MEDTOX® DIAGNOSTICS, INC.

EZ-SCREEN® CUP (LO)

Training and Certification Program

www.medtoxdiagnostics.com
800-334-1116

Intended Use

The EZ-SCREEN® Cup Drugs of Abuse Test is a one-step immunochromatographic test for the rapid, qualitative detection of one or more of the following: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Methamphetamine, Methadone, Opiates, Oxycodone, Phencyclidine, and TH (Cannabinioids) in human urine. It is intended for prescription use. EZ-SCREEN® Cup is not for over-the-counter sale.

Operators that may use this device are defined as individuals with at least a high school education, with no formal laboratory testing education or laboratory experience, and who have some experience running other tests similar to EZ-SCREEN®. Additionally, individuals are to satisfy the following training and certification guidelines:

(1)Training should be conducted by a qualified professional and include a demonstration of the EZ-SCREEN® Cup test system and (2) the use of quality assurance samples for monitoring and confirming the performance of the test system. Trainers should observe and confirm that the operator (3) uses proper technique when running a test sample and quality assurance samples, (4) has a basic understanding of test results, including the potential for false positive and false negative results, (5) knows how to prepare a sample for shipment to the laboratory for confirmation testing, (6) has reviewed the information contained in the MEDTOX EZ-SCREEN® Cup Training and Certification Program (available at www.medtoxdiagnostics.com) and that the operator (7) achieves an acceptable score of 80% on the written exam provided by MEDTOX.

Operators achieving a score of 80% will be provided with a certificate of training participation. Quality assurance samples appropriate for training are available from MEDTOX. Additionally, MEDTOX Technical Support will provide access to assistance from individuals who are experienced in the interpretation of drug testing results.

The test detects drug classes at the following cutoff concentrations:

AM	Amphetamine (d-Amphetamine)	300 ng/mL
BA	Barbiturates (Butalbital)	200 ng/mL
BZ	Benzodiazepines (Nordiazepam)	200 ng/mL
BU	Buprenorphine (Buprenorphine)	10 ng/mL
CO	Cocaine (Benzoylecgonine)	100 ng/mL
mA	Methamphetamine (d-Methamphetamine)	1000 ng/mL
MT	Methadone (Methadone)	200 ng/mL
OP	Opiates (Morphine)	100 ng/mL
OX	Oxycodone (Oxycodone)	100 ng/mL
PC	Phencyclidine (Phencyclidine)	25 ng/mL
TH	Cannabinoids (11-nor-9-carboxy-Δ^9-THC)	40 ng/mL

Many of the cutoff concentrations for these tests are below those recommended by SAMHSA. Additionally, many of these tests are positive at levels significantly below the claimed cutoff concentration. The rate of false positive results with tests having sensitivities this low has not been studied. However, the rate of false positives generally increases as the cutoff concentration of the test is lowered. See the Precision/Sensitivity section of the device package insert for more information.

The EZ-SCREEN® Cup Drugs of Abuse Test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography / tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any Drug of Abuse test result, particularly when presumptive positive results are obtained.

It is the responsibility of those organizations required to follow Department of Transportation (DOT) or Substance Abuse Mental Health Services Administration (SAMHSA) Workplace Drug Testing Guidelines to determine that use of this product satisfies the criteria for workplace testing established under DOT and SAMHSA authority.

Product Quality

- During manufacturing, the EZ-SCREEN® Cup products are tested multiple times to verify that they perform appropriately and meet stated performance and test cutoff criteria.
- *Any production lot that does not pass the extensive quality control criteria is destroyed – it is not released for sale.*
- Product that is released for sale should continue to perform properly until expiration date when the product is stored properly and tested in accordance with the manufacturer's instructions.
- In a few cases, device failure is due to improper storage or running tests with a cold device and/or cold specimen.

Precautions

- Urine specimens and all materials coming into contact with them should be handled and disposed of as if infectious and capable of transmitting infection. Avoid contact with broken skin.
- Avoid cross-contamination of urine samples by using a new urine specimen container for each urine sample.
- The device should remain in its original sealed foil pouch until ready to use. If the pouch is damaged, do not use the test.
- Do not use tests after the expiration date printed on the package label.
- The drug screen portion of the device is for *in vitro* diagnostic use only. The Adulterant strip is for forensic/ toxicology use only.

Storage Conditions

- Do not store the test kit at temperatures above 25˚C (77˚F).
- Kits must be stored at 2-25˚C (36-77˚F).
- Do not store EZ-SCREEN® Cup devices next to heat sources or in areas where temperatures may go above 25˚C (77˚F). This may include cars, areas next to anything electrical that generates heat, or areas next to windows.
- Do not store the test kit at temperatures below 2˚C (36˚F).
- If devices have been stored refrigerated, bring to ambient temperature (18-25˚C / 64-77˚F) prior to opening foil pouch.

Sample Preparation

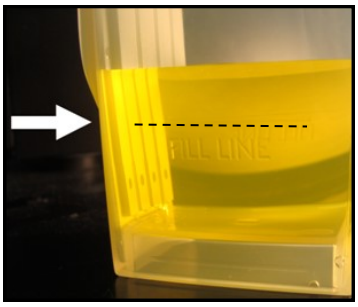
- When using the EZ-SCREEN® cup device, sample volume MUST be at or above the FILL LINE on the cup.
- No preservative should be added to the urine specimen.

Instructions

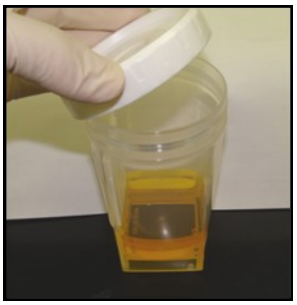
1. Bring pouched device to room temperature (18-25°C/64-77°F) before opening it.

2. Open pouch and label the device with the patient or sample

3. Remove desiccant from cup.

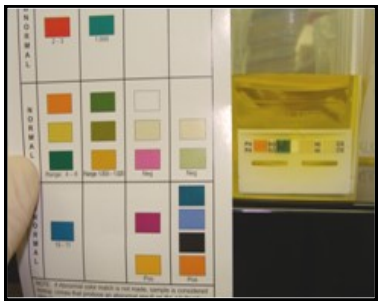


4. Fill urine sample cup to at least the Fill line.



5. Secure and tighten lid onto the cup to prevent leakage in the event the sample needs to be shipped to the lab. Avoid cross threading the cap.

6. Keep cup in upright position and minimize handling before reading.



7. If Adulterant strip is present, read pH, Specific Gravity, and Nitrites in vertical position as soon as color changes. Read Oxidant at 60 seconds.

8. If device has a temperature strip, temperature must be read within 4 minutes of collection.

9. Allow the test cup to sit for 5 minutes after voiding into the cup.

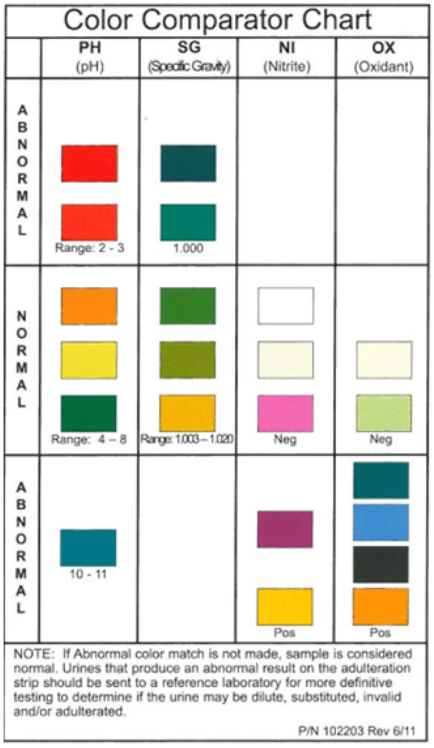
10. Remove the privacy tab and read the results. Control line (C) must be present to read results.

11. If moisture or urine obscures your view of the test results, tip the closed container forward so the liquid wipes the moisture off of the sidewalls and then tip backward so you can see the lines clearly.

NOTE: Using a timing device (like a wall clock, kitchen timer, watch or cell phone) is recommended to ensure that you are reading the test results in the appropriate time intervals.

NOTE: Read results at 5 minutes or within 15 minutes of voiding into the cup. Oxycodone should be read at 5 minutes. Test results interpreted after 15 minutes (for Oxycodone after 5 minutes) may not be consistent with the original results obtained at 5 minutes.

Reading and Interpreting the Adulterant Strip



The Adulterant strip is a rapid qualitative screening assay for the detection of Oxidants and Nitrites and the determination of Specific Gravity and pH values in human urine. It is used to evaluate specimens for possible adulteration and/or dilution prior to Drugs of Abuse urine (DAU) testing.

Shortly after voiding into the specimen cup, the test pads will be activated (wetted) as urine flows onto the Adulterant strip. At this point you may begin to read the Adulterant strip.

Use the Color Comparator Chart that accompanies the test kit to assist in reading Adulterant strip results.

The pH, Specific Gravity, and Nitrite can be read immediately after they are wetted.

The Oxidant pad is read at 60 seconds after wetting the pad.

Note: If Abnormal color match is not made, sample is considered normal. Urines that produce an abnormal result on the adulteration strip should be sent to a reference laboratory for more definitive testing to determine if the urine may be dilute, substituted, invalid and/or adulterated.

Reading Test Results

(5 Minutes)

EZ-SCREEN® Cup Drugs of Abuse Tests may include various drug tests based on your facility's needs. (The example at the right has nine different drugs for testing.)

For examples at right, C = Control

VALID TEST:

A reddish-purple line must appear in the "C" area of the test strip for that test to be valid.

INVALID TEST:

If no control line "C" is present on a test strip the tests are invalid. Retest the urine with a new device. If the second test is also invalid, send the urine sample to a reference laboratory for additional testing. The control line must be present for the test strip to be valid.

NEGATIVE:

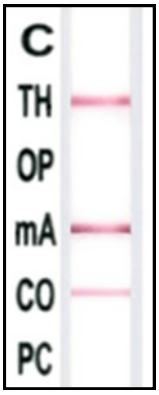
Any reddish-purple line (even a faint or broken line) visible at 5 min. in both the test area and the control (C) line is a negative result.

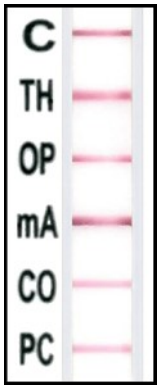
Example below: All five test results are negative, the control line is present, and the tests are valid.

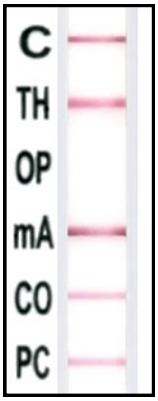
PRESUMPTIVE POSITIVE:

The absence of a line in the test area is a presumptive positive result. Presumptive positive results can be read after 5 minutes but not longer than 15 minutes. Oxycodone results must be read at 5 minutes.

Example below: OP (Opiates) test is a presumptive positive. All tests are valid.







Interpreting Test Results

- Any reddish-purple line (even a faint or broken line regardless of the color intensity) visible at 5 minutes in the test area (along with a valid control) indicates a negative test result.
- A NEGATIVE test result for a specific drug indicates that the sample does not contain the drug/drug metabolite above the cutoff level. Cutoff levels are found in the Intended Use section (Page 1) of this training document.
- A PRESUMPTIVE POSITIVE test result for a specific drug indicates that the sample may contain drug/drug metabolite near or above the cutoff level. It does not indicate the level of intoxication or the specific concentration of drug in the urine sample. Presumptive positive samples or those with abnormal Adulterant strip results should be sent to a reference laboratory for more definitive testing.

Limitations of Procedure

- The EZ-SCREEN® Cup Drugs of Abuse Test is only for use with unadulterated human urine samples collected in the EZ-SCREEN® Cup. Urine samples which are either extremely acidic (below pH 4.0) or basic (above 9.0) may produce erroneous results.
- Urine samples which are collected in another cup and then poured into an EZ-SCREEN® Cup may produce erroneous results.
- Keep the EZ-SCREEN® Cup upright while strips are developing. Turning the EZ-SCREEN® Cup upside down or on its side may produce erroneous or invalid results.
- Shaking or excessive agitation of the EZ-SCREEN® Cup may produce erroneous or invalid results.
- A positive result for any drug(s) does not indicate or measure intoxication.
  It only indicates the presence of reacting compound(s) in the urine specimen.
- Test results interpreted after 15 minutes (5 minutes for OX) may not be consistent with the original result obtained at 5 minutes.
- The EZ-SCREEN® Cup Drugs of Abuse Test was not evaluated in point of care settings.
- There is a possibility that other substances and/or factors (e.g. technical or procedural errors) may interfere with the test and cause erroneous results.

You have now completed the EZ-SCREEN® Cup Training Program. To achieve certification as a Tester for this device, you must complete the accompanying Certification Quiz with a score of 80% or higher.

For complete product information refer to the current version of the EZ-SCREEN® Cup Package Insert-I available at www.medtoxdiagnostics.com/Resources or contact Technical Support at 1-877-643-5703 or TechServices@medtoxdiagnostics.com.

MEDTOX®
DIAGNOSTICS, INC.

EZ-SCREEN® CUP (LO)

Certification Quiz

www.medtoxdiagnostics.com
800-334-1116

EZ-SCREEN® CUP Certification Quiz

Before beginning this quiz, be sure to thoroughly read the preceding training program materials.

After reading each question completely, choose the best answer and record your answers on the answer sheet provided at the end of this quiz.

1. EZ-SCREEN® Cup devices should be stored at 36-77˚F (2-25˚C).

   A. True
   B. False

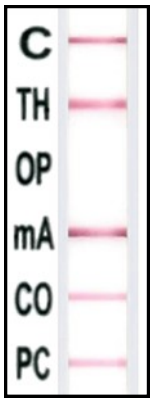
2. After allowing five minutes for test and control lines to develop, if one or more control lines are missing on the device:

   A. The tests on the strip/strips with missing control lines are invalid and sample should be rerun on a new device.
   B. The tests on the strip/strips with missing control lines are valid
   C. Missing control lines have no impact on the validity of the tests.

3. The test kit may be used after the expiration date:

   A. If the kit has been frozen
   B. Never
   C. Within one month after the expiration date
   D. Only if the kit has been refrigerated and control line is present

4. Interpret the following results: →

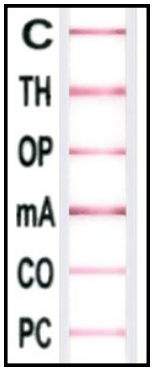


   A. Presumptive Positive for OP and the test is valid
   B. Presumptive Positive for TH, mA, CO, and PC
   C. Invalid and test should be repeated
   D. Presumptive Positive for OP and the test is invalid

5. The presence of any reddish-purple line, regardless of color intensity (whether faint or broken) is to be interpreted as a negative result.

   A. True
   B. False

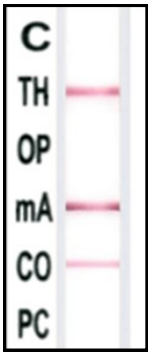
6. Interpret the following results: →



   A. Presumptive Positive for five drugs
   B. Presumptive Positive for six drugs
   C. All drug test results are invalid
   D. Negative for all drugs

For complete product information refer to the current version of the EZ-SCREEN® Cup Package Insert-I available at www.medtoxdiagnostics.com/Resources or contact Technical Support at 1-877-643-5703 or TechServices@medtoxdiagnostics.com.

7. Interpret the following results: ⟶



   A. All drug test results are valid
   B. All drug test results are invalid
   C. Opiates (OP) and Phencyclidine (PC) are both presumptive positive.

8. Excluding Oxycodone (OX), all test results should be read:

   A. Before 5 minutes
   B. Between 5 and 15 minutes
   C. After 15 minutes

9. Urine levels in the specimen cup should be at or above the FILL LINE.

   A. True
   B. False

10. The Adulterant strip should be read after 15 minutes and following the interpretation of the drug results.

   A. True
   B. False

11. On the Adulterant strip, the pH, Specific Gravity, and Nitrite can be read immediately after they are wetted.

   A. True
   B. False

12. Shaking or tipping the EZ-SCREEN® Cup may produce erroneous results

   A. True
   B. False

13. Tightly twisting the lid of the collection container is important in the prevention of urine leakage during transport.

   A. True
   B. False

14. EZ-SCREEN® Cup devices should not be stored next to heat sources or in areas where the temperature exceeds 77˚F (25˚C) or below 36˚F (2˚C). This may include areas next to windows and in cars.

   A. True
   B. False

15. Urine samples which are collected in another cup and then poured into an EZ-SCREEN® Cup may produce erroneous results.

   A. True
   B. False

For complete product information refer to the current version of the EZ-SCREEN® Cup Package Insert-I available at www.medtoxdiagnostics.com/Resources or contact Technical Support at 1-877-643-5703 or TechServices@medtoxdiagnostics.com.

EZ-SCREEN® CUP

Certification Quiz Answer Sheet
Enter your answers in the spaces below, fill in your name and other requested information, and email/fax your answer sheet to MEDTOX Diagnostics. To receive a Certificate of Achievement, participants must achieve a score of at least 80% or retake the quiz until an acceptable result is achieved.

Question 1	_____	Question 9	_____
Question 2	_____	Question 10	_____
Question 3	_____	Question 11	_____
Question 4	_____	Question 12	_____
Question 5	_____	Question 13	_____
Question 6	_____	Question 14	_____
Question 7	_____	Question 15	_____
Question 8	_____		

Name (please print): _____

Company Name: _____

Address: _____

City, State, Zip: _____

Telephone: _____

Fax: _____

Email: _____

Email Completed Answer Sheet To: customerservice@medtoxdiagnostics.com
or Fax Completed Answer Sheet To: 1-336-227-7302

If you have questions, please call 800-334-1116 or email customerservice@medtoxdiagnostics.com