



TOXICOLOGY

FENTANYL SCREENING DEVICE

iCassette™ Urine Test Dx Drug Screen Cassette

January 2024

Overview

The information in this presentation is a general overview on performing and interpreting the iCassette™ Urine Test Dx Drug Screening device.

PRODUCT TRAINING CONTENTS

- Technical Information
- Product Overview
- Specimen Collection and Testing Procedures
- Interpretation of Results
- Additional Support Services

Technical Information

FOR COMPLETE INSTRUCTIONS, LIMITATIONS AND WARNINGS, PLEASE REFER TO THE PACKAGE INSERT (INSTRUCTIONS FOR USE) BEFORE USING THIS SCREENING DEVICE

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

Gaschromatography-mass spectrometry or Liquid Chromotography with Mass Spectrometry is the preferred confirmatory method.

For *in vitro* diagnostic use only

iCASSETTE™ URINE TEST Dx DRUG SCREEN CASSETTE

Product Overview

Overview

FEATURES AND BENEFITS

- CLIA waived
- Single-use 1.0 ng/mL
- Results available at 5 minutes

TEST DEVICE COMPONENTS



Abbreviations and Cutoff Level Concentrations

DRUG	CUTOFF (ng/mL)
FTY (Fentanyl)	1

Precautions, Storage and Stability

PRECAUTIONS

- Do not use the test after the expiration date printed on the package.
- Do not use the test if the foil pouch is torn or damaged
- For single use. Discard after first use.
- The test device should remain in the sealed pouch until use.

STORAGE AND STABILITY

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

iCASSETTE™ URINE TEST Dx DRUG SCREEN CASSETTE

Performing a Urine Drug Screen

Specimen Collection and Preparation

- Allow the test to reach room temperature before testing.
- Wash your hands thoroughly.

Gather all the Necessary Testing Supplies

MATERIALS PROVIDED

- One (1) test cassette and dropper (sealed in foil pouch with a desiccant)
- User instructions
- Procedure card

REQUIRED BUT NOT PROVIDED

- Watch, clock or timer
- Urine collection cup

Foil Pouch with Device

- Do not use beyond expiration date.
- Do not use if the pouch is punctured or not sealed.



DO NOT USE BEYOND THE EXPIRATION DATE.

iCASSETTE™ URINE TEST Dx DRUG SCREEN

Interpretation of Results

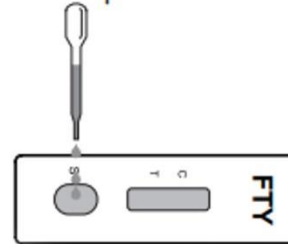
How to Perform the Test

1. Collect urine in a clean and dry container.
2. 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.
3. Read the results at 5 minutes, do not read results after 10 minutes.

· Collect urine.



· Add 3 drops of urine.

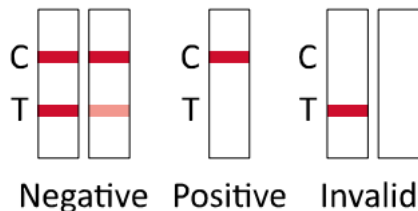


INTERPRETATION OF RESULTS

Reading Drug Test Results

INTERPRETING DRUG TEST RESULTS

Read results at 5 minutes. Do not read results after 10 minutes.



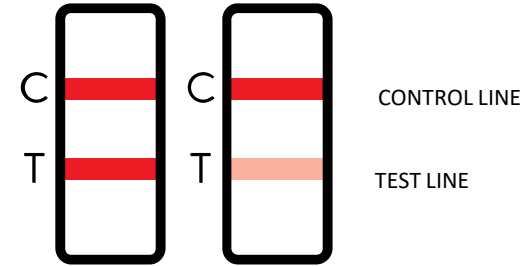
CONFIRM VALIDITY OF RESULTS BY CHECKING NEG AND POS CONTROL REGIONS

NOTE: 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.

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

Negative Test Results

- A line **must appear** next to the negative control region (NEG) and **no lines appear** next to the positive control region (POS).
- A false positive test result means the drug is not present but shows detected by the device. The most common cause of a false positive test are cross reactants.
- A false negative result means the drug present is not detected by the device. If the sample is diluted, or the sample is contaminated that may cause a false negative result.



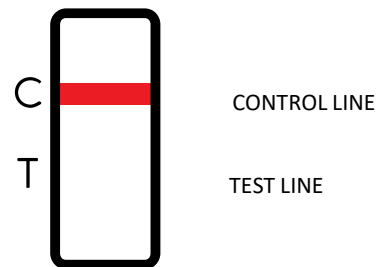
NEGATIVE RESULTS

Line present in both
Control and Test Regions

INTERPRETATION OF RESULTS

Preliminary Positive Results

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



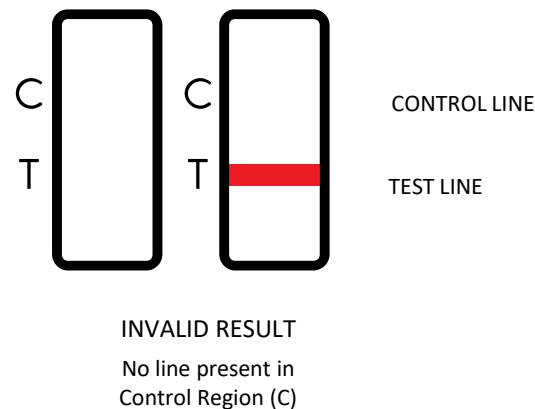
PRELIMINARY
POSITIVE RESULT
No line present in
Test Region (T)

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.

INTERPRETATION OF RESULTS

Invalid Test Results

- If a colored band is not visible in the control region, the test is invalid.
- Another test should be run to re-evaluate the specimen. If test still fails, please contact your Toxicology representative.
- When calling be sure to provide the lot number and the catalog number of the test.



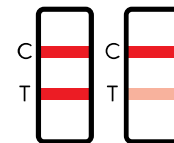
INTERPRETATION OF RESULTS

Summary

NEGATIVE

The control line must be colored to indicate the test is valid.

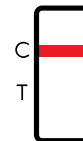
Any visible line next to the letter T, indicates a negative result.



PRELIMINARY POSITIVE

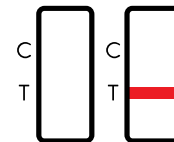
The control line must be colored to indicate the test is valid.

No line next to the letter T, indicates a positive result.



INVALID

If a colored band is not visible in the control region, the test is invalid.



Congratulations!

You have completed the training course.

CLOSE WINDOW TO ACCESS QUIZ

You can now take a quiz with questions that represent hypothetical situations for you to analyze. You need to score 100% to pass and receive your Certificate of Completion. Take the quiz as many times as you like to pass. Helpful tips are available for incorrect answers.

For additional information or assistance with this device contact your Toxicology representative.

Technical Assistance

It is recommended that external positive and negative controls be tested with each new lot or shipment of product, and as otherwise required by your laboratory's internal quality system procedures.

Questions? Contact your Abbott sales representative for any inquiries.



Abbott