



# Fentanyl/Xylazine Residue Test Cassette

Familiarize yourself with this test and read the Instructions For Use carefully before testing.

## Instructions For Use

### For Forensic Use Only

A rapid, screening test for the simultaneous, qualitative detection of Fentanyl and Xylazine residue (e.g. dried liquid or powder) on surfaces, including the outer surface of pills.

### INTENDED USE

The Healgen® Fentanyl/Xylazine Residue Test Cassette is a competitive binding lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Fentanyl (FEN) and Xylazine (XYL) residue on surfaces, including the outer surface of pills, at the following cutoff concentrations:

Test	Calibrator	Cut-off (ng/mL)
Fentanyl (FEN)	Fentanyl	5
Xylazine (XYL)	Xylazine	50

This test provides only a preliminary result. A more specific alternative chemical method should be used to obtain a confirmed preliminary positive result if the donor doesn't admit use or anytime required by testing procedures. Gas Chromatography/Mass Spectrometry (GC-MS), Liquid Chromatography/Mass Spectrometry (LC-MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drug screen test result, particularly when evaluating preliminary positive results.

### TEST PRINCIPLE

The Healgen® Fentanyl/Xylazine Residue Test Cassette is a rapid immunoassay based on the principle of competitive inhibition binding. Therefore, drugs that may be present in the sample compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the fluid specimen migrates upward by capillary action. A drug, if present in the 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 in the specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug positive specimen will not generate a colored line in the specific test line region of the strip because of the drug competition, while a drug negative specimen will generate a line in the test line region due to the absence of drug competition.

For a procedural control, a pink colored line will always appear at the control line region, indicating proper specimen volume was added and membrane wicking occurred.

### REAGENTS

The Healgen® Fentanyl/Xylazine Residue Test Cassette contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

### PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date.
- The device should remain in the sealed pouch until use.
- For single use only. Do not reuse tests.
- Professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.
- Evaluate the specificity and the cross-reactivity data when interpreting results.

- Wear disposable gloves and eye protection when handling harmful substances.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.
- Do not eat, drink, or smoke in the area where the samples are being tested.

### STORAGE AND STABILITY

- DO NOT FREEZE.
- Store as packaged in the sealed pouch either at room temperature or refrigerated [2-30°C (36-86°F)].
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch before use.
- Keep away from direct sunlight, moisture, and heat.
- Do not use beyond the expiration date.

### MATERIALS

#### Material Provided:

- Test cassette
- Buffer bottle with swab
- Instructions For Use
- Quick Reference Instructions

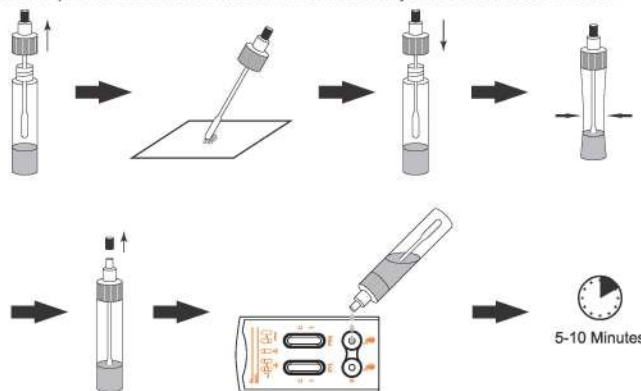
#### Materials Required but not Provided:

- Timer, clock, or watch
- Quality controls

### DIRECTIONS FOR USE

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

1. Remove the swab tool from the Buffer bottle, use the swab tool to wipe across a surface several times to ensure adequate specimen is collected.
2. Insert the swab tool back into the Buffer bottle, then **gently shake and pinch the Buffer bottle for 5-10 times** to mix the specimen thoroughly in the buffer.
3. Unscrew the small opening at the upper end of the Buffer bottle and place 3 drops of the liquid to be tested in the sample well of the cassette.
4. Set a timer for 5 minutes.
5. Interpret results at 5-10 minutes. **Do not interpret results after 1 hour.**



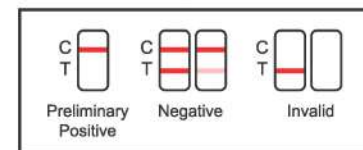
### INTERPRETATION OF RESULTS

**PRELIMINARY POSITIVE:** Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T). A positive result indicates the drug concentration exceeds the detectable level.

