

Rapid Response™ Fentanyl Test Strip Kit

(Liquid / Powder)

REF FYL-18S7-5

For forensic use only.
Not an IVD

Product Insert

WARNING: THIS TEST DOES NOT EVALUATE DRUG SAFETY OR PURITY

Intended Use

The Rapid Response™ Fentanyl Test Strip Kit (Liquid / Powder) is a rapid visual immunoassay for the qualitative, presumptive detection of drugs in suspicious substance on from surfaces and liquids from suspicious receptacles. By means of this test strip, you can determine whether or not your sample contains fentanyl. The detection limit of this test is below 200 ng/ml.

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

Materials

Materials provided

- Test strips
- Buffer Tubes
- Tube Stand
- Swabs
- Package insert
- Result interpretation card

Materials required but not provided

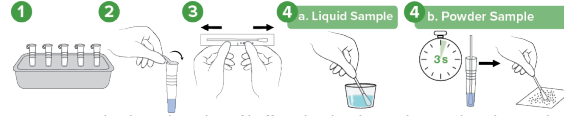
- Timer

Precautions

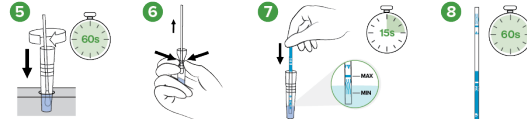
- **The test device is NOT intended to determine the purity, composition, or if the substance being examined is safe to use.**
- **A positive or negative test result is NOT an indication that the substance being examined is safe to use.** Many factors come into play when examining the samples, including 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 humans being, nor do they restore, modify or correct a body structure, function of the human body.
- The Rapid Response™ Fentanyl 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 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 Kit (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).

Test Procedure

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



1. Prepare the desired number of buffer tubes by placing them in the tube stand.
2. Remove the buffer tube seal.
3. Remove the swab from its packaging.
4. **Collect the Sample**
 - a. **For Liquid Samples:** Dip the swab into the liquid sample if necessary rotate and swipe the sample to absorb as much liquid as possible.
 - b. **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.



5. Insert the swab into the buffer tube, stir the swab gently for 1 to 2 minutes to extract the sample from the swab.
6. Remove the swab from the buffer tube while squeezing the sides of the tube to remove as much liquid from the swab tip as possible.
7. 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 (FYL) 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.
8. 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 - Fentanyl Detected
Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

Negative – Fentanyl 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:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. 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 specimen.
2. Insufficient specimen 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

1. **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 Kit (Liquid / Powder) and cause false results.**
2. **A positive result indicates the presence of fentanyl only and does not indicate quantity.**
3. **A negative result does not at any time rule out the presence of fentanyl, as they may be present below the minimum detection level of the test.**
4. The Rapid Response™ Fentanyl Test Strip Kit (Liquid / Powder) is for forensic use and should be only used for the qualitative detection of fentanyl.
5. 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.
6. 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.
7. This test may not distinguish between fentanyl and other illicit substances
8. 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, such as U-47700, cyclopentyl fentanyl, is yet to be determined.

Performance Characteristics

Accuracy

Accuracy of the Rapid Response™ Fentanyl Test Strip Kit was established by running samples against GC/MS specification. The results were tabulated:

Method	Results	% Agreement with GC/MS		Total Results
		Positive	Negative	
Rapid Response™ FYL Test Strips	Positive	61	0	61
	Negative	2	56	58
Total Results		63	56	119
% Agreement		96.8%	100%	98.3%

Sensitivity

The sensitivity of the Rapid Response™ Fentanyl Test Strip Kit 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 table lists compounds that are positively detected in fluid by the Rapid Response™ Fentanyl Test Strip Kit (Liquid / Powder) at 5 minutes.

Fentanyl 200 related compounds	
Carfentanil	5,000 ng/ml
Butyryl Fentanyl	700 ng/ml
p-Fluoro Fentanyl	200 ng/ml
Acetyl Fentanyl	150 ng/ml
Fentanyl	200 ng/ml
Furanyl Fentanyl	500 ng/ml
Valeryl Fentanyl	700 ng/ml
Ocfentanil	250 ng/ml
3-Methyl Fentanyl	500 ng/ml
Remifentanil	70,000 ng/ml
Sufentanil	100,000 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.

Cross Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free buffer or Fentanyl positive buffer. The following compounds show no cross-reactivity when tested with the Rapid Response™ Fentanyl Test Strip Kit (Liquid / Powder) at a concentration of 100µg/ml.

(-)-Ephedrine	Chlorpheniramine	Oxalic Acid
(+)-Naprofen	Creatine	Penicillin-G
(+)-Ephedrine	Dextromethorphan	Pheniramine
4-Dimethylaminoantipyrine	Dextrophan tartrate	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceril Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	Vitamin C (Ascorbic Acid)
Bilirubin	Imipramine	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	
Chloroquine	Methadone	

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				

BTNX Inc.
722 Rosebank Road,
Pickering, ON L1W 4B2
Canada

Technical support: 1-888-339-9964

