

## EZ-SCREEN® CUP

Package Insert-I



Training and Certification Program  
Presented by:

# **MEDTOX®**

## Concept

MEDTOX trains and certifies collectors.

## Intended Use

The EZ-SCREEN<sup>®</sup> 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 THC (Cannabinoids) in human urine. It is intended for prescription use. The EZ-SCREEN<sup>®</sup> Cup is not for over-the-counter sale.

Operators that may use the 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<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> Cup Training and Certification Program (available at [www.medtox.com](http://www.medtox.com)) and that the operator (7) minimally achieves a score of 100% on the written exam provided by MEDTOX.

Operators achieving a score of 100% will be provided with a certificate of training participation. Quality assurance samples appropriate for training are available from MEDTOX Laboratories Inc. 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- $\Delta^9$ -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.

**Intended Use (continued)**

The EZ-SCREEN<sup>®</sup> Cup Drugs of Abuse Test provides only a preliminary analytical test result. A more specific alternate chemical method must be used 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. Any confirmatory testing should be performed on the original sample. 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 formulation and manufacturing, the EZ-SCREEN<sup>®</sup> 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.
- Based on extensive collection of data, the most common causes of product failure are not 'a bad lot number' or a 'bad box of product', but rather, failure to read, understand, and/or follow the testing directions.
- 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<sup>®</sup> 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.

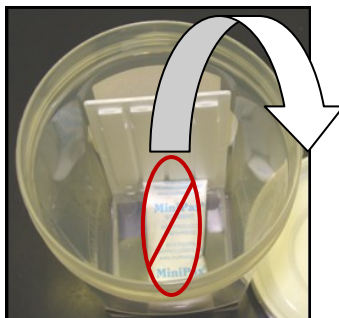
## Sample Preparation

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

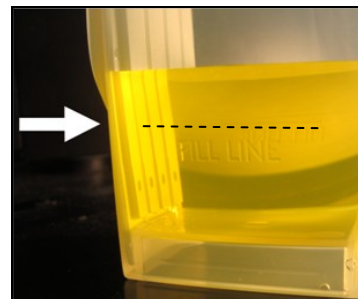
## Instructions



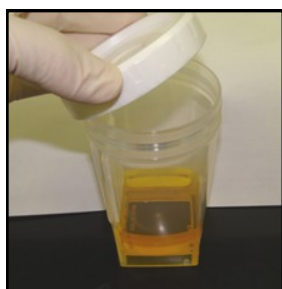
1. Bring pouched device to room temperature before opening it.
2. Open pouch and label the device with the patient or sample identification.



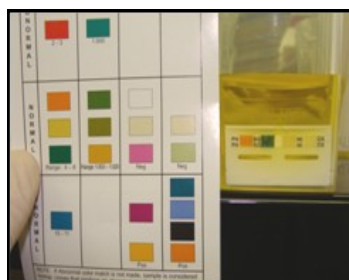
3. Remove desiccant from cup.



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



5. Tighten lid onto the cup.
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. Allow the test cup to sit for 5 minutes after voiding into the cup.



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



10. If you remove the privacy tab before 5 minutes, negative results can be read as soon as a test line and control line (C) are visible, and presumptive positive results can be read at 5 minutes after voiding into the cup.



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.

Color Comparator Chart				
	PH (pH)	SG (Specific Gravity)	NI (Nitrite)	OX (Oxidant)
ABNORMAL	 2 - 3	 1.000		
NORMAL	   Range: 4 - 8	   Range: 1.003 - 1.020	   Neg	  Neg
ABNORMAL	 10 - 11		  Pos	    Pos
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.				
P/N 102203 Rev 7/10				

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<sup>®</sup> Cup Drugs of Abuse Tests may include varying number of drugs for testing 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:

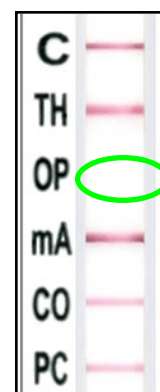
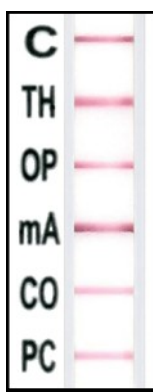
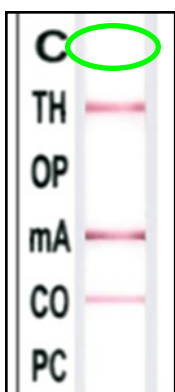
Any reddish-purple line (even a faint or broken line regardless of color intensity) visible in the test area (along with a valid control) is a negative result.