**NEGATIVE:** Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

Negative results can be read as soon as test and control line appear on any strip (often within 2 minutes). A negative result indicates the drug concentration is below the detectable level.

**INVALID: Control band fails to appear.** Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the test immediately.



### UNDERSTANDING THE TEST RESULTS

1. A preliminary positive test result does not always mean a person took illegal drugs, and a negative test result does not always mean a person did not take illegal drugs. Several factors influence the reliability of drug tests.

**IMPORTANT:** The result you obtained is called preliminary for a reason. The sample must be tested by laboratory to determine if a drug of abuse is actually present in the sample. <sup>7</sup>

2. What Is a False Positive Test?

The definition of a false positive test would be an instance where the test is positive even though target drugs are not in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also cause a false positive test result with this product.

3. What Is a False Negative Test?

The definition of a false negative test is that the initial target drugs are present but are not detected by the drug test.

### LIMITATIONS

- The Healgen® Fentanyl/Xylazine Residue Test Cassette 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), Liquid Chromatography/Mass Spectrometry (LC-MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods.
- There is a possibility that other substances and/or factors not listed below may interfere with the test and cause incorrect results (e.g., technical or procedural errors). Insufficient specimen volume, incorrect operating procedure, or expired tests are the most likely reasons for control band failure.
- This test has been developed for testing fentanyl and xylazine in the provided buffer. **DO NOT use this device to test any other fluids.**
- A negative result may not necessarily indicate a drug-free specimen. Negative results can be obtained when drug is present but below the cutoff level of the test.
- A positive result indicates the presence drugs only and does not indicate quantity.
- The test does not distinguish between drugs of abuse and certain medications.
- The test is NOT intended to determine the purity, composition, or if the substance being examined is safe to use.
- A positive or negative test result is NOT an indication that the substance being tested is safe to use.
- Multiple factors can affect the test results, including, but not limited to, mixtures of multiple substances, solubility, and pH of the sample.
- ~~Healgen Scientific Limited Liability Company does not encourage the use, supply, or production of illegal drugs or controlled substances in any way. The device is intended for harm reduction. Follow the advice of your local harm reduction regulations or public health agency.~~
- There are no direct therapeutic or diagnostic claims being made for this product. This test is not involved in diagnosing, treating, mitigating, or

preventing a disease, disorder or symptom in humans, nor does it restore, modify or correct a body structure or function of the human body.

- There is a possibility that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.

#### QUALITY CONTROL

- The Healgen® Fentanyl/Xylazine Residue Test Cassette provides a built-in control band for each test strip to indicate that the test has performed correctly. The control band should always appear, regardless of the presence of drugs, to confirm sufficient sample volume, adequate membrane wicking, and correct procedural technique.
- ~~Control materials are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control testing should be performed with each new lot, each new shipment, and every thirty days to check storage.~~

#### PERFORMANCE CHARACTERISTICS

##### Accuracy

Accuracy of the Healgen® Fentanyl/Xylazine Residue Test Cassette was established by analyzing 30 specimens in parallel with LC-MS/MS. The results are summarized below:

Drug Conc. (Cut-off range)	Samples Tested	FEN5		XYL50	
		Neg	Pos	Neg	Pos
0% Cut-off	30	30	0	30	0
-50% Cut-off	30	30	0	30	0
-25% Cut-off	30	30	0	30	0
Cut-off	30	13	17	12	18
+25% Cut-off	30	2	28	0	30
+50% Cut-off	30	0	30	0	30
+300% Cut-off	30	0	30	0	30

##### Specificity

The following table lists compounds that are positively detected in the Healgen® Fentanyl/Xylazine Residue Test Cassette

