XYL

Xylazine Test (Urine) Dip Card

A rapid test for the qualitative detection of Xylazine *in human urine.*
For Forensic use only.

INTENDED USE

The **Xylazine Test (Urine) Dip Card** is a lateral flow chromatographic immunoassay for the detection of Xylazine in human urine.

Test	Calibrator	Cut-off
Xylazine (XYL)	Xylazine	50 ng/ml

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Xylazine (colloquially known as tranq/tranq dope) is a non-opioid tranquilizer used as a sedative, analgesic, and muscle relaxant in animals such as horses and cattle[1,3]. In humans, it could cause central nervous system depression, respiratory depression, bradycardia, hypotension, and even death[1]. Most of the non-fatal cases required medical intervention. In recent years, xylazine has emerged as an adulterant in recreational drugs such as heroin[2]. Chronic use of xylazine is reported to be associated with physical deterioration and skin ulceration. Combining xylazine with other drugs that cause central nervous system depression compounds the sedative effects and can increase the risk of overdose and death[2].

PRINCIPLE

The **Xylazine Test (Urine) Dip Card** is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a urine specimen migrates upward by capillary action. Xylazine, if present in the urine specimen below 50 ng/ml, will not saturate the binding sites of the antibody coated particles in the test dip card. The antibody coated particles will then be captured by immobilized Xylazine 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 50 ng/ml because it will saturate all the binding sites of anti-Xylazine antibodies.
A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen 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 dip card contains mouse monoclonal anti-Xylazine antibody-coupled particles and Xylazine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For Forensic use only. Do not use after the expiration date.
- The test dip card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test dip card should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test dip card is stable through the expiration date printed on the sealed pouch. The test dip card must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

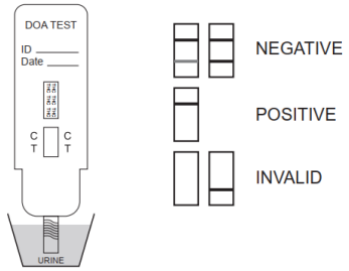
- Test dip card
- Package insert

Materials Required but Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.
1) Remove the test device from the foil pouch.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic device.
4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.
5) Read results at 5 minutes.
DO NOT INTERPRET RESULT AFTER 10 MINUTES.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
NEGATIVE: * Two lines appear. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Xylazine concentration is below the detectable level (50 ng/mL).
***NOTE:** The shade of red in the test line region (T) may vary, but it should be considered negative whenever there is even a faint pink line.
POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Xylazine concentration exceeds the detectable level (50 ng/mL).
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 dip card. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red 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.
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

1. The **Xylazine Test (Urine) Dip Card** 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) is the preferred confirmatory method.[4,5]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

Xylazine conc.(ng/mL)	Total number of Determinations	Result	Precision
No Drug present	40	40 negative	>99%
25	40	40 negative	>99%
75	40	40 positive	>99%
100	40	40 positive	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

XYL Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
37.5	-25%	30	30	0
50	Cut-off	30	12	18
62.5	+25%	30	0	30
75	+50%	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by The **Xylazine Test (Urine) Dip Card** at a read time of 5 minutes.

Drug	Concentration (ng/ml)
Xylazine	50
4-Hydroxy xylazine	50
±MBDB HCL	25,000
Clonidine	25,000
Butylone Hcl	780
N-Acetylprocainamide	70,000

Effect of Urinary Specific Gravity

Twelve (12) urine samples of normal, high, and low specific gravity ranges 1.000 to 1.035 were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **Xylazine Test (Urine) Dip Card** was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **Xylazine Test (Urine) Dip Card**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Xylazine positive urine. The following compounds show no cross-reactivity when tested with the **Xylazine Test (Urine) Dip Card** at a concentration of 100 μg/mL.

