



Fentanyl (FTY) Liquid & Powder Drug Test Strip

Catalog No.: WSPFTY-101

The SAFElife™ Fentanyl (FTY) Liquid & Powder Drug Test Strip is a lateral flow immunoassay that allow for the rapid, qualitative determination of fentanyl in liquid, powder or pill samples at the cut-off concentration listed below:

Drug (Identifier)	Calibrator	Cut-off Level
Fentanyl (FTY)	Fentanyl	10 ng/mL

It is intended for forensic use only.

The SAFElife™ Fentanyl (FTY) Liquid & Powder Drug Test Strip provides only preliminary test results. To obtain a confirmed analytical result, a more specific alternative analytical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method. Professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

WARNINGS AND PRECAUTIONS

1. This test kit is for external use only. Do not swallow.
2. Discard after first use. The test kit cannot be used more than once.
3. Do not use the test kit beyond expiry date.
4. Do not use the test kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Read the entire procedure carefully prior to testing.
7. **The device cannot determine the purity, composition of liquid, powder or pill samples.**
8. **A negative or positive test result does NOT indicate that the test substance is safe to use.** A positive result does not indicate quantity of fentanyl. 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 and does not guarantee detection of all fentanyl analogues.
9. The use of gloves is recommended to handle urine samples to avoid unnecessary contact.
10. Humidity and temperature can adversely affect results.
11. The used testing materials should be discarded in accordance with local regulations.
12. **The kit is intended for harm reduction purposes.** Follow the advice of your local harm reduction or public health agency.
13. The test shall not encourage the use, supply, or production of illegal drugs or controlled substances in any way.

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test strip and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Package Insert.

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer or clock
- Measuring cup or Measuring scoop
- Testing cup
- Pill crusher

STORAGE AND STABILITY

- Store at 36°F -86°F (2°C -30°C) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

HOW TO COLLECT SAMPLES?

For Pill/Powder Sample:

Crush the pill into powder or collect the powder directly. Dilute the drug to be tested in water. The Center for Forensic Science Research and Education (CFSRE) recommends adding one scoop (5-10mg) of drug sample to 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.

For Liquid Sample:

Pour liquid directly into the Testing cup or use Measuring scoop to add the liquid into the Testing cup.

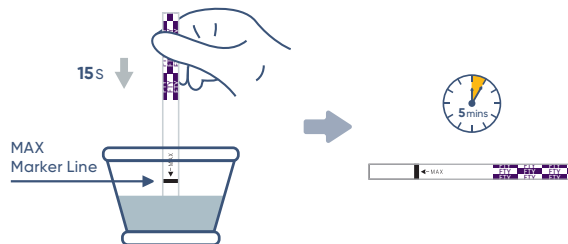


TEST PROCEDURES

Test should be performed at room temperature 65°F -86°F (18°C -30°C).

1. Remove the test strip from the foil pouch by tearing at the notch and use it as soon as possible. For best results, the test should be performed within one hour.
2. Hold the end of the strip where the product name (FTY) is printed. Holding the strip vertically, dip the absorbent end into the liquid close to the MAX Marker Line for at least 15 seconds or until you start to see liquid migrating upwards.
3. Remove the strip from the sample and lay it flat on a clean, dry, non-absorbent surface.
4. Read the result at 5 minutes. **Do not read results after more than 5 minutes.**

IMPORTANT: Do not allow the liquid level to exceed the MAX Marker Line, otherwise the test will not perform correctly.



Note: Results after more than 5 minutes may be not accurate and should not be read.

INTERPRETATION OF RESULTS

Preliminary positive (+)

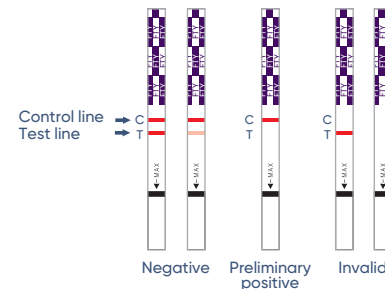
One colored band should appear. A band is visible in the Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates that the drug concentration is above the detection limit of the test.