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

- If you are unsure of the test results, send the specimen to a reference laboratory for confirmation. 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. Confirmatory testing should be done to Limit of Detection or low Limit of Quantification (LOD or LOQ) using expanded panels that encompass a wider range of cross reactant drugs—see individual section of product insert for related cross reactants.

## Limitations of Procedure

- The EZ-SCREEN<sup>®</sup> Cup Drugs of Abuse Test System is only for use with unadulterated human urine samples collected in the EZ-SCREEN<sup>®</sup> 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 (non-EZ-SCREEN<sup>®</sup> Cup) and then poured into an EZ-SCREEN<sup>®</sup> Cup may produce erroneous results.
- Keep the EZ-SCREEN<sup>®</sup> Cup upright while strips are developing. Turning the EZ-SCREEN<sup>®</sup> Cup upside down or on its side may produce erroneous or invalid results.
- Shaking or excessive agitation of the EZ-SCREEN<sup>®</sup> Cup may produce erroneous or invalid results.
- A non-negative (presumptive 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. Confirmation testing at a reference laboratory is recommended.
- Test interpreted after 15 minutes (5 minutes for Oxycodone) may not be consistent with the original result obtained at 5 minutes.
- The EZ-SCREEN<sup>®</sup> Cup Drugs of Abuse Test System 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.

**For complete product information** refer to the current version of the EZ-SCREEN<sup>®</sup> Cup Package Insert-I available at <http://www.medtox.com/ProductTraining.aspx> or contact Technical Support at 1-877-643-5703.

**MEDTOX Diagnostics, Inc.** • 1238 Anthony Road • Burlington, NC 27215  
Phone: 1-877-457-0613 • Fax: 651-286-6222 • E-mail: [sales@medtox.com](mailto:sales@medtox.com)



## Preparing a Specimen to send to a Reference Laboratory for Confirmation Testing

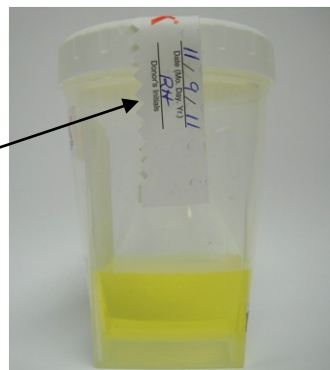
1. Ensure that the lid to the specimen cup is tightly sealed to prevent leakage during transport.
2. Fill out Chain-of-Custody form and attach Chain-of-Custody seal. (see pages 9-10 for Chain-of-Custody)

**Correct placement of Chain-of-Custody seal.**

**Missing seals, signatures and/or information may cause sample rejection or delay confirmation testing.**

Contact your lab for Chain-of-Custody forms and seals.

3. Donor should initial and date the seal in space provided prior to applying the seal to the container.
4. Place Chain-of-Custody form in rear pocket and specimen cup in the front pouch of the biohazard bag. (Front pouch contains an absorbent pad.)
5. Package biohazard bag with its contents for shipping. This includes packing biohazard bag with urine and chain-of-custody in a lab pack.
6. Contact your confirmation laboratory to obtain the proper materials for shipping specimens.






## Chain-of-Custody Form

**MEDTOX<sup>®</sup>** LABORATORIES, INC.  
402 W. County Rd D  
St. Paul, MN 55112  
(651) 636-7466  
(800) 832-3244

Client: MEDTOX DEMO CONFIRMATION ACCOUNT  
ATTN JANE SMITH  
402 WEST COUNTY ROAD D  
ST PAUL, MN 55112

**ONSITE CONFIRMATION REQUISITION**



Specimen ID: **V12284342**

**V12284342**

**1 To be completed by COLLECTOR / DONOR**

Donor Name: Larson Last Lars First Case No.           

