



GenaCheck™ Fentanyl Urine Home-Use Test Cassette

Instructions For Use

Intended Use

GenaCheck™ Fentanyl Urine Home-Use Test Cassette is competitive binding, lateral flow immunochromatographic assay for qualitative detection of Fentanyl in human urine at the cut-off 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)
- Instructions for Use
- Pre-addressed mailing box for shipping samples for confirmatory testing.
- Plastic transportation bag
- Identification label (with bar code).

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.

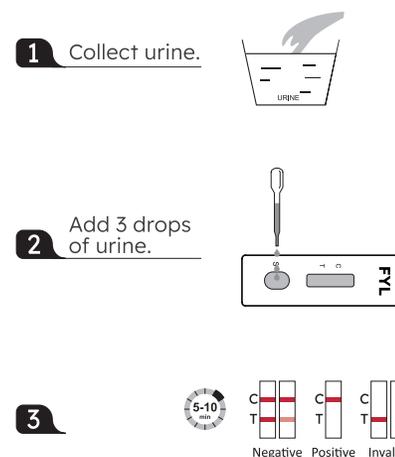
Step 2: Testing

- 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.

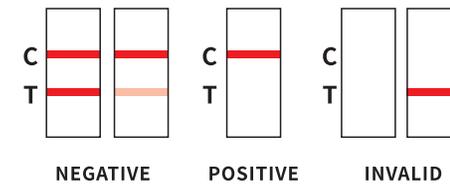
Step 3: Read Results

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

TEST PROCEDURE



Read The Results



NEGATIVE: Two colored lines appear.

One line appears next to the letter ‘C’ and the other line appears next to the letter ‘T’.

POSITIVE: Only one colored line appears next to the letter ‘C’.

No colored line appears next to the letter ‘T’

INVALID: Control line fails to appear.

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

Q. How do I know if the test worked well?

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

Q. How soon can I read my results?

A: You can read your 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.

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

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

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

A: 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.

Q. What is a false positive test?

A: 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.

Q. What is a false negative test?

A: 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

- The test is for use with human urine only.
- The test provides only a preliminary result.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

Mailing A Urine Sample To The Laboratory For Confidential Confirmation Testing

- Attach the Identification label (with bar code) to the collection cup. Ensure that the labeled cup is tightly closed.
- Place the labeled cup in the plastic bag and seal the plastic bag and place into the mailing box.
- Close the pre-addressed mailing box and

secure it with packing tape. The mailing address for the laboratory is already on the mailing box.

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.

The mailing box is pre-addressed for shipping samples for confirmation testing. Results will be ready within 7 days after we receive your sample in our laboratory.

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**

Index Of Symbols

	Do Not Re-use		Consult Instructions For Use
	Test Per Kit		Store At 2-30°C (36-86°F)
	Batch Number		Catalog #
	Unique Device Identifier		For <i>in vitro</i> diagnostic Use Only
	Expiration Date		Keep Away From Sunlight
	Keep Dry		Do Not Use If Package Is Damaged And Consult Instructions For Use

Assistance

For questions or comments please call [Genabio Customer Service at 1-800-614-3365 \(9:00-17:00 EST\)](tel:1-800-614-3365).

Manufactured For Genabio Diagnostics Inc.

Address: 19 Crosby Dr., Ste 220, Bedford, MA 01730, USA
Phone: 1-800-614-3365
Hours of Operation: 9:00-17:00 EST
Email: info@genabio.com
Website: www.genabio.com
Document No.: RA9-U02501
Rev. 00
Effective Date: March 1, 2024