

**Multi-Drug Rapid Test Cassette  
(Urine & Powder)  
Package Insert  
AT-DOA-X125**

*A rapid test for the detection of Xylazine and Fentanyl in human urine or powder.  
For forensic use only, not for in vitro diagnostic use.*

**【INTENDED USE】**

The Multi-Drug Rapid Test Cassette (Urine & Powder) is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug in human urine or powder at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Xylazine (XYL)	Xylazine	1,000
Fentanyl (FYL)	Fentanyl	10

Configurations of the Multi-Drug Rapid Test Cassette(Urine & Powder) come with any combination of the above listed drug analytes. This assay provides only a 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) 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 indicated.

**【SUMMARY】**

**Xylazine (XYL)**

Xylazine is a veterinary tranquilizer, which is not approved for human use in the United States, but is commonly used for sedating large animals. Although human intoxication with xylazine has been reported sporadically over the past several decades in a number of case studies. It was also noted in the literature describing drug overdose deaths in Philadelphia as early as 2006, yet it did not appear in high prevalence at that time. However, since the mid-2010 s, xylazine has been noticed by people who inject drugs (PWID) and public health practitioners as an increasingly commonplace additive in the street opioid supply of Philadelphia. Further, recent reports from Connecticut implicated xylazine in a rising fraction of overdose deaths in 2019–2020.<sup>1</sup>

In Puerto Rico, heroin is commonly adulterated with xylazine. Also, xylazine is frequently found in speedball (a cocaine and heroin mixture). Xylazine has also been reported to be misused as a horse doping agent, a drug of abuse, a drug for attempted sexual assault, and as source of accidental or intended poisonings. From human reported cases, central nervous system depression, respiratory depression, bradycardia, hypotension, and hyperglycemia were observed. Literature shows some similar pharmacologic effects between xylazine and heroin in humans.<sup>2</sup>

**Fentanyl (FYL)**

Fentanyl, belongs to powerful narcotics analgesics, and is a  $\mu$  special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations “Single Convention of narcotic drug in 1961”. Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain<sup>3</sup>. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc<sup>4</sup>,<sup>5</sup> which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose<sup>6</sup>.

**【PRINCIPLE】**

During testing, the 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 antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the drug Cassette. 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 region.

A drug-positive specimen will not generate a colored line in the test region of the Cassette because of drug competition, while a drug-negative specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**【REAGENTS】**

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

**【PRECAUTIONS】**

- For forensic use only, not for *in vitro* diagnostic use.
- Do not use after the expiration date.
- The test 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 should be discarded according to local regulations.

**【STORAGE AND STABILITY】**

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test Cassettes 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 a clear specimen for testing.

**Specimen Storage**

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

**【MATERIALS】**

- Test cassettes
- Package insert
- Dropper

**Materials Required but Not Provided**

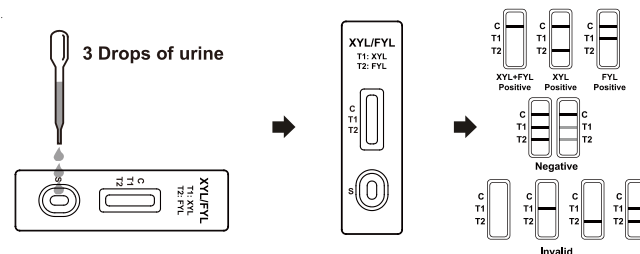
- Specimen collection containers
- Timer

**【DIRECTIONS FOR USE】**

**For urine specimen:**

**Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 120  $\mu$ L) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.

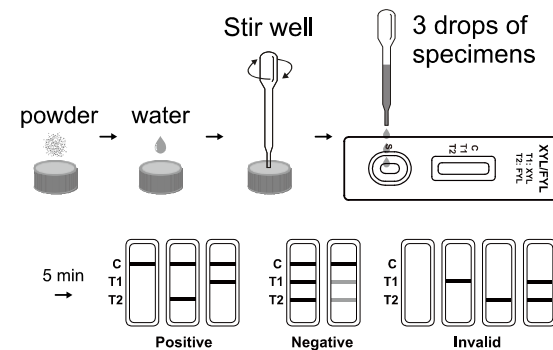


**For powder specimen:**

**Allow the test, specimen, water to reach room temperature (15-30°C) prior to testing.**

1. Prepare specimen collection containers and powder sample.
2. Pour powder sample into the specimen collection containers.
3. Dilute 50mg powder with 5mL water (1 mineral water bottle cap  $\approx$  5mL). Stir well with a dropper.
4. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

5. Transfer 3 drops of specimens (approximately 120  $\mu$ L) into specimen well of the test cassette and start the timer.
6. Wait for colored lines to appear. **Read the results at 5 minutes.** Do not interpret the result after 10 minutes.



**【INTERPRETATION OF RESULTS】**

(Please refer to the illustration above)

**NEGATIVE:\*** A colored line appears in the Control region (C) and a colored line appears in the Test region (XYL/FYL). This negative result means that the concentrations in the sample are below the designated cut-off levels for a particular drug tested.

**\*NOTE:** The shade of the colored lines(s) in the Test region (XYL/FYL) may vary. The result should be considered negative whenever even there is a faint line.

**POSITIVE:** A colored line appears in the Control region (C) and **No line appears in the Test region (XYL/FYL).** The positive result means that the drug concentration in the sample is greater than the designated cut-off for a specific drug.

**INVALID:** No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

**【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 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 Multi-Drug Rapid Test Cassette (Urine & Powder) provides only a qualitative preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. A negative result may not necessarily indicate drug-free sample. Negative results can be obtained when drug is present but below the cut-off level of the test.
3. This test does not distinguish between drugs of abuse and certain medications.
4. Test does not distinguish between drugs of abuse and certain medications. 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.

**【PERFORMANCE CHARACTERISTICS】**

**Analytical Sensitivity**

The following table lists different concentration drugs that are detected in buffer by the Multi-Drug Rapid Test Cassette (Urine & Powder) at 5 minutes.

Drug Concentration Cut-off Range	XYL 1,000		FYL10	
	-	+	-	+
0% Cut-off	30	0	30	0
-50% Cut-off	30	0	30	0
-25% Cut-off	28	2	26	4
Cut-off	15	15	13	17

+25% Cut-off	4	26	3	27
+50% Cut-off	1	29	0	30
+300% Cut-off	0	30	0	30

**Analytical Specificity**

The following table lists compounds that are positively detected in buffer by the Multi-Drug Rapid Test Cassette (Urine & Powder) at 5 minutes.

Analytes	Concentration (ng/mL)	Analytes	Concentration (ng/mL)
<b>XYLAZINE (XYL 1,000)</b>			
Xylazine	1000		
<b>FENTANYL (FYL 10)</b>			
Fentanyl	10	Cyclopro Fentanyl	250
Norfentanyl	>100,000	(±)cis-3-Methylfentanyl	250
Butyl fentanyl	150	Valeryl Fentanyl	100
Methoxyacetyl-I-Fentanyl	20	Acetyl Fentanyl	20
Ocfentanil	100	para-Fluorobutyryl fentanil	100
		PBPF)	
4-Fluoro-isobutyryl Fentanyl	100	para-Fluorofentanil	50

**【BIBLIOGRAPHY】**

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Number:

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