

Rapid Response

Fentanyl Test Strip (Liquid / Powder)

REF FYL-18S7-100, FYL-18S7-10

Product Insert

WARNING: THIS TEST DOES NOT EVALUATE DRUG SAFETY OR PURITY

For Forensic Use Only Not an IVD

Intended Use

The Rapid Response™ Fentanyl Test Strip (Liquid / Powder) is a rapid visual immunoassay for the qualitative, presumptive detection of fentanyl in suspicious substances at the cut-off concentration listed below:

Parameter	Calibrator	Cut-off(ng/mL)
FYL (Fentanyl)	Fentanyl	200

Materials

Materials Provided

- Individually packed test strips and microscopes
- Results interpretation card
- Product insert

Materials Required but not Provided

- Timer

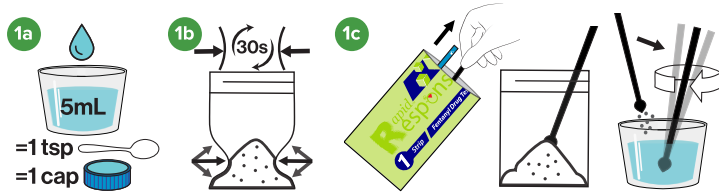
Precautions

- 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.
- 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 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™ Fentanyl Test Strip (Liquid / Powder) has been tested for extreme shipping conditions and its performance has not been impacted.**
- The kit should be stored at 36-86°F (2-30°C) until the expiry date printed on the sealed pouch.

Test Procedure

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

Step 1 Option 1: Preparing Powder or Pill Samples



A. Add 5mL of water (1 teaspoon or about 1 bottle cap) of clean water to a clean container like a cooker, bottle cap, plastic bag or similar.

B. Mix the drugs thoroughly before testing. If testing a pill crush it completely. Powders or crushed pills should be mixed thoroughly in a plastic bag by pinching and shaking the bag for at least 30 seconds.

C. Mix the drugs with water. Open the pouch and remove the microscop. Using the microscop, collect one scoop (5-10mg) of the powdered drug and add it to the water. Stir with the microscop until the drug is completely dissolved in the water.

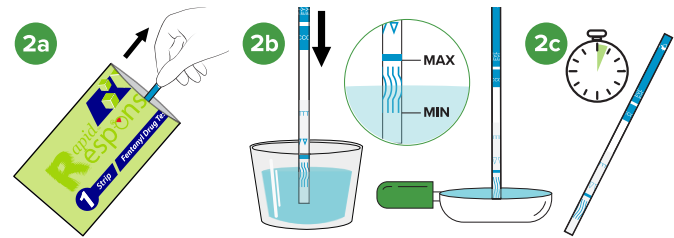
Step 1 Option 2: Preparing Liquid Drug Residue Samples:



A. After the drug shot is prepared and taken into the syringe, the leftover residue can be tested for the presence of Fentanyl. Add 1mL of clean water to the container or cooker having the residue.

NOTE: Refer to the advice of your local public health or harm reduction authority for how much water and drug sample you should use. **Visit our website for details on testing other sample types** www.btnx.com/harmreduction

Step 2: Testing



A. Remove the test strip from the pouch. It's best to use the strip immediately after opening. Do not use the strip if the pouch has been opened for more than one hour. Do not throw away the pouch until you have read the results.

B. Hold the test strip by the blue end where "FYL" is printed. Avoid touching the strip's white membrane. Dip the strip into the solution, submerging it up to the wavy lines but not past the solid line. Hold it there for 10-15 seconds.

C. Remove the strip from the solution and place it on a non-absorbent flat surface. Start the timer and wait for the colored line(s) to appear.

D. 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. Compare the results to the "Results Interpretation" section below or to the back of the pouch.

Results Interpretation

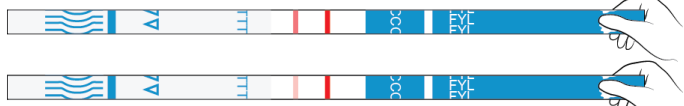
Positive - Fentanyl Detected

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



Negative – Fentanyl Could Not be Detected

Two colored lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T). Even faint lines are considered negative. All negative results are presumptive. Confirmation should be performed using GC-MS or LC-MS analysis. There is still a risk of overdose, even if fentanyl is not present in your drugs.



Invalid

Control line fails to appear. Results from any test which has not produced a control line 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 line 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™ Fentanyl Test Strip (Liquid / Powder) and cause false results.**
- A positive result indicates the presence of fentanyl only and does not indicate quantity.**
- A negative result does not at any time rule out the presence of fentanyl, as it may be present below the minimum detection level of the test.**
- The Rapid Response™ Fentanyl Test Strip (Liquid / Powder) test is for forensic use and should be only used for the qualitative detection of fentanyl.
- 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 drug is present but below the cut-off level of the test.
- This test may not distinguish between fentanyl and other illicit substances
- The test does not distinguish between different fentanyl analogues and certain medications. Other compounds found in illicit drugs may display cross reactivity with the test device. Cross reactivity with other emerging fentanyl analogs is yet to be determined.

Performance Characteristics

Sensitivity

The sensitivity of the Rapid Response™ Fentanyl Test Strip (Liquid / Powder) was determined by tested GC/MS confirmed controls to the concentration at negative, -75%, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff and 3 times of cutoff. The results are summarized below:

Drug Conc. (Cut-off Range)	n	FYL	
		-	+
0% Cut-off	50	50	0
-50% Cut-off	50	50	0
-25% Cut-off	50	50	0
Cut-off	50	22	28
+25% Cut-off	50	0	50
+50% Cut-off	50	0	50
+300% Cut-off	50	0	50

Specificity

The following compounds were spiked into water, respectively, to examine the ability of the Rapid Response™ Fentanyl Test Strip for detecting fentanyl and fentanyl-related analogues. The concentration listed in the table represents the substance concentration at which the test strip will begin to show a mix of positive and negative results.

Fentanyl 200 related compounds			
Acetyl Fentanyl	150 ng/mL	Furanyl Fentanyl	500 ng/mL
Butyryl Fentanyl	700 ng/mL	Ocfentanil	500 ng/mL
Carfentanil*	5,000 ng/mL	p-Fluoro Fentanyl	500 ng/mL
Fentanyl	200 ng/mL	Valeryl Fentanyl	1000 ng/mL

*The test strip reacts with Carfentanil to give an extremely faint line above the concentrations of 5000 ng/mL.

The test device is designed to screen for the presence of Fentanyl 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.

Fentanyl 200 Interfering Substances			
MDMA	5 mg/mL	Lidocaine	5 mg/mL
Methamphetamine	5 mg/mL	Levamisole	5 mg/mL
Methadone	5 mg/mL	Diphenhydramine	5 mg/mL
Heroin	3 mg/mL	Tramadol	3 mg/mL
Morphine	5 mg/mL	Cocaine	5 mg/mL
Ketamine	5 mg/mL	Codeine	5 mg/mL
Acetaminophen	5 mg/mL	Procaine	3 mg/mL
Quinine	5 mg/mL	Caffeine	5 mg/mL

Glossary of Symbols

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

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