LEARNING XCHANGE

URINE DRUG SCREEN PROCEDURE

iScreen™ Urine Test Drug Screen Square Cup

Self-paced training – does not contain audio

The information in this presentation is a general overview on performing and interpreting the iScreen™ Urine Test Drug Screen Square Cup

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 iScreen™ Urine Test Drug Screen Square Cup is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs, drug metabolites and alcohol at specific cut-off concentrations in urine.

We offer two iScreen™ Urine Test Drug Screen Square Cup options, each one is intended for a different setting.

1. For professional in vitro diagnostic use only.

2. CLIA Waived*. CLIA Waived devices may be used by laboratories with a CLIA Certificate of Waiver.

These tests provide only a preliminary result. A more specific alternative chemical method should be used to obtain a confirmed presumptive positive result if the donor doesn't admit use or anytime required by testing procedures. Gas Chromatography / Mass Spectrometry (GC-MS), Liquid Chromatography / Mass Spectrometry (LC/MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drug screen test result, particularly when evaluating preliminary positive results.

iSCREEN™ URINE TEST DRUG SCREEN SQUARE CUP

Product Overview

THE ISCREEN™ URINE TEST DRUG SCREEN SQUARE CUP IS A CONVENIENT, RAPID AND MULTI-DRUG ASSAY THAT PROVIDES VALUABLE TESTING AT THE POINT OF CARE.

FEATURES AND BENEFITS

- Screens for 5–12 prescription and illicit drugs
- Simple to use, no need to tilt cup to activate test — read results in as little as 5 minutes
- Low-level opiate cutoff (300 ng/mL) and buprenorphine (BUP) screening available on some configurations.
- Available with specimen validity testing (SVT) and temperature strip — helps to monitor specimen tampering
- Self-contained cup is ideal for sending preliminary positive specimens to the lab for confirmation

TEST DEVICE COMPONENTS

Abbreviations and Cutoff Level Concentrations

DRUG	CUTOFF (ng/mL)
Amphetamine (AMP 1000, AMP 500)	1,000/500
Barbiturates (BAR)	300
Benzodiazepines (BZO)	300
Buprenorphine (BUP)	10
Cocaine (COC 300, COC 150)	300/150
EDDP (EDDP)	300
Cannabinoids (THC)	50
Methamphetamine (mAMP 1000, mAMP 500)	1000/500
Opiate/Morphine (MOP/OPI 2000, MOP/OPI 300)	2000/300
Methadone (MTD)	300

DRUG	CUTOFF (ng/mL)
Oxycodone (OXY)	100
Phencyclidine (PCP)	25
Propoxyphene (PPX)	300
Tricyclic Antidepressants (TCA)	1,000

SPECIMEN VALIDITY TESTS AVAILABLE: Creatinine (CR), Glutaraldehyde (GL), Nitrite (NI), pH (PH), Specific Gravity (S.G.) and Oxidants (OX)

Various configurations available.

Precautions, Storage and Stability

PRECAUTIONS

- This kit is for external use only.
- Do not use if pouch is punctured or not sealed.
- Discard after first use. The test cannot be used more than once.
- Do not use test kit beyond expiration date.
- Keep out of the reach of children.
- Do not read results after 5 minutes.

DEVICE STORAGE AND STABILITY

- Store at 4°C–30°C (39°F–86°F) in the sealed pouch up to the expiration date
- Keep away from direct sunlight, moisture and heat
- **Do Not Freeze**

iSCREEN™ URINE TEST DRUG SCREEN SQUARE CUP

Performing a Urine Drug Screen

Specimen Collection and Preparation

- Collect the urine sample for the test in the minimum detection time after the suspected drug use.
- Urine collection time is very important in detecting any drug of abuse.
- Each drug is cleared by the body and is detected in the urine at different times and rates.
- Please refer to the minimum or maximum detection time for each drug in the instructions for use.

