BTNX INC.

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Rapid™ Response Fentanyl Test Strip (Liquid / Powder)

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

For Forensic Use Only
Not an IVD

WARNING: THIS TEST DOES NOT EVALUATE DRUG SAFETY OR PURITY

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
- Product insert

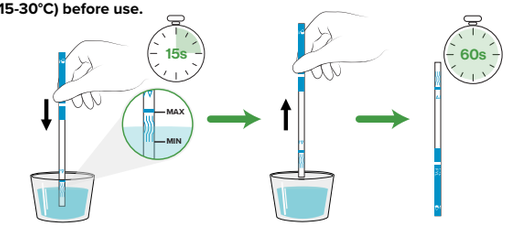
Materials Required but not Provided
- Timer

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.

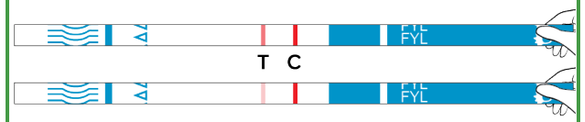


1. Mix your drug sample thoroughly before testing. Dilute the drug to be tested in water. One scoop (5-10mg) of drug sample should be diluted in 5mL of water. Refer to the advice of your local health or harm reduction authority on how much water and drug sample you should use.
2. Remove the test strip from its sealed pouch and use it as soon as possible. For best results, the test should be performed within one hour.
3. Hold the strip by the end, where the product name (FYL) is printed. To avoid contamination, do not touch the strip membrane (the white section of the strip).
4. 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.
5. Remove the strip from the sample and place it on a non-absorbent flat surface. Start the timer and wait for the colored line(s) to appear.
6. A negative result can be interpreted as soon as both the test (T) and control (C) lines appear. A result can be interpreted as positive when 60 seconds have passed since the control line has appeared and no line for that drug is present. Do not read results after 10 minutes.

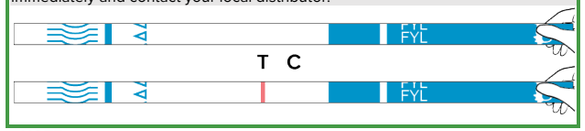
Results Interpretation

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.



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:
1. 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.
2. 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

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 (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 it may be present below the minimum detection level of the test.**
4. The Rapid Response™ Fentanyl Test Strip (Liquid / Powder) test 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 Fentanyl Test Strip was established by running samples against GC/MS specification. The results were tabulated:

% Agreement with GC/MS

Method		GC/MS		Total Results
	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 (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 table lists compounds that are positively detected in fluid by the Rapid Response™ Fentanyl Test Strip (Liquid/ Powder) at 5 minutes.

Fentanyl 200 related compounds			
Carfentanil	5,000 ng/ml	Valeryl Fentanyl	700 ng/ml
Butyryl Fentanyl	700 ng/ml	Ocfentanil	250 ng/ml
p-Fluoro Fentanyl	200 ng/ml	3-Methyl Fentanyl	500 ng/ml
Acetyl Fentanyl	150 ng/ml	Remifentanil	70,000 ng/ml
Fentanyl	200 ng/ml	Sufentanil	100,000 ng/ml
Furanyl Fentanyl	500 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 Strips (Powder/Liquid) at a concentration of 100µg/ml.

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

Glossary of Symbols

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

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Document Number: H10110336601
Effective Date: 2023-06-09 V1.0 EN