Donor I.D. 54321 AND/OR           

Probation Officer/ Case Manager Name Hans Hanson

Test(s) Ordered: ☐ 9377 ☐ 5395 ☒ 9147 ☐ 4752

☐ 693 ☐ 1512 ☐ 61745 ☐ 3074

☐ 3108 ☐ 11405 ☐ 839

☐ PPX ☐ BHP ☐ CDC

**2 To be Completed by COLLECTOR / CUSTODIAN**

Date of Collection Month 08 Day 20 Year 11 **44781**

I, the collector, by signing below certify that the specimen identified on this form is the specimen given to me by the donor identified above and that it has been collected, labeled and sealed in accordance with applicable requirements. I also certify that I performed the on-site test and released the specimen for shipment to the laboratory if additional testing is required unless signed by the tester and/or shipper. The tester and/or shipper certify that the specimen was received from temporary storage and handled in accordance with standard procedures.

COLLECTOR	TESTER	SHIPPER
Printed Name <u>Hans Hanson</u>	Printed Name <u>          </u>	Printed Name <u>          </u>
Signature <u>Hans Hanson</u>	Signature <u>          </u>	Signature <u>          </u>

**3 To be Completed by DONOR**

Donor Signature / Certification

I certify that the information provided by me on this form is true and correct. I also certify that the specimen bottle was sealed with a tamper-evident seal in my presence and that the specimen provided on this date is my own and has not been substituted or adulterated.

Donor Name Lars Larson Donor Signature Lars Larson Date (Mo./Day/Yr.) 08/08/11

**4 LABORATORY USE ONLY**

RECEIVED AT LAB:

X Signature of Accessioner           

(PRINT) Accessioner's Name (First, MI, Last)            Date (Mo./Day/Yr.)

**SPECIMEN BOTTLE(S) RELEASED TO:**


Primary Specimen           

Bottle Seal Intact           

☐ Yes

☐ No, Enter Remark Below

**HOLD THUMB HERE WHEN REMOVING LABEL**



**V12284342**

**MEDTOX<sup>®</sup>** LABORATORIES, INC.

PLACE OVER CAP

08/08/11  
Date (Mo. Day, Yr.)

            
Donor's Initials

COPY 1 - MUST BE SENT WITH SPECIMEN TO MEDTOX • DO NOT USE RED INK A107 (8/10)

All areas highlighted in green must be completed to ensure testing can be performed once received at confirmation laboratory and to ensure that there is no delay in testing. It is especially important to mark the test/test(s) to be ordered which appears between step 1 and step 2 of the Chain-of-Custody (see above example).

YOU HAVE NOW COMPLETED THE EZ-SCREEN<sup>®</sup> CUP TRAINING PROGRAM. TO ACHIEVE CERTIFICATION AS A TESTER FOR THIS DEVICE, YOU MUST COMPLETE THE ACCOMPANYING CERTIFICATION QUIZ WITH A SCORE OF 100%.



## EZ-SCREEN® CUP

Package Insert-I



Troubleshooting Guide  
Presented by:

**MEDTOX®**



## Troubleshooting Guide

### Common Problems Associated with Failure to Perform Testing Procedure Correctly:

- Failure of Control line(s) to form; Invalid test(s)
- Failure of urine to migrate up the test strip
- False Positive Screen Result; when test is repeated, the result is a strong negative (not a faint line)

### Most Common Procedural Testing Errors:

#### Handling/manipulating the cup in an attempt to 'hurry test line appearance'.

The urine and test reagents need to 'migrate' up the test strip by capillary action. Attempts to 'activate' the strips by swirling/rocking/shaking the cup are likely to disrupt the flow and potentially cause the reagents to be 'washed away' resulting in false positives and invalids.

#### Reading 'presumptive positive' drug screen results before 5 minutes have elapsed.

Most control lines and many test lines will appear within two minutes of starting the test. The product is formulated for a 5 minute read time and released for sale based on passing set criteria at the 5 minute read time. Presumptive positive results should be read at 5 minutes. Note: it is 'ok' to read a totally negative drug screen result 'early' if the controls are valid. When negative results are read 'early', the lines are likely to be 'light' since they haven't had the full 5 minutes to develop.

