June 2024

BTNX Rapid Response™ Fentanyl 2.0 Test Strip

200 ng/mL

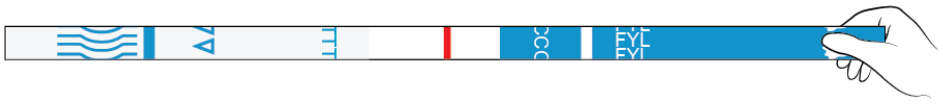
Introduction

Fentanyl is a synthetic opioid related to phenylpiperidines, initially being developed for use as an analgesic and anesthetic. It is now most commonly used for moderate to severe pain relief in health care settings, with its potency being approximately 100 times that of morphine and 50 times that of heroin. In the 2010s, fentanyl became increasingly found in the illicit opioid supply and has since become a mainstay in the supply. The presence of fentanyl and its use in unregulated settings pose significant concerns due to the drug's high potency, as even miniscule amounts of fentanyl can cause an overdose. The CDC has reported an increasing trend of opioid-related overdoses correlating to the rise of fentanyl and fentanyl-related analogues in the illicit drug supply. Fentanyl is currently listed as a Schedule II narcotic, while fentanyl-related analogues are currently listed as Schedule I narcotics by the US DEA.

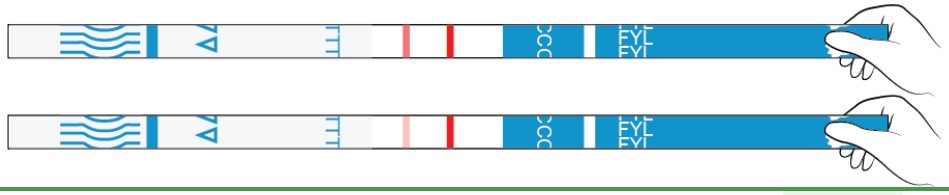
Several modifications have been applied to the chemical structure of fentanyl, namely to the carbonyl group and benzene rings, resulting in a series of fentanyl analogues. Many of these analogues have similar potencies to fentanyl, however, in some cases, the modifications result in compounds with significantly heightened potency (e.g., carfentanil).

The **Rapid Response™ Fentanyl 2.0 Test Strip** from BTNX is specifically designed for the swift screening of fentanyl and fentanyl analogues in liquid/powder samples. The test incorporates an antibody that selectively identifies fentanyl and fentanyl analogues from other substances. Like other harm reduction test strips, it operates on a competitive binding principle and generates a colorimetric result. If any of the listed fentanyl substances are present in the sample at a concentration surpassing the designated cut-off, a singular-colored line will appear in the test.

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.



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Test Performance – What has been Improved?

BTNX is committed to maintaining a high level of efficacy and consistency with all its products. Since the beginning of 2023, additional efforts have been made to ensure the original Rapid Response™ Fentanyl Test Strip continues to perform to its specifications, allowing users to be confident in the results they obtain. Building on this foundation the Rapid Response™ Fentanyl 2.0 Test Strip uses the latest improvements in lateral flow testing to consistently maintain the same level of detection for fentanyl and its analogues while decreasing the cross reactivity with non-fentanyl related compounds.

Fentanyl 2.0 Test Strip vs Fentanyl Test Strip

Analytical Sensitivity

The following compounds were spiked into water, respectively, to compare the Rapid Response™ Fentanyl Test Strip (FYL 1.0 Test Strip) and **Rapid Response™ Fentanyl 2.0 Test Strip** (FYL 2.0 Test Strip)for detecting fentanyl and fentanyl-related analogues. The cut-off 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 and fentanyl analogues that are detected below 100 µg/mL		
Compounds	**FYL 1.0 Test Strip**	**FYL 2.0 Test Strip**
Fentanyl	200 ng/mL	200 ng/mL
Acetyl Fentanyl	150 ng/mL	150 ng/mL
Butyryl Fentanyl	700 ng/mL	700 ng/mL
Carfentanil	5000 ng/mL	5000 ng/mL*
p-Fluoro Fentanyl	200 ng/mL	500 ng/mL
Furanyl Fentanyl	500 ng/mL	500 ng/mL
Ocfentanil	250 ng/ml	500 ng/mL
Valeryl Fentanyl	700 ng/ml	1000ng/mL

*The FYL 2.0 test strip reacts with Carfentanil to give an extremely faint line above the concentrations of 5000 ng/mL.

Analytical Specificity

The following compounds were spiked into water to examine possible cross-reactivity for the two versions of the FYL test strips. Significant improvements were found for most of the compounds with the FYL 2.0 Test Strip. Most fentanyl strips on the market cross-react with diphenhydramine, which is a very common cutting agent.[1] FYL2.0 is the first fentanyl test strip designed to address this issue.

Compound	Concentration	FYL 1.0	FYL 2.0
Methamphetamine	5 mg/mL	Negative	Negative
MDMA	5 mg/mL	False Positive	**Negative**
Diphenhydramine	5 mg/mL	False Positive	**Negative**
Lidocaine	5 mg/mL	False Positive	**Negative**
Levamisole	5 mg/mL	Negative	Negative
Methadone	5 mg/mL	False Positive	**Negative**
Heroin	3 mg/mL	Negative	Negative
Morphine	5 mg/mL	Negative	Negative
Codeine	5 mg/mL	False Positive	**Negative**
Quinine	5 mg/mL	Negative	Negative

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References

1. Lieberman, M. (n.d.). *FTS lot characteristics public facing draft*. Google Docs. https://tinyurl.com/LotResults