

One Step[®] NICOTINE Rapid Urine Test Strips

User Instructions - For Self-testing

A rapid test for the qualitative detection of Cotinine in human urine.

For self-testing in vitro diagnostic use only.

INTENDED USE

The One Step Nicotine Rapid Urine Test Strips are competitive binding, lateral flow immunochromatographic assay for qualitative detection of Cotinine in human urine at the cutoff concentrations of 30 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.

WARNING

Read the entire information prior to performing the test.

The Nicotine Rapid Urine Test Strips provides only preliminary results and any urine with preliminary positive result is recommended to send it to a laboratory for confirmation.

Have a watch, clock or timer available.

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.

The test is for one time use only, do not reuse the test.

Certain foods or medications may cause the test to give false results.

Contaminated or tainted urine samples may give false results.

Keep out of reach of children.

SUMMARY

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.¹ While cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.² Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 30 ng/mL is expected to be up to 2-3 days after nicotine use.

The Nicotine Rapid Urine Test Strips are a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Cotinine in urine. The Nicotine Rapid Urine Test Strips yield a positive result when the Cotinine in urine exceeds 30 ng/mL.

PRECAUTIONS

- Read the entire user instructions prior to performing the test.
- For self-testing in vitro diagnostic use.
- 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 samples may give false results.
- Keep out of reach of children.

MATERIALS PROVIDED

- Drug Test Strips (sealed in foil pouch with a desiccant)
- Single use Urine Sample Cups
- User Instructions

MATERIALS REQUIRED BUT NOT PROVIDED

- Watch, clock or timer

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.**

DIRECTIONS FOR USE

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 strip, discard the desiccant.
- With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine for at least 10-15 seconds.

Note: Do not pass the maximum line (MAX) on the Test Strip when immersing in the strip.

- Place the test strip on a non-absorbent flat surface.
- Start the timer.

Step 3: Read Results

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

TEST PROCEDURE

1. Immerse 10-15 seconds
• Do not immerse past the max line

2. Sumergir 10-15 segundos
• No sumergir más allá de la línea máxima

3. Read Result at 5 minutes
• Leer resultado a los 5 minutos

Max Line
Línea máxima

Reading Result
Resultado de lectura

Negative
Negativo

Positive
Positivo

Invalid
Inválido

INTERPRETATION OF 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 the laboratory in order to confirm the result.

Detection Items, Levels and Approximate Detection Times

Drug Name (Abbreviation)	Detectable Level (ng/mL)	Minimum Detection Time*	Maximum Detection Time*
Cotinine (COT)	30	4-6 hours	3-5 days

* **NOTE:** The times are only estimates.

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 only provides 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.

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Edition. Biomedical Publications, Foster City, CA. 2002; 744-747
2. Hardman JG, Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

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