Gather All Necessary Testing Supplies

MATERIALS PROVIDED

- 25 iScreen™ Urine Test Dx Drug Screen Square Cups, each in one pouch with desiccant. The desiccants are for storage purposes only and are not used in the test procedures.
- One (1) Package Insert
- One (1) Procedure Card
- One (1) Adulteration Color Comparison Chart (if equipped).
- 25 Security Seals

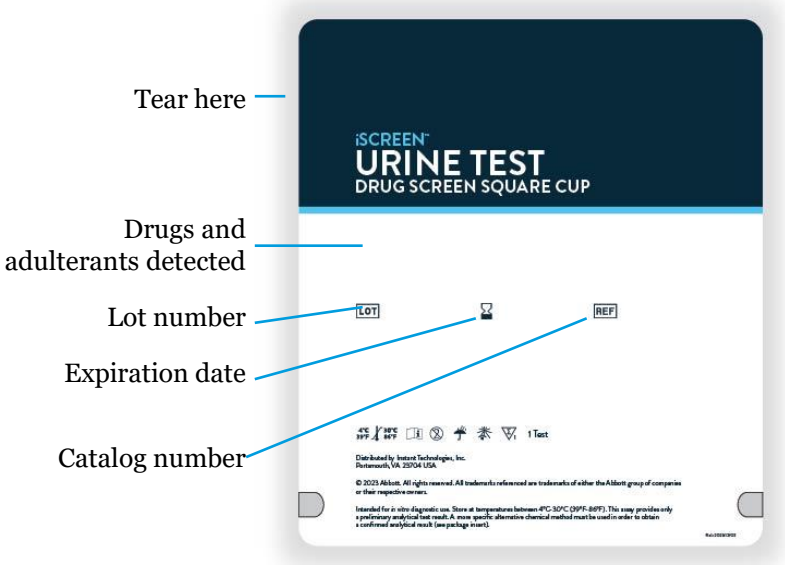
RECOMMENDED BUT NOT PROVIDED

- Timer

Foil Pouch with Device

THE FOIL POUCH CONTAINS THE FOLLOWING INFORMATION: LIST OF DRUGS SCREENED, ADULTERANTS (WHEN APPLICABLE), CATALOG NUMBER, LOT NUMBER AND EXPIRATION DATE.

- Allow the test cup to come to room temperature, 18°C–30°C (65°F–86°F), prior to test
- Test Cup must remain in the sealed pouch until use
- Do not use after the expiration date
- Do not use if pouch is punctured or not sealed.



Collecting a Urine Specimen

- Remove a test cup from the foil pouch by tearing at the notch.
- Use it as soon as possible.
- Instruct the donor to remove the cap from the test cup, and void directly into the test cup.
- Instruct the donor to fill the cup to the 30 mL mark.
- It is acceptable to collect an extra sample.
- Immediately read the temperature to verify that the urine temperature is within the acceptable range 32-38°C (90-100°F).

REMOVE FOIL POUCH

REMOVE CAP AND VOID INTO CUP, FILLING TO 30 ML MARK

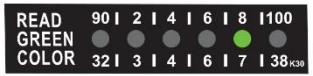
iSCREEN™ URINE TEST DRUG SCREEN SQUARE CUP

Interpretation of Results

How To Perform the Test

- Test must be performed at room temperature, 18-30°C (65-86°F).
- After the urine has been collected, tighten lid, and place the test cup on a flat surface.
- Read the temperature immediately to verify that the urine temperature is within the acceptable range 32-38°C (90-100°F).

ATTACH LID SECURELY

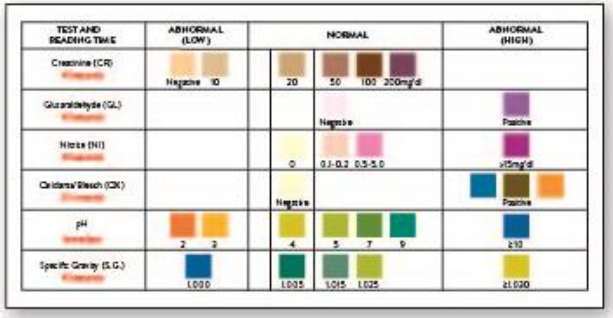


IMMEDIATELY READ TEMPERATURE STRIP

Reading Adulteration Test Results

For the adulteration strip(s) if equipped, read results immediately, or at 30 seconds, or at 45 seconds and compare each adulterant pad to verify pad color is within acceptable range according to the Adulteration Color Comparison Chart. If the results indicate adulteration, do not read the drug test results. Instruct the donor to provide urine specimen again with another new test cup.