Drug	Concentration (ng/mL)
<b>FENTANYL (FEN5)</b>	
Fentanyl	5
Norfentanyl	100,000
Carfentanyl	6,000
Acylovir	6,250
Levofloxacin Hydrochloride	6,250
Domperidone	6,250
Alfentanil	50,000
Acetyl fentanyl	5
Acrylfentanyl	8
3-cis-methylfentanyl	8
Isobutyl fentanyl	10
Ocfentanyl	8
Butyl fentanyl	6
Furanyl fentanyl	8
Valeryl fentanyl	10
(±) β-hydroxythiofentanyl	45

4-Fluoro-isobutyrylfentanyl	50
Para-fluorobutyrylfentanyl (p-FBF)	40
Norcarfentanil	>100,000
Despropionyl fentanyl (4-ANPP)	10,000
Remifentanil	50,000
Sufentanil	3,000
Acetyl norfentanyl	>100,000
<b>XYLAZINE(XYL50)</b>	
Xylazine	50
4-Hydroxy xylazine	50
±MBDB HCL	25,000
Clonidine	25,000
Butylone HCl	780
N-Acetylprocainamide	70,000
Tizanidine Hydrochloride	12,500

##### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the Healgen® Fentanyl/Xylazine Residue Test Cassette with compounds in either drug-free buffer or Xylazine and Fentanyl positive buffer. The following compounds show no cross-reactivity when tested with the Healgen® Fentanyl/Xylazine Residue Test Cassette at a concentration of 100 µg/mL.

