

CLIA Waived User Instruction

【INTENDED USE】

Identify Fentanyl Urine Test Cassette is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Fentanyl in human urine at the cutoff concentrations of 1 ng/mL.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. For *in vitro* diagnostic use only.

【WARNINGS AND PRECAUTIONS】

- Read the entire user Instructions prior to performing test.
- For *in vitro* diagnostic use only.
- For external use only.
- Do not use the test after expiration date printed on the package.
- Do not use the test if its foil pouch is torn or damaged.
- For single use. Discard after first use
- The test device should remain in the sealed pouch until use.
- Contaminated or tainted urine sample may give false results.
- Keep out of reach of children.

【ITEMS PROVIDED】

- Test cassette and dropper (sealed in foil pouch with a desiccant)
- User Instruction

【ITEMS REQUIRED BUT NOT PROVIDED】

- Watch, clock or timer
- Urine collection cup

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 35.6-86°F (2-30°C) up to the date of expiration. **Keep away from direct sunlight, moisture and heat.** DO NOT FREEZE.

【TEST PROCEDURE】

Allow the test to reach room temperature before testing.

Wash your hands thoroughly.

Step 1: Collect Urine Sample

- Collect urine in a clean and dry container.

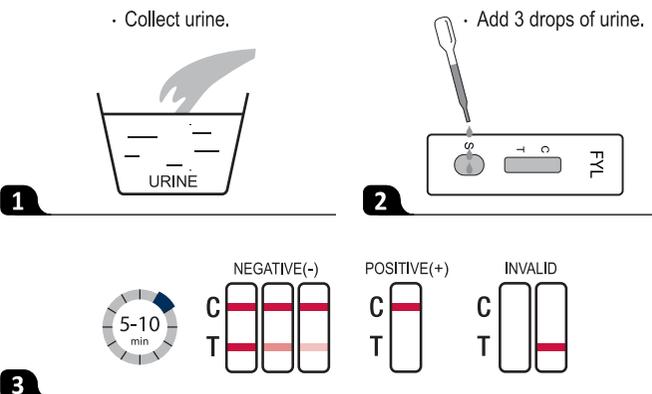
Step 2: Testing

- Open the foil pouch, remove the test cassette and dropper, discard the desiccant.
- Place the test cassette on a clean and level surface.
- Hold the dropper vertically and transfer **3 full drops of urine** to the specimen well next to the letter “S” on the test cassette **Do not spill urine into the test window.**
- Start a timer.

Step 3: Read Results

- **Read the test results at 5 minutes**, do not read results after 10 minutes.

TEST PROCEDURE



【READ THE RESULTS】

	<p>NEGATIVE: Two colored lines appear. One line appears next to the letter 'C' and the other line appears next to the letter 'T'.</p>
	<p>POSITIVE: Only one colored line appears next to the letter 'C'. No colored line appears next to the letter 'T'</p>
	<p>INVALID: Control line fails to appear.</p>

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to confirm the result.

【Q&A】

1. How do I know if the Test worked well?

When the control line(C) appears, it means that the test unit is working well.

2. How soon can I read test results?

You can read test results after 5 minutes as long as a red line or pink colored line has appeared next to the Control region(C), do not read results after 10 minutes.

3. When is the best time to run the test?

You can run the test at any time of the day.

4. How to read the test if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The test should be considered as negative whatever the color intensity of the test line (T) is.

5. What is A False Positive Test?

A false positive test result means the drug is not present but shows detected by the device. The most common causes of a false positive test are cross reactants.

6. What is A False Negative Test?

A false negative test means the drug is present but is not detected by the device. If the sample is diluted, or the sample is contaminated that may cause a false negative result.

【LIMITATIONS】

1. The Test is for use with human urine only.
2. The Test provides only a preliminary result.
3. Substances, such as bleach and/or alum, in urine specimens may produce incorrect results. If adulteration is suspected, the test should be repeated with another urine specimen.
4. Test does not distinguish between drugs of abuse and certain medications.
5. A positive test result may be obtained from certain foods or food supplements.

IMPORTANT: By itself, this test will not confirm if someone used a drug of abuse. These types of tests may incorrectly detect the presence of a drug of abuse when the person has consumed certain foods, medicines, diet plan drugs, or nutritional supplements. These are just some examples of the types of things that can cause a false result and there may be others as well. In order to show if someone used a drug of abuse, you will need to send the urine sample to a laboratory to have a second test, called a confirmation test, performed. The cost of the additional testing is not included in the purchase price of this screening test kit.

【ADDITIONAL INFORMATION AND REFERENCES】

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
1-800-729-6686

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

Manufactured for:

Identify Diagnostics / Medical Distribution Group, Inc.
2361 Whitfield Park Avenue. Sarasota, FL 34243
Hours of operation: Monday - Friday 9am - 4pm (EST)
1-727-744-2967 IdentifyDiagnostics.com

Number: 14601879600

Revision date: 2023-11-01