tested with the One step Xylazine Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

INTERFERENCE

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free substances or urine, or drug positive substances or urine containing Xylazine.
The following compounds show no cross-reactivity when tested with the One Step Xylazine Test at concentrations of 100µg / mL.

Acebutolol Hydrochloride
N-Acetylprocainamide
Acetophenetidin
Albumin, Human recombinant
Alprazolam
Alphenal
Amoxicillin
Ampicillin
Amitriptyline Hydrochloride
Tablets
S(+)Amphetamine
R(-)-Amphetamine
Amobarbital
(±)Amphetamine
R-(-)-Apomorphine
Aprobarbital
Aspirin
Aspartame
L-Ascorbic Acid
Atropine
6-Acetylmorphine
Acetylsalicylic acid
Benzphetamine
Benzilic acid
SS Benzoic Acid
Bilirubin,Mixed Isomers
Bromazepam
Brompheniramine maleate
Buprenorphine
Butalbital
Butabarbital
Cannabinol
Citalopram hydrobromide
Dextromethorphan
Desalkylflurazepam Desipramine
Delorazepam
Diazepam
Diclofenac Sodium salt
Dicyclomine
Diflunisal
Digoxin
Dihydrocodeine HCL Dopamine
Dihydromorphine
Ecgonine methylester Ecgonine
HCL
Efavirenz
Emetine dihydrochloride hydrate
Ephedrine-(+/-) hydrochloride
(-) -Ephedrine HCL
[1R,2S] (-) Ephedrine
Erythromycin
Physostigmine
Estazolam
β-Estradiol
(±)-EDDP
Bata-D-glucuromicle
EthylMorphine
Fenoprofen
Flunitrazepam
Furosemide
Gentisic acid
D-Glucuronic acid
Glutethimide
Guaifenesin
Cetirizine Hydrochloride
Chlordiazepoxide HCL
Chlorothiazide
Chloroquine
Chlorpheniramine Maleate
Chloramphenicol
ChloralHydrate
Cholesterol
Chlorothiazide Clomipramine
Clomzepate dipotasium
Clonazepam
Clobazam
Clozapine
(-) Cotinine
Cocaethylene
Codeine
Cortisone Cyclopentobarbital
JWH-073 butanoic acid
Labetalol Hydrochloride
Levorphanol
Loperamide Hydrochloride
Lormetazepam
(±)-MDEA
(±)-MDA
Meprobamate
(±)Methadone
S(+)D-methamphetamine
L-methamphetamine
Methylphenidate
(±)-MDPV
Methyprylon
Midazolam
Morphine
Morphine-3β-D-glucuronide
Morphine sulfate salt solution
Nalidixic acid
Naloxone
Naltrexone hydrochloride
Nicotinamide (vitamin B3)
Nimesulide
Nitrazepam
Nifedipine
Norcodeine
Nordiazepam
Nordoxepin hydrochloride
Norfloxacin Capsule
Norethisterone Tablets
d-Norpropoxyphene maleate
salt Noscapine
Nortriptyline Hydrochloride
Noroxymorphone HCL
Nylidrin hydrochloride
Norchlordiazepoxide
Norfentanyl
Normorphine
Oxymorphone
Papaverine
PCP
Pentobarbital
Pentazocine
Perphenazine
Penicillin G Sodium salt
Phenobarbital
Phentermine HCL
Phenylethylamine
Gabapentin
Hemoglobin porcine
Hydralazine hydrochloride
Hydromorphone
Hydrocodone
α-Hydroxyhippuric acid
21-Hydroxy progesterone p-
Hydroxymethamphetamine
Hydrocortisone
Hydrochlorothiazide Ibuprofen
Imipramine
Isoxsuprine hydrochloride
Isoproterenol Hydrochloride
Injection
Ketamine hydrochloride
JWH-018 pantanoic acid
Phenylpropanolamine
hydrochloride
Predinsolone
Prednisone Acetate Tablets
Propoxyphene,d-
Propranolol Hydrochloride
Pseudoephedrine
Phendimetrazine
Phenytoin
Quinidine
Quinacrine
Ranitidine Hydrochloride
Tablets Salicylic Acid
Secobarbital
Serotonin
Sertraline HCI
Sulfamethazine,min 99%
Sulindac
Temazepam
Terfenadine
Terbutaline
Tetrahydrocannabinol,
Delta-8- ((-)-delta-8-THC)
Tetracycline
Tetrahydrocortisone 3-(β-D-
glu-curonide
(-)-delta-9-THC)
(+/-)11-Hydroxy-delta-9-THC
(-)-11-nor-9-Carboxy-delta9-
THC Thebaine
Thioridazine
Thiamine, (Vitamin B1 Tablets
)HCL
Tolbutamide
Triamterene
Trimipramine
Tryptamine
Trifluoperazine
dihydrochloride DL-
Tryptophan
Triazolam
Trans-2-phenylcyclo-
propylamine hydrochloride
Tyramine
Uric Acid
Verapamil Hydrochloride
Valproic acid
Zopiclone
Zolpidem

BIBLIOGRAHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980

Manufactured By:
W.H.P.M., Inc.
5358 Irwindale Ave.
Irwindale, CA 91706
www.whpm.com

DGP36196-2.0