Negative (-)

Two colored bands appear. One band is visible in the Control Region (C) and another band appears in the Test Region (T). It indicates that the drug is not present in the specimen or the concentration of the drug is below the detection limit of the test.

Invalid

If a colored band is not visible in the Control Region (C) or a colored band is only visible in the Test Region (T), the test is invalid. Another test should be run to re-evaluate the specimen. If the new test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number of the test.



Note: Even if the test result is negative, take caution as test strips might not detect all potent fentanyl-related drugs, like Carfentanyl.

The colored band intensity in the Test Region (T) may vary depending on the concentration of analytes present in the sample. Therefore, any faint distinguishable color band at the test region should be considered negative. Please note that this is only a qualitative test and cannot determine the concentration of Fentanyl in the sample.

What is the False Positive Test?

The definition of the false positive test would be an instance where a substance is identified incorrectly by SAFElife™ Fentanyl (FTY) Liquid & Powder Drug Test Strip. The most common cause of a false positive test is cross reactivity. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What is the False Negative Test?

The definition of the false Negative test is that the initial Fentanyl is present but isn't detected by SAFElife™ Fentanyl (FTY) Liquid & Powder Drug Test Strip. If the specimen is diluted, or the specimen is adulterated that may cause false negative result.

TEST LIMITATIONS

1. The SAFElife™ Fentanyl (FTY) Liquid & Powder Drug Test Strip is for forensic use, and provides only a qualitative, preliminary results for the detection of Fentanyl.
2. The possibility exists that substances and factors not described in this directional insert may interfere with the test, causing false results (e.g. technical or procedural error).
3. A positive result indicates the detection of Fentanyl only. It is not designed to determine the quantitative concentration of the drug or the level of intoxication.
4. This test does not distinguish between Fentanyl, Fentanyl Analogs, and certain medications.
5. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drug or the level of intoxication.

SUMMARY

Fentanyl (FTY) is a potent, synthetic opioid analgesic with a rapid onset and short duration of action. Fentanyl is approximately 50 times stronger than heroin and 100 times stronger than morphine. It has become a major contributing factor to fatal and nonfatal overdoses in the U.S. Although fentanyl and some analogs are used clinically for severe pain, especially after surgery and for advanced-stage cancer, most fentanyl-related overdose death cases are linked to illegal drug markets for its heroin-like effect. In response to fentanyl crisis, highly sensitive screening methods are needed to detect low concentrations of fentanyl or its metabolite.

PRINCIPLE

The SAFElife™ Fentanyl (FTY) Liquid & Powder Drug Test Strip is a competitive immunoassay that is used to screen for the presence of Fentanyl in samples. It is chromatographic absorbent device in which Fentanyl and its structure-similar Fentanyl analogs in a specimen competitively combined to a limited number of anti-Fentanyl monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end of the test device is immersed into the liquid samples, the liquid is absorbed into the device by capillary action, mixes with the Fentanyl monoclonal antibody conjugate, and flows across the pre-coated membrane. When specimen drug levels are zero or below the target cut-off level (the detection sensitivity of the test), anti-Fentanyl monoclonal antibody (mouse) conjugate binds to the Fentanyl-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored band that, regardless of its intensity, indicates a negative result. When specimen drug levels are at or above the target cutoff, the drug in the specimen binds to the anti-Fentanyl monoclonal antibody conjugate preventing the anti-Fentanyl monoclonal antibody conjugate from binding to the Fentanyl-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored band will appear at the Control Region (C), where the goat anti-rabbit IgG polyclonal antibody immobilized in, if the test has been performed properly.

QUALITY CONTROL

Internal procedural controls are included in the test strip. A colored band appearing in the Control Region (C) is considered as a procedural control. It confirms sufficient specimen volumes and adequate membrane wicking.

Use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of tests received, each new shipment and each new operator to determine that tests are working properly.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The analytical sensitivity study was carried out using commercially standard solution of Fentanyl. A drug-free water pool was spiked with Fentanyl at concentration listed. The cut-off level of Fentanyl was determined at 10 ng/mL. The results are listed in the following table.

