INTENDED USE

The One Step Fentanyl Substance Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of Fentanyl in substances at the following cut-off concentration:

TEST	CALIBRATOR	CUT-OFF
Fentanyl (FEN)	Fentanyl	10 ng/mL

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (CC/MS) or Liquid chromatography/mass spectrometry (LC/MS) is the preferred confirmatory method. Apply clinical and professional judgment to fentanyl test result, particularly when a preliminary positive result is obtained. This fentanyl substance test is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of fentanyl in substances without the use of an instrument. The fentanyl assay contained within this fentanyl substance test yields a positive result when the concentration of fentanyl in substances exceeds 10 ng/ml.

This fentanyl substance test is an immunoassay based on the principle of competitive binding. A drug which may be present in the substance being tested competes against it's respective drug conjugate for binding sites on its specific antibody. During testing, the substance migrates upward by capillary action. If the fentanyl content is below the cut-off concentration, it will not saturate the binding sites of it's specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip.

The presence of fentanyl above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test the region. A drug-positive substances will not generate a colored line in the specific test line region of the strip because of drug competition, whereas a drug-negative substance specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Limitations:

- Do not use beyond the expiration date.
- The test device should remain in the sealed pouch until use.
- The test is for single use.
- While substances are not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood, the use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test device and substances should be discarded according to federal, state, and local regulations.

Store as packaged in the sealed pouch at 4-30°C (39-86° F). The test is stable up to the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Allow the substance to come to room temperature [15-30°C (59- 86°F)] prior to testing.

DO NOT FREEZE.

SUBSTANCES ASSAY

If the substance you are testing is in liquid form proceed to the Step 1 (see directions). If the substance you are testing is in powder form, place 1 micro scoop (included in kit) of the substance into the liquid vial buffer and mix well, then proceed to Step 1 (see directions). If the substance you are testing is in pill format, crush or scrape some of the pill, place 1 micro scoop (included in kit) of the crushed substance into the liquid vial buffer and mix well, then proceed to Step 1 (see directions).

Materials Provided:
• Test device • Liquid vial • Micro scoop • Package insert

Materials Not Provided:
• Timer • Disposable gloves

Directions:

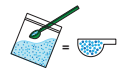
1. Remove the test device from its foil pouch (bring the container to room temperature before opening to avoid condensation of moisture in container).

2. Add one scoop (10 mg) of pill/powder substance to the 1 ml buffer vial of deionized water. Allow the substance to dissolve in the solution (2a, 2b).

3. Using the specimen dropper on the buffer vial, withdraw the substance sample from the specimen container and slowly dispense 3 drops (approximately 120 µL) into the circular sample well, being careful not to overfill the absorbent pad (3).

4. Read the result at 3 minutes. DO NOT READ RESULT AFTER 10 MINUTES.

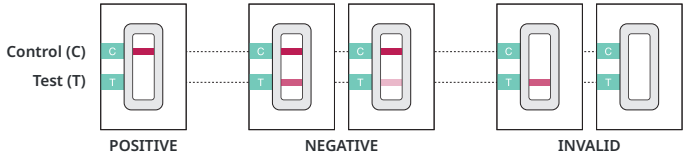
(2a)



(2b)

(3)

Interpreting the Results:



Interpreting the Results continued on back page.

NEGATIVE: Two lines appear. One color line should be in the control region (C) and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.
*NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative when there is even a faint distinguishable color line.

POSITIVE: One color line appears in the control region (C). No line appears in the test region (T). The positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons from control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your supplier.

Quality Control:
The control line is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

1. There is a possibility that technical or procedural errors, as well as other interfering substances in the sample may cause erroneous results.
2. A negative result may not necessarily indicate drug-free substances. Negative results can be obtained when the drug is present but below the cut-off level of the test.
3. Test does not distinguish between substances and certain medication.
4. A positive test result may be obtained from certain foods or food supplements.

A Negative Result Does Not Guarantee the Substance is Safe to Use.

FOR EXTERNAL USE ONLY. NOT FOR CONSUMPTION.

Samples of normal, high, and low specific gravity ranges from 1.000 - 1.025 were spiked with drug at 50% below and 50% above cut-off levels respectively and tested using One Step Fentanyl Substance Test. The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test.

The pH of an aliquoted negative pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0, and 9.0 and spiked with drug at 50% below and 50% above cut-off levels. The spiked, pH adjusted pool was tested with the One Step Fentanyl Substance Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Improper use may lead to inaccurate results. The manufacturer and distributors disclaim any liability for misuse, misinterpretation, or reliance on the information provided by the test strip. The user assumes all risk associated with their use. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Reproducibility:
Reproducibility studies were carried out using commercially available stock solutions of the drug analytes listed. The results are listed in the following table.

FENTANYL CONCENTRATION (ng/mL)	TOTAL NUMBER OF DETERMINATIONS	RESULT	PRECISION
No Drugs Present	60	60 negative	>99%
5	60	60 negative	>99%
15	60	60 positive	>99%

Analytical Sensitivity:
A drug-free pool was spiked with drug at concentrations listed. The results are summarized below.

DRUG CONCENTRATION CUT-OFF RANGE	n	FEN	
		-	+
0% Cut-Off	30	30	0
-50% Cut-Off	30	30	0
-25% Cut-Off	30	30	0
Cut-Off	30	3	27
+25% Cut-Off	30	0	30
+50% Cut-Off	30	0	30

Analytical Specificity:
The following table lists the concentration of compounds (ng/mL) that were detected positive in substance by the One Step Fentanyl Substance Test at a read time of 5 minutes.

DRUG	CONCENTRATION (ng/mL)
Fentanyl	20
Valeryl fentanyl HCL	5,000
Butyryl fentanyl	50
Furanyl fentanyl HCL	250
Nor fentanyl oxalate	25
Ocfentanil	5,000
Para-Fluorofentanyl	25
(+)-cis-3-Melhylfenlanyl HCL	250
Acetyl fentanyl	1,000