 **REF** FYL-1CAH156-1 **REF** FYL-1CAH156-5 **REF** FYL-1CAH156-25

Rapid Response™

At-Home Fentanyl Test Cassette

User Instruction

For *in vitro* Diagnostic Use Only.

Unfold leaflet and flip this sheet over for instructions.

Intended Use

The Rapid Response™ At-Home Fentanyl 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.

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.

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.**

Items Provided

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

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 my results?

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.

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 and certain medications.
5. A positive test result may be obtained from certain foods or food supplements.

Mailing a Urine Sample To The Laboratory For Confidential Confirmation Testing

1. Attach the Identification Label (with bar code) to the collection cup. Ensure that the Labeled cup is tightly closed.
2. Place the Labeled cup in the plastic bag. Seal the plastic bag and place into the mailing box.
3. 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 drugs. These types of tests may incorrectly detect the presence of a drug 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 drugs, 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. You can retrieve your test results during our normal business hours via phone (877-466-3837).

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

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Allow the test to reach room temperature (59-86°F; 15-30°C) before testing.

Step 1: Collect Urine Sample

Wash your hands thoroughly.

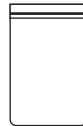


Unpack the test components from the kit and make sure that all the packaging is intact.

For each test you will need:



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



Plastic transportation bag



User Instruction
(This Document)



Urine collection cup
(Not provided)



Stopwatch or Timer
(Not provided)

Collect urine in a clean and dry container.

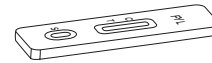


Step 2: Testing

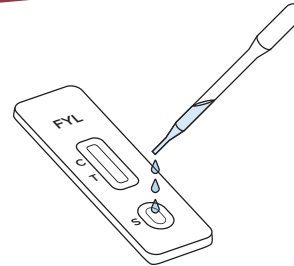
Open the foil pouch, remove the test cassette and dropper, discard the desiccant.



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.

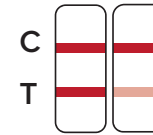


Results Interpretation



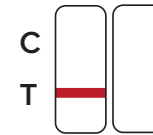
POSITIVE:

Only one colored line appears next to the letter 'C'. No colored line appears next to the letter 'T'.



NEGATIVE:

One line appears next to the letter 'C' and the other 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.

Glossary of Symbols



Consult instructions for use



Test per Kit



Catalogue number



Store between 35.6-86°F (2-30°C)



Use by date



Do Not Reuse



In vitro diagnostic medical device



Lot Number



Manufacturer



Do not use if package is damaged



BTNX, Inc.
722 Rosebank Road
Pickering, ON, L1W 4B2, Canada
Technical Support: 1-888-339-9964
Hours: 9:00 AM - 5:00 PM (EST)