ADULTERATION COLOR CHART*



*For illustrative purposes only. Please refer to color comparison chart included with kit.

ADULTERATION TEST RESULTS

Drug and adulterant strip placement on the cup may vary depending on the configuration

Reading Drug Test Results

INTERPRET RESULTS AT 5 MINUTES

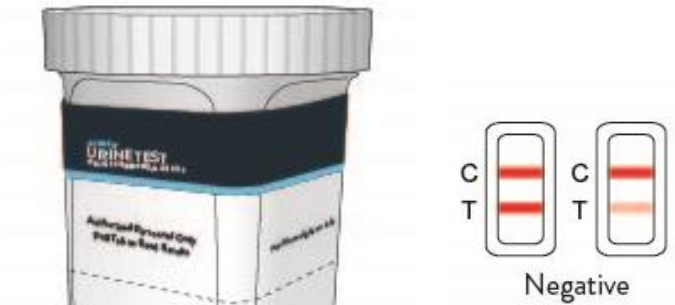
- Read test results at 5 minutes.
- Refer to graphics in the Package Insert for result interpretation.

DRUG TEST RESULT AREA

Drug and adulterant strip placement on the cup may vary depending on the configuration.

Negative Test Result

- Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.
- The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.
- **There is no meaning attributed to line color intensity or width.**

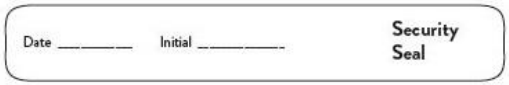


NEGATIVE RESULT

Line present in both the control and test regions

Preliminary Positive Test Result

- One red line appears in the control region (C). No line appears in the test region (Drug/T).
- This positive result indicates that the drug concentration is above the detectable level.
- If there is a preliminary positive test result, the operator should attach the security seal label over the cap.
- Security seal must include donor's name, initials and test date. Do not cover test result window with security seal.
- Preliminary positive test results should be confirmed by an alternate methodology. Send the cup containing the urine specimen with security seal label intact to a toxicology laboratory for GC-MS or LC-MS/MS confirmation.

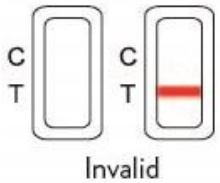


PRELIMINARY POSITIVE RESULT

No line present in the test region (T)

Invalid Test Result

- Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.
- Review the procedure and repeat the test using a new test device.
- If the problem persists, discontinue using the lot immediately and contact Technical Support.



INVALID RESULT

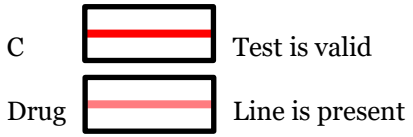
No line present in the control region (T)

Summary

NEGATIVE

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

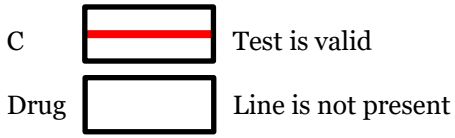
Any visible line, even a faint line, indicates a negative result.



PRELIMINARY POSITIVE

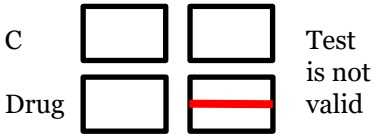
The control line must be colored to indicate the test is valid.

No line indicates a positive result.



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.



Urine Drug Control Kits

Users should follow the appropriate federal, state and local guidelines concerning the frequency of assaying external quality control materials. Though there is an internal procedural control line in the test device of control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

For assistance obtaining controls, contact Technical Support.

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 your Toxicology representative.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