Non-Cross-Reacting Compounds

Citalopram HBr
L-Thyroxine
y-aminobutyric acid
(±)-Octopamine hydrochloride
(-)-11-nor-9-carboxy-delta
(-)-Cotinine
(±)-Epinephrine hydrochloride
(±)-Methamphetamine
(±)-N'-Nitrosonornicotine
(±)-Nornicotine
(1R,2S)-(-)-Ephedrine HCl
(R,S)-Norcotinine
(S)-(-)-Nicotine-d3
(S)-N-Nitrosoanabasine (NAB)
(S)-N-Nitrosoanatabine
(t)-methadane
±MDEA
1-Adamantanamine hydrochloride
2-Phenylethylamine hydrochloride
3,4-Methylenedioxypyrovalerone HCl
4CN-CUMYL-BUTINACA
Dexamethasone acetate
Dextromethorphan
Diazepam
Diclofenac sodium
Dicyclomine
Diethylstilbestrol
Diflunisal
Dihydrocodeine HCl
Diltiazem
Dimenhydrinate
Diphenhydramine HCl
Dirithromycin
Disopyramide
Domperidone
Dopamine Hydrochlorid
Doxylamine succinate
Droperidol
Duloxetine
Ecgonine
Ecgonine methyl Esten
EMDP HCl
morphine
Mosapride Citrate
Nalidixic acid
Nalorphine
Naloxone hydrochloride
Naltrexone Hydrochloride
Naproxen
Narcotine
N-Benzylisopropylamine
Nicotinamide
Nicotinic acid
Nifedipine
Nimodipine
Nitazene
Norbuprenorphine
Nordoxepin hydrochloride
Norethindrone
Norfloxacin
Normorphine
Norsertraline -13C6 HCl
Nortrptyline Hcl
4F-ABUTINACA
4F-MDMB-BUTICA
5.5-Diphenylhydantoin
5F-ADBICA
5F-EMB-PICA
5F-MDMB-PICA
5-Hydroxytryptamine
6-MAM
7-beta-Estradiol
8-Chloro Caffeine
AB-PINACA 4-Hydroxypentyl metabolite
Acetaminophen
Acetylsalcylic
Acyclovir
ADB-4en-PINACA
Albumin
Amikacin
Amiloride
Amiodarone Hydrochlorid
Amitriptyline
Amlodipine besylate
Amoxicillin
Ampicillin
APINACA (AKB-48) 5-Hydroxypentyl metabolite
Apomorphine hydrochloride
a-Pyrrolidnoraler phenore hcl
Aripiprazole
ascorbic acid
Atenolol
Atomoxetine hydrochloride
Atorvastatin
Atrazine
Atropine
Atroscine
Azithromycin
Baclofen
Benzocaine
Benzoic acid
Benzoylecgonine
Berberine
Bilirubin
Buprenorphine
Bupropion hydrochloride
Bupropion HCl
Buspirone HCl
Butalbital
cocaine Hcl
Enalapril Maleate
Enoxacin
Erythromycin
Esomeprazole Magnesium
EStrone
Ethopropazine hydrochloride
Ethylmorphine
Ethylone
Ethyl-p-aminobenzoate
Fenofibrate
Fenoprofen
Fexofenadine Hydrochloride
Fluconazole
Fluoxetine hydrochloride
folic acid
FUB-144
Furosemide
Gabapentin
Gatifloxacin
Gemfibrozil
Gentamicin
Gentisic
Glibenclamide
Gliclazide
Glipizide
Glucose
Hemoglobin
Herion
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
Ibuprofen
Icilin
Imipramine Hydrochloride
Indapamide
Iproniazid
Isoproterenol hydrochloride
Isoproterenol-(+/-)
Isosorbide Dinitrate
Isoxsuprine
JEH-018 5-Hydroxypentyl
JEH-018 N-(4-hydroxypentyl) metabolite
JWH-018 (Spice Cannabinoid)
JWH-019 5-Hydroxyhexyl
JWH-01965-Hydroxyhexyl metabolite
JWH-073 (Spice Cannabinoid)
Noscapine
Ofloxacin
O-Hydroxyhippuric acid
Olanzapine
Omeprazole
Ondansetro
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymorphone
OXYPHENBUTAZONE
Paclitaxel
p-Aminobenzoic
Paroxetine
Penfluridol
Penicillin