##### Non Cross-Reacting Compounds

Acetaminophen	Cefoperazone sodium	Diflunisal	1-Adamantanamine hydrochloride	Cyclobenzaprine HCl	Ethyl-β-D-glucuronide(Ethyl-β-D-glucuronide-D5)
Acetone (10mg/mL)	Cefuroxime Axetil	Digoxin	Baclofen	Citalopram HBr	(±)-Epinephrine hydrochloride((±)-Epinephrine-D6)
Acetylsalicylic acid	Cephalexin	Dihydrocodeine HCL	Beclomethasone	(-)-Cotinine	β -Estradiol
Albumin (Albumin human)	Cephadrine	Diltiazem	Benzilic acid	8-Chloro Caffeine	Fenofibrate
Albuterol	Chloral Hydrate	Dimenhydrinate	Benzocaine	d l 3-4-MDA	Fenoprofen
Alprazolam	Chloramphenicol	Diphenhydramine	Benzoic acid	D L-Tryptophan	Fexofenadine Hydrochloride
Amikacin	Chlordiazepoxide	Dirithromycin	Benzoylcegonine	D,L-Methamphetamine	Flephedrone(4-fluoromethcathinone)
Amiloride	Chloroquine diphosphate salt	Disopyramide	Berberine	D/L-Tyrosine	Fluconazole
Amiodarone Hydrochlorid	Chlorothiazide	Dopamine Hydrochlorid	Bilirubin	D-Amphetamine	Flunitrazepam
Amitriptyline	Chlorpromazine hydrochloride	Doxepin	Bromazepam	Delactose Chlordiazepoxide	Fluoxetine hydrochloride
Amlodipine besylate	Cholesterol	Doxylamine	Brompheniramine maleate	Delorazepam	Furosemide
Amobarbital	Cimetidine	Duloxetine	Buprenorphine	Demoxepam	Norchlordiazepoxide
Amoxicillin	Citalopram hydrobromide	5,5-Diphenylhydantoin	Buprenorphine -3-D-Glucuronide(Buprenorphine Glucuronide)	Desalkylflurazepam	Norclomipramine hydrochloride
Ampicillin	Citalcoline Sodium	Ecgonine methyl ester	Gemfibrozil	Lamotrigine	Norcocaine
Apomorphine hydrochloride	Clarithromycin	EDDP perchlorate	Gentamicin	Loperamide hydrochloride	Norcodeine
Aprobarbital	Clobazam	EMDP hydrochloride	Gentisic	L-Thyroxine	Nordiazepam
Aripiprazole	Cloethocarb	Enalapril Maleate	Gentisic acid	Maprotiline	Nordoxepin hydrochloride
Ascorbic acid	Clomipramine	Enoxacin	Glibenclamide	Meperidine	Norethindrone
Aspartame	Clonazepam	Ephedrine hydrochloride((1R,2S)-(-)-Ephedrine hydrochloride)	Glipizide	Mepredrone	Norfloxacin
Atenolol	Clopidogrel Hydrogen Sulfate	Erythromycin	Glucose	Meprobamate	Normeperidine (Normeperidine-D4)
Atomoxetine hydrochloride	Clorzepate Dipotassium	Esomeprazole Magnesium	Hemoglobin	Metformin	Normorphine
Atorvastatin	Clorprenaline	Estriol	Heroin	Methaqualone	Noroxycodone HCl
Atrazine	Clozapine	Estrone	Hydralazine	Methedrone	Norsertaline-13C <sub>6</sub> hydrochloride
Atropine	Cocaethylene	Estrone 3-sulfate sodium salt	Hydrochlorothiazide	Methylmorphinan	Nortriptyline hydrochloride
Atrosine hydrobromide	Cocaine HCl	Ethopropazine hydrochloride	Hydrocodone	Methylone hydrochloride	(+)-Norpropoxyphene maleate
Azithromycin	Codeine	Ethylmorphine	Hydrocortisone	Methylphenidate hydrochloride	(±)-N'-Nitrosoanabine (NAB)
6-Acetylmorphine	Cortisone	Ethylone hydrochloride	Hydromorphone	Methyltestosteronetablets	(±)-Norketamine hydrochloride
γ -aminobutyric acid	Creatinine	Ethyl-p-aminobenzoate	5-Hydroxytryptamine	Metoclopramide hydrochloride	(±)-Normicotine
			7-Hydroxymytragynine	Metoprolol	(R,S)-Norcotinine
			9-Hydroxyrisperidone	Metronidazole	(S)-(-)-Nicotine-d3
			17α-Hydroxyprogesterone	Midazolam	(S)-N-Nitrosoanabine (NAB)
			a-Hydroxyalprazolam	Mifepristone	(S)-N-Nitrosoanabine
			α -Hydroxyhippuric acid	Minocycline	6β-Naltrexol
			Icilin	Mirtazapine	Octopamine
			Imipramine Hydrochloride	Montelukast Sodium Salt	O-Desmethyl-cis-tramadol hydrochloride
			Indapamide	Morphine	Ofloxacin
			Iproniazid	Morphine-3-β-D-glucuronide	O-Hydroxyhippuric acid
			Isoproterenol hydrochloride	Mosapride Citrate	Olanzapine
			Isoproterenol- (+/-)	(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Omeprazole
			Isosorbide Dinitrate	Methylenedioxyamphetamine (MDA)	Ondansetron
			Isoxsuprine	(±)-MDMA solution	Oxalic acid
			Ketamine	(±)-Methadone	Oxazepam
			Ketoconazole	3,4-Methylenedioxypropylvaleron e HCl (MDPV)	Oxolinic acid
			Ketoprofen	N,N-Dimethyltryptamine (DMT) solution	Oxycodone
			Kynurenic	NaCl (40mg/mL)	Oxymetazoline hydrochloride











Lactose	Nalidixic acid	Oxymorphone (Oxymorphone-D3)
Lamotrigine	Nalorphine HCl	Oxyphenbutazone
Lansoprazole	Naloxone hydrochloride	Paclitaxel
Levonorgestrel	Naltrexone hydrochloride	p-Aminobenzoic acid
Levorphanol tartrate	Naproxen	Papaverine hydrochloride
Levothyroxine Sodium	N-Desmethyl-cis-tramadol	Paroxetine
Lidocaine solution	Nicotinamide (Vitamin B3)	PCP (Phencyclidine)
Lignocaine	Nicotinic acid	Penfluridol
Lisinopril	Nifedipine	Penicillin
Lomefloxacin Hydrochloride	Nimodipine	Penicillin G Sodium Salt
Loraladine	Nitazene(citrate)	Pentachlorophenol
Lorazepam glucuronide	Nitrazepam	Pentobarbital
l-phenylephrine (R-(-)-Phenylephrine hydrochloride solution)	Norbuprenorphine	Perphenazine
LSD	Norbuprenorphine-3-D-Glucuronide	Phencyclidine
Quetiapine	Spirolactone	Phenelzine
Quinidine	Sulfamethazine	Phenobarbital
Quinine	Sulfamonomethoxine	Phentermine
Quinine Monohydrochloride Dihydrate	Tadalafil	Phentolamine
R (-)-Amphetamine	Telmisartan	Phenytoin Sodium
R (+)-Methcathinone	Tetrahydrocortisone-2,2,3,4,4-d5	p-Hydroxymethamphetamine
Rabeprazole sodium	Tetrahydrozoline	Pioglitazone Hydrochlorid
Ranitidine	Thebaine	Piracetam
Rifampicin	Theophylline	Prazosin hydrochloride
Risperidone	Thiamine	Prednisone
S (-)-Methcathinone	Thioridazine	Prilocaine
S (+)-Methamphetamine	Tizanidine Hydrochloride	Procaine hydrochloride
S,S (+)-Pseudoephedrine	Tolazamide	Promazine
Salicylic	Topiramate	Promethazine hydrochloride
S-Doxylamine	Tramadol hydrochloride	Propoxyphene
Secobarbital	Trazodone HCL	Propylthiouracil
Serotonin	Triamterene	Pyrovalerone hydrochloride
Sertraline	Triazolam	(±)-Phenylpropanolamine hydrochloride
Sildenafil	Trifluoperazine	2-Phenylethylamine hydrochloride
Simvastatin	Trimethobenzamide Hydrochloride	β -Phenylethylamine
Sodium Valproate	Trimethoprim	ω -
Ursodeoxycholic Acid	Tryptamine	Pyrrolidinoveraloperone hydrochloride
Valproic Acid	Tyramine hydrochloride	Zomepirac sodium Salt
Venlafaxine Hydrochloride	3,3',5,5'-Tetramethylbenzidine dihydrochloride hydrate	Zonisamide
Verapamil	Zolpidem	Zopiclone
Vitamin C	Trazodone	Zaleplon
Perphenazine	Paliperidone	Buspirone
Risperidone	Tramadol	Tapentadol
Diphenhydramine	Tramadol-O- Desmethyl	Thioridazine
6-Acetyl morphine	Heroin	Tilidine
Amphetamine	Hydrocodone	Naltrexone
Buprenorphine	Hydromorphone	Norbuprenorphine
Buprenorphineglucuronide	Ketamine	Norcodeine
Codeine	Levorphanol	Norketamine
Dextromethorphan	Meperidine	Normeperidine
Dihydrocodeine	Methadone	Normorphine
EDDP	Morphine	Noroxycodone
EMDP	Morphine-3-glucuronide	Oxycodone
Fluoxetine	Naloxone	Oxymorphone
Tramadol-N- Desmethyl		Pentazocine (Talwin)

**MORE INFORMATION AND RESOURCES**

A health care provider, or any of the following organization can be contacted for additional information and/or counseling regarding substance abuse prevention and treatment:


- Center for Substance Abuse Treatment (CSAT)1-877-SAMHSA-7 / www.samhsa.gov

**INDEX OF SYMBOLS**

	Do not reuse		See Instruction for Use		Expiration Date
	Tests per Kit		Store Between 2-30°C (36-86°F)		Keep Dry
	Batch Number		Catalog#		Keep Away from Sunlight
	Manufacturer				

**ASSISTANCE**

If you have any questions regarding the use of this product, please call our Technical Support Number 1-866-982-3818 (8:30 a.m. to 5 p.m. CDT).

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