Fentanyl Conc. (ng/mL)	Number of Tests	Test Results	
		Neg (-)	Pos (+)
0	20	20	0
5	20	20	0
7.5	20	20	0
10	20	0	20
15	20	0	20

Precision

Test precision was determined by blind tests with control solutions. Controls with Fentanyl at 50% of the cut-off level (5 ng/mL) yielded negative results, and controls with fentanyl at 150% of the cut-off level (15 ng/mL) yielded positive results.

Analytical Specificity and Inclusivity

The following table lists the concentrations of FTY related drugs (ng/mL) that were detected positive in water by the SAFElife™ Fentanyl (FTY) Liquid & Powder Drug Test Strip at 5 minutes.

FTY related drugs	Concentration (ng/ml)
Acryl fentanyl	20
Cyclopropyl fentanyl	20
Methoxyacetyl fentanyl	20
Norfentanyl	20
p-Fluorofentanyl	20
Butyryl fentanyl	30
Furanyl fentanyl	30
Isobutyryl fentanyl	50
4-Fluoro-isobutyryl fentanyl	50
para-Fluorobutyryl fentanyl (PFBF)	100
Acetyl fentanyl	250
(±)-cis-3-Methylfentanyl	750
Valeryl fentanyl	1,200
Ocfentanil	3,000
o-Fluorofentanyl	15,000
Remifentanil	20,000

Note: Alfentanil, 4-ANPP, Carfentanil, and Sufentanil at up to 100 µg/mL were NOT detected by the SAFElife™ Fentanyl (FTY) Liquid & Powder Drug Test Strip.

Interference

All potential interferents were added at the concentration of 100 µg/mL. None of the samples showed any deviation from the expected results.

4-Acetamidophenol	(-)Isoproterenol
Acetylsalicylic acid	JWH-018 5-Pentanoic acid
Alprazolam	Metabolite
(±)-Amphetamine	Levamisole
Amobarbital	(±)-MDA
Atropine	Methylenedioxymethamphetamine
Benzoyllecgonine	Meprobamate
Brompheniramine maleate	S(+)-Methamphetamine
Buprenorphine	Methylphenidate HCl
Caffeine	Methadone
Chlordiazepoxide	Morphine
Chloroquine diphosphate	Nalorphine HCl
cis-Tramadol	Naloxone
Clomipramine HCl	Naltrexone
Clonidine	Naproxen
Cotinine	Norcodeine
Cocaine	Norephedrine
Codeine	Noscapine HCl
Cortisone	Octopamine
Creatinine	Oxazepam
Dextromethorphan	Oxycodone
Diazepam	Papaverine HCl
Ephedrine	Phencyclidine
Ethyl-β-D-glucuronide	Pentazocine
1S,2R(+)-Ephedrine HCl	Pentobarbital
Heroin	Phenobarbital
3-Hydroxytyramine	Phentermine

Prednisolone
Secobarbital
Temazepam
Tetrahydrocannabinol
Tramadol

L-Thyroxine
L-Tryptophan
Vitamin B3
WH-073 4-Butanoic acid metabolite

ASSISTANCE

If you have any question regarding the use of this product, please call our Toll Free Number 1-888-444-3657 (9:30 a.m. to 5:00 p.m. CDT M-F).

BIBLIOGRAPHY OF SUGGESTED READING

- Wilson N, Kariisa M, Seth P, Smith H IV, Davis NL. Drug and Opioid-Involved Overdose Deaths – United States, 2017–2018. MMWR Morb Mortal Wkly Rep 2020 (69): 290–297.
- Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986.
- Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
- Poklis, A. (1995) Fentanyl: a review for clinical and analytical toxicologists. Journal of Toxicology Clinical Toxicology, 33, 439–447.
- Drug Enforcement Administration (DEA), Department of Justice. (2010) Control of immediate precursor used in the illicit manufacture of fentanyl as a schedule II controlled substance. Final rule. Federal Register, 75, 37295–37299.

ADDITIONAL INFORMATION AND RESOURCES

- The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.
- National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686
- Center for Substance Abuse Treatment www.health.org 1-800-662-HELP
- The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL
- American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG.

INDEX OF SYMBOLS

	Keep away from sunlight
	Store between 36°F–86°F (2°C–30°C)
	Keep dry
	Do not re-use
	Consult instructions for use

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