Penicillin G Sodium Salt
Pentachlorophenol
Pentobarbital
Perphenazine
phenethylamine
Phenobarbital
Phentermine
Phenytoin Sodium
p-Hydroxymethamphetamine
Pioglitazone Hydrochlorid
Piracetam
Prazosin hydrochloride
Prednisone
Procainamide hydrochloride
Procaine hydrochloride
Promazine
Promethazine hydrochloride
Propranolol Hydrochloride
Propylthiouracil
Pseudoephedrine Hydrochloride
Pseudoephedrine(r)
Pseudoephedrine(s)
Quetiapine fumarate
quinidine
Quinine
Quinine Monohydrochloride Dihydrate
R(-)-Methamphetamine (levo-Methamphetamine)
R-(-)-Phenylephrine HC
R(+)-Methcathinone HCl
Rabeprazole sodium
Cannabidiol
Captopril
Carbamazepine
Carisoprodd
Cefaclor
Cefadroxil
Cefalexin
Cefixime
Cefoperazone sodium
Cefuroxime Axetil
Cephalexin
Cephradine
Chloramphenicol
Chloroquine diphosphate salt
Chlorothiazide
Chlorpromazine hydrochloride
Cholesterol
Cimetidine
Citalopram hydrobromide
Citicoline Sodium
Clarithromycin
Cloethocarb
Clomipramine
Clomipramine
Clopidogrel Bisulfate
Clopidogrel Hydrogen Sulfate
clorprenaline
Clozapine
Cocaethylene
Cocaethylene
Cocaine
Codeine
Cortisone
Creatuinine
d l 3-4-MDA
D L-Tryptophan
D/L-Tyrosine
Deoxycorticosterone
Desalkyl futazepam
Desipramine HCl
Desloratadine
Desloratadine Citrate Disodium
deta-9-THC
6β-Naltrexol
Bromazepam
Cyclobenzaprine
Mephedrone
Pregabalin
JWH-073 4-Hydroxybutyl
JWH-122 5- Hydroxypentyl meabolite
JWH-210 5-Hydroxypentyl meabolite
JWH-250 4-Hydroxypentyl
JWH-250 5-Hydroxypeentyl metabolite
Ketamine
Ketoconazole
Ketoprofen
Kynurenic
Lactose
Lamotrigine
Lansoprazole
Levetiracetam
Levofloxacin Hydrochloride
Levonorgestrel
Levorphanol tartrate
Levothyroxine Sodium
Lignocaine
Lisinopril
Lodeine
Lomefloxacin Hydrochloride
Loperamide hydrochloride
Loratadine
Lorazepam gluronide
Maprotiline HCl
MDMA
MDMB-4en-PINACA
Meperidine
Metformin
Methaqualone
Methoearbm01
methoxyphenamine
Methylmorphinan
Metoclopramide hydrochloride
Metoprolol
Metronidazole
Midazolam
Mifepristone
Minocycline
mirtazapine
Mitragynine
MMB-CHMICA
Montelukast sodium
Alprazolam
Brompheniramine
Doxepin
Nitrazepam
Diflunisal
Ranitidine
Rifampicin
Risperidone
S(-)Cathinone
S(+)methamphetamine
Salbutamol
Salicylic
S-Doxylamine
Serotonin
Sertraline HCl
Sildenafil
Simvastatin
Sodium Valproate
Spice Cannabinoid Mix
Spice Cannabinoid Mix 2
Spice Cannabinoid Mix 3
Spironolactone
Sulfamonomethoxine
Tadalafil
Telmisartan
Thebaine
Theophylline
Thiamine
Tolazamide
Topiramate
Tramadel hcl
Trazodone HCL
Triamterene
Triazolam
Trimethobenzamide Hydrochloride
Trimethoprim
Tryptamine
Tyramine hydrochloride
Ursodeoxycholic Acid
Valproic Acid
Venlafaxine hydrochlorid
Verapamil hydrochloride
Vitamin C
Zomepirac
Zonisamide
α-Hydroxyhippuric acid
β-Estradiol
R(-)Amphetamine
Clobazam
Hydrocodone
Papaverine
Cholesterol
Aspartame

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