Reditest® 6 Cassette
URINE DRUG SCREENING PROCEDURE

SELF-PACED TRAINING. DOES NOT CONTAIN AUDIO.
The information in this presentation is a general overview on performing and interpreting the RediTest® 6 Cassette urine drug screening device.

PRODUCT TRAINING CONTENTS

• TECHNICAL INFORMATION
• PRODUCT OVERVIEW
• SPECIMEN COLLECTION AND TESTING PROCEDURES
• INTERPRETATION OF RESULTS
• ADDITIONAL SUPPORT SERVICES
Technical information

IT IS IMPORTANT TO READ THE PACKAGE INSERT BEFORE USING THE REDITEST® 6 CASSETTE URINE SCREENING DEVICE.

Screening Results:
The CLIA waived Reditest® 6 Cassette is used for Screening Only. Positive results obtained with this device are preliminary. Additional testing is necessary to confirm the preliminary positive results. Positive results should be “confirmed” by an alternate method such as GC-MS (Gas chromatography-mass spectrometry) is the preferred confirmatory method.

Product categorized as CLIA-waived. Product may be used by laboratories with a CLIA Certificate of Waiver.

Professional judgment should be applied to any drug of abuse test result, particularly with preliminary positive results.

The Reditest® 6 Cassette screening device is a rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.
Product overview
Reditest® 6 Cassette Overview

FEATURES AND BENEFITS

• Available tests include: AMP, COC, THC, mAMP, OPI, and PCP
• Simple to use pipette and cassette
• Results in 5 minutes
• In vitro diagnostic device for U.S. market
• Product categorized as CLIA-waived
<table>
<thead>
<tr>
<th>DRUG</th>
<th>TARGET DRUG</th>
<th>CUTOFF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine (AMP1000)</td>
<td>d-Amphetamine</td>
<td>1,000 ng/mL</td>
</tr>
<tr>
<td>Cocaine (COC300)</td>
<td>Benzoylcegonine</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Marijuana (THC50)</td>
<td>11-nor-Δ9-THC-9 COOH</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Methamphetamine (mAMP)</td>
<td>d-Methamphetamine</td>
<td>1,000 ng/mL</td>
</tr>
<tr>
<td>Opiates (OPI2000)</td>
<td>Morphine</td>
<td>2,000 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PCP25)</td>
<td>Phencyclidine</td>
<td>25 ng/mL</td>
</tr>
</tbody>
</table>
Precautions, storage, and stability

PRECAUTIONS

• For healthcare professionals including professionals at point of care sites
• For in vitro diagnostic use only
• Do not use after the expiration date
• The test device should remain in the sealed pouch until use
• All samples should be considered potentially hazardous and handled in the same manner as an infectious agent
• The used test device should be discarded according to federal, state and local regulations

FOIL POUCH

Lists available tests, part number, lot number, storage temperature, and expiration date.
Precautions, storage, and stability

DEVICE STORAGE AND STABILITY

• Store packaged in the sealed pouch at 36-86°F (2-30°C)
• The test device is stable through the expiration date printed on the sealed pouch
• Test cards must remain in the sealed pouch until use
• DO NOT FREEZE
• Do not use beyond the expiration date
Performing a urine drug screen
Performing a urine drug screen

SPECIMEN STORAGE AND PREPARATION

• Urine specimens may be stored at 36-46°F (2-8°C) for up to 48 hours prior to testing.

• For prolonged storage, samples may be frozen and stored below -20°C. Frozen samples should be thawed and mixed well before testing.

Specimen storage temperature 48 hours prior to testing.
Performing a urine drug screen

GATHER ALL NECESSARY TESTING SUPPLIES

Materials provided

- 25 individually sealed test devices and disposable droppers
- Package insert

Recommended but not provided

- Sample collection container
- External Positive & Negative Controls
- Timer
Urine specimen collection

SPECIMEN COLLECTION PROCEDURE

• The urine sample must be collected in a clean and dry container.
• Urine collected at any time of the day may be used.
• Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

INSTRUCT DONOR ON PROPER SPECIMEN COLLECTION PROCESS.

FILL COLLECTION CUP AT LEAST 1/3 FULL.
Testing the specimen

TESTING PROCEDURE

The foil pouch contains the following information: list of drugs screened, part number and expiration date.

• Ensure expiration date printed on foil pouch is within range.

• Do not open pouch until ready to perform the test.

Allow test device, urine specimen, and/or controls to reach room temperature (59-86°F, 15-30°C) prior to testing.
Testing the specimen

TESTING PROCEDURE (CONT.)

Tear open the foil pouch and remove the Reditest® 6 Cassette screening device and plastic pipette.

Note: The desiccant pouches are part of the packaging, they are not a part of the screening device.
Testing the specimen

TESTING PROCEDURE (CONT.)

• Place the test device on a clean level surface.

• Hold the dropper vertically and transfer 3 full drops of urine into the specimens (S) well of the test device. Avoid trapping air bubbles in the specimen well.

• Start the timer.

• Wait for the colored lines to appear.
Interpretation of results
Interpreting drug test results

READING DRUG TEST RESULTS

• Read the drug test results at 5 minutes.

• Do not interpret the result after 60 minutes as false results may occur.

• Each test strip within the device includes an internal procedural control (C) that ensures proper device function.

• Control lines should form all control (C) lines, indicating proper functioning of the test device.
Negative example

NEGATIVE TEST RESULT

• A colored line appears in the Control region (C) and a colored line appears in the Test region (Drug/T) next to each drug name or number specific drug test.

• Negative results means the drug concentrations in the urine sample are below the designated cutoff levels for a particular drug tested.

Note: Any indication of a colored line, regardless of color intensity, is considered a negative test result.
Preliminary positive example

PRELIMINARY POSITIVE TEST RESULT

- A colored line appears in the Control region (C) and NO line appears in the Test region next to the name or number of a specific drug tested.
- The preliminary positive result means the drug concentrations in the urine sample is greater than the designated cutoff levels for a specific drug.

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

PRESUMPTIVE POSITIVE FOR MARIJUANA (THC)
Invalid example

INVALID TEST RESULT

• No line appears in the Control region (C).
• Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.
• Read the directions again and repeat the test with a new test cassette.
• If the result is still invalid, contact technical support.
Interpreting test results

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 card.
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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