



# Rapid Response

## Xylazine Test Strip Kit (Liquid / Powder)

REF XYL-18S2-5K

Product Insert

**WARNING: THIS TEST DOES NOT EVALUATE  
DRUG SAFETY OR PURITY**

**A rapid visual immunoassay for the detection of Xylazine in  
suspicious substances from surfaces and liquids from  
suspicious receptacles.**

For forensic use only.

Not an IVD.

### Intended Use

The Rapid Response™ Xylazine Test Strip Kit (Liquid / Powder) is a rapid visual immunoassay for the qualitative, presumptive detection of drugs in suspicious substances from solids, liquids and surfaces. By using this test strip, you can determine if your sample contains Xylazine. The detection limit of this test is 1000 ng/mL.

Parameter	Calibrator	Cut-off(ng/mL)
XYL (Xylazine)	Xylazine	1,000

### Materials

#### Materials provided

- Test strips with microscoops
- Swabs
- Buffer Tubes
- Product insert
- Tube Stand
- Result interpretation card

#### Materials required but not provided

- Timer

### Precautions

- The test device 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 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.
- BTNX Inc. does not encourage the use, supply, or production of illegal drugs or controlled substances in any way. The device is intended for harm reduction purposes.** Follow the advice of your local harm reduction or public health agency.
- There are no direct therapeutic or diagnostic claims being made for this product. These tests are not involved in diagnosing, treating, mitigating, or preventing a disease, disorder or symptom in human beings, nor do they restore, modify or correct a body structure, function of the human body.
- The Rapid Response™ Xylazine Test Strip Kit only gives an indication and should be used solely as a presumptive guide to work in conjunction with further analysis such as Gas Chromatography- Mass Spectrometry or High Performance Liquid Chromatography (HPLC). For complete analysis, we recommend all samples should be sent to a professionally certified laboratory.
- Do not use after expiration date indicated on the package. Do not use

- the test if its foil pouch is damaged. Do not reuse tests. This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing the usual safety precautions (do not ingest or inhale).
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the samples and kits are handled. It is recommended to wear protective clothing such as 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.
- The Rapid Response™ Xylazine Test Strip Kit has been tested for extreme shipping conditions, and its performance has not been impacted.
- The test can be stored between 36-86°F (2-30°C).

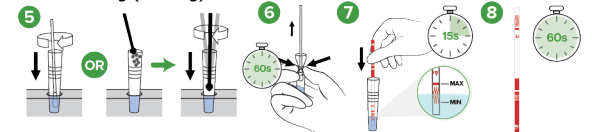
### Test Procedure

**Bring tests, samples, buffer and/or controls to room temperature 59-86°F (15-30°C) before use.**

1 2 3 4 a. Liquid Sample b. Solid Sample c. Powder Sample



- Prepare the desired number of buffer tubes by placing them in the tube stand.
- Remove the buffer tube seal.
- Remove the swab from its packaging.
- Collect the Sample**
  - For Liquid Samples:** Dip the swab into the liquid sample if necessary rotate and swipe the sample to absorb as much liquid as possible
  - For Solid Samples:** Dip the swab into the buffer tube for 3 seconds to moisten the swab. Wipe the tip of the swab in the substance several times. The more times the swab is wiped into the substance, the more of the drug can be absorbed.
  - For Powder Samples:** Using the microscop, collect one scoop of drug (5-10mg).



- Insert the swab or the microscop into the buffer tube, stir gently for 1 to 2 minutes and remove.
- When using the swab, squeeze the sides of the tube to remove as much liquid from the swab tip as possible.
- Remove the test strip from its sealed pouch and use it as soon as possible. Hold the strip by the end, where the product name (XYL) is printed. Do not touch the strip membrane (the white section of the strip). Holding the strip vertically, dip the test strip in the liquid for at least 10-15 seconds. Immerse the strip where the wavy lines are, but not above the solid (maximum) line on the test strip.
- Remove the strip from the sample and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear.
- A negative result can be interpreted as soon as both the test (T) and control (C) lines appear. A positive result can be interpreted once the control line has appeared and the background has cleared to white, typically by 60 seconds. Do not read results after 10 minutes.

### Results Interpretation

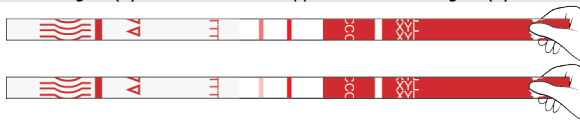
#### Positive - Xylazine Detected

Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).



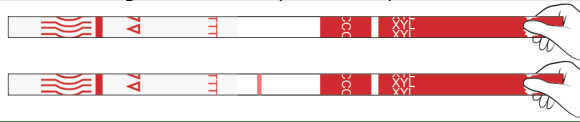
#### Negative – Xylazine Could Not be Detected

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



#### 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 kit immediately and contact your local distributor.



#### NOTE:

- The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the sample. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only and cannot determine the concentration of analytes in the sample.
- Insufficient sample volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

### Quality Control

#### Internal Procedural Controls

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient sample volume and correct procedural technique.

### Limitations of the Test

- There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the Rapid Response™ Xylazine Test Strip Kit (Liquid / Powder) and cause false results.**
- A positive result indicates the presence of xylazine only and does not indicate quantity.**
- A negative result does not at any time rule out the presence of xylazine, as they may be present below the minimum detection level of the test.**
- The Rapid Response™ Xylazine Test Strip Kit (Liquid / Powder) test is for forensic use and should be only used for the qualitative detection of xylazine.
- This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.

- A negative result may not necessarily indicate drug-free sample. Negative results can be obtained when the drug is present but below the cut-off level of the test.
- This test may not distinguish between xylazine and other illicit substances.

### Performance Characteristics

#### A. Reproducibility

The reproducibility of the Rapid Response™ Xylazine Test Strip Kit (Liquid / Powder) was verified by blind tests performed at four different locations. Samples with xylazine concentrations at 50% of the cut-off were all determined to be negative, while samples with xylazine concentrations at 200% of the cut-off were all determined to be positive.

#### B. Precision

Test precision was determined by blind tests with control solutions. Controls with xylazine concentrations at 50% of the cut-off yielded negative results, and controls with xylazine concentrations at 150% of the cut-off yielded positive results.

#### C. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the Rapid Response™ Xylazine Test Strip Kit (Liquid / Powder) identified positive results at 5 minutes.

Xylazine 1000 related compounds	Concentration (ng/ml)
Xylazine	1000

The test device is designed to screen for the presence of Xylazine in suspicious solids or liquids. Other compounds found in illicit drugs may display cross reactivity with the test device. The following compounds were spiked into water, respectively, to examine possible cross-reactivity. No false positive was observed at the concentrations listed in the table. No significant cross-reactivities have been observed when following the testing and dilution procedure described in the IFU.

Xylazine 1000 Interfering Substances			
Acetaminophen	5 mg/mL	Levamisole	5 mg/mL
Caffeine	5 mg/mL	Lidocaine	5 mg/mL
Dimethylsulphone	5 mg/mL	MDMA	5 mg/mL
Diphenhydramine	5 mg/mL	Methamphetamine	5 mg/mL
Disopyramide	3 mg/mL	Phenacetin	5 mg/mL
Doxylamine	3 mg/mL	Quinine	5 mg/mL

### Glossary of Symbols

	Consult instructions for use		Test per Kit		Do Not Reuse
	Store between 36°F to 86°F (2-30°C)		Use by		Catalogue #
	Lot Number				

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