Reditest® Smoke Cassette cotinine screening device

URINE COTININE SCREEN PROCEDURE
The information in this presentation is a general overview on using the Reditest® Smoke Cassette cotinine screening device.

PRODUCT TRAINING CONTENTS

• REDITEST® SMOKE CASSETTE OVERVIEW
• COLLECTION PROCEDURE
• TESTING PROCEDURE
• INTERPRETATION OF RESULTS
• SENDING PRELIMINARY POSITIVES FOR CONFIRMATION
Technical information

IT IS IMPORTANT TO READ THE PACKAGE INSERT BEFORE USING THE REDITEST® SMOKE CASSETTE COTININE SCREENING DEVICE.

Screening Results:
The Reditest® Smoke Cassette is a rapid, one step test for the qualitative detection of Cotinine (nicotine metabolite) in human urine, and is used for determination of smoking status only. Positive results obtained with this device are preliminary.

Additional testing is necessary to confirm the presumptive positive results. Positive results should be “confirmed” by an alternate method such as gas chromatography-mass spectrometry (GC-MS).

For professional in vitro diagnostic use only.
Product overview
Reditest® Smoke Cassette Overview

Now you can easily and quickly find out if they use cigarettes and other tobacco products. The Reditest® Smoke Cassette qualitatively detects Cotinine (nicotine metabolite) in a simple one-step urine test.

**FEATURES AND BENEFITS**

- Detects Cotinine, a Nicotine metabolite, in urine at 200 ng/mL
- Convenient to use and interpret
- Fast onsite results in 5 minutes
Precautions, storage, and stability

PRECAUTIONS:

• The device is for professional in vitro diagnostic use only. Do not use after the expiration date.

• The test device should remain in the sealed pouch until use.

• All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

• The used test device should be discarded according to local regulations.

DEVICE STORAGE AND STABILITY:

• Store as packaged in the sealed pouch at 36-86°F (2-30°C)

• The test devices are stable through the expiration date printed on the sealed pouch

• DO NOT FREEZE

• Do not use beyond the expiration date
### Abbreviations and cutoff level concentration

<table>
<thead>
<tr>
<th>DRUG</th>
<th>TARGET DRUG</th>
<th>CUTOFF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine</td>
<td>Cotinine</td>
<td>200ng/mL</td>
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Performing a urine continine screen
Performing a urine cotinine screen

SPECIMEN COLLECTION AND PREPARATION

• The urine specimen must be collected in a clean and dry container.

• Urine collected at any time of the day may be used.

• Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed settle to obtain a clear supernatant for testing.

• Allow test device, urine specimen to reach room temperature (15-30°C) prior to testing.

For further details, refer to the package insert under: Directions for Use.
Performing a urine cotinine screen

GATHER ALL NECESSARY TESTING SUPPLIES

Materials provided:
• 25 individually sealed test devices
• Droppers
• Package insert

Recommended but not provided:
• Timer
• Specimen collection container
Performing a urine cotinine screen

Collect urine specimen in a clean and dry collection container.

Fill the cup to at least 1/3 full. This helps ensure proper specimen volume for initial test and possible confirmation tests.
Performing a urine cotinine screen

SPECIMEN COLLECTION PROCEDURE

• Bring the pouch to room temperature before opening it.
• Place cassette on a flat surface.
• Hold the dropper vertically and transfer 3 full drops of urine to the specimen well (S) of the test device, and then start the timer.
• Avoid trapping air bubbles in the specimen well (S).
Interpretation of results
Interpreting test results

READING TEST RESULTS

• Interpret the test results at 5 minutes.
• Do not interpret the result after 10 minutes.
• The test strip in the device includes an internal procedural Control (C) ensuring proper device function.
• Control lines should form next to the C on the device.
Negative example

NEGATIVE TEST RESULTS

• The appearance of a line next to the Drug area and the C or control area indicates a negative test result.

• Any indication of a line regardless of color intensity is correctly interpreted as a negative test result.

• Discard test device according to federal, state and local regulations.

ANY INDICATION OF A COLORED LINE, REGARDLESS OF COLOR INTENSITY, IS CONSIDERED A NEGATIVE TEST RESULT.
Preliminary positive example

PRELIMINARY POSITIVE TEST RESULTS

• The absence of a line next to the Drug area indicates a preliminary positive test result.

• Example shows: preliminary positive test result for Nicotine.

The test device provides only a qualitative, preliminary analytical results. Gas chromatography-mass spectrometry (GC-MS) is the preferred confirmatory method.
Invalid example

INVALID TEST RESULTS

- The test strip within the device includes an internal procedural control (C) ensuring proper device function.
- Control lines should form on the test strip, indicating the test functioned properly.
- The absence of a control line on the test strip indicates the test is INVALID.
- Discard the test device.
- Perform another test with a new sample and a new device.
Interpreting test results (cont.)

NEGATIVE

The control line must be colored to indicate the test is valid. Any visible line, even a faint line, indicates a negative result.

PRELIMINARY POSITIVE

The control line must be colored to indicate the test is valid. The test area must be white to be considered positive.

Additional testing is necessary to confirm the preliminary positive results. Positive results should be “confirmed” by an alternate method such as GC-MS.

INVALID

When there is no line in the control line area, the result is invalid. If an invalid result is obtained repeat the test using a new test device.
Congratulations!
You have completed the training course.

CLOSE WINDOW TO ACCESS QUIZ

You can now take a quiz with 10 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 Technical Support at 877-444-0049.

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