- *Timing suggestion: use a simple 'digital timer' set to 5 minutes to keep track of the read time.*

### Storage Issues:

Storage of the device at temperatures above 25°C/77°F will ultimately destroy the product. Examples: In a car, hot storage areas, non air-conditioned trailers, near lights/equipment that generate heat, and in direct sunshine. Initially some of the lines may become fainter, but as time progresses, false positives may occur or all lines may fail to appear. Devices may be stored in a refrigerator if needed, but the device **MUST** be allowed to come to ambient temperature (18-25°C/64-77°F) before use.

Note: These are relatively easy devices to use, but it is imperative that you read and understand the Quick Reference Guide supplied with the product and perform testing in accordance with those instructions. Failure to do so may result in testing/interpretation errors and false results.

## EZ-SCREEN® CUP

Package Insert-I




Certification Quiz  
Presented by:

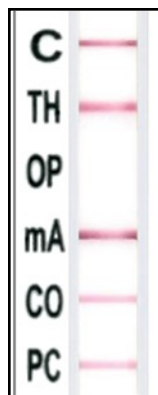
**MEDTOX®**

## EZ-SCREEN<sup>®</sup> CUP Certification Quiz

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

Go to [www.medtox.com](http://www.medtox.com) and click on the My Medtox tab to take the quiz online or use the Certification Quiz Answer Sheet provided at the end of this quiz to submit your answers to the following questions.

1. EZ-SCREEN<sup>®</sup> Cup devices should be stored at 36-77°F (2-25°C).
  - A. True
  - B. False
  
2. The EZ-SCREEN<sup>®</sup> Cup device should be at ambient temperature (18-25°C or 64-77°F) before opening foil pouch for testing.
  - A. True
  - B. False
  
3. Tests are invalid and sample should be rerun on a new device if:
  - A. No control (C) line is present on one or more strips
  - B. The urine is yellow and looks concentrated
  - C. Control (C) lines are present
  - D. The urine is pale, colorless, and looks dilute
  
4. 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
  
5. Interpret the following test: 
  - A. Non-Negative (presumptive positive) for OP and the test is valid
  - B. Non-Negative (presumptive positive) for TH, mA, CO, and PC
  - C. Invalid and test should be repeated
  - D. Non-Negative (presumptive positive) for OP and the test is invalid



6. The presence of any reddish-purple line (even a faint or broken line regardless of color intensity) visible in the test area (along with a valid control) is a negative result.

- A. True
- B. False

7. Interpret the following results:

- A. Non-Negative (presumptive positive) for five drugs
- B. Non-Negative (presumptive positive) for six drugs
- C. All drug test results are invalid
- D. Negative for all drugs



8. 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.



9. Excluding Oxycodone, all test results should be read:

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

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

- A. True
- B. False

11. It is ok to read the EZ-SCREEN<sup>®</sup> Cup drug screen results at 5 minutes.

- A. True
- B. False

12. Results read after 15 minutes may not be consistent with results at 5 minutes.

- A. True
- B. False

13. Shaking or tipping the EZ-SCREEN<sup>®</sup> Cup may produce erroneous results
- A. True
  - B. False
14. The adulteration strip should be read after 15 minutes and following the interpretation of the drug results.
- A. True
  - B. False
15. Tightly twisting the lid of the collection container is important in the prevention of urine leakage during transport.
- A. True
  - B. False
16. Chain-of-Custody must be properly completed prior to sending a specimen for further testing. Missing seals, signatures and/or information may cause sample rejection or delay confirmation testing.
- A. True
  - B. False
17. Based on the extensive collection of data, which of the following is the most common cause of product failure when performing the EZ-SCREEN<sup>®</sup> Cup Drugs of Abuse test?
- A. Bad lot number
  - B. Bad box of product
  - C. Failure to read, understand, and/or follow the testing directions.
18. On the adulterant strip, the pH, Specific Gravity, and Nitrite can be read immediately after they are wetted.
- A. True
  - B. False
19. EZ-SCREEN<sup>®</sup> 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
20. Urine samples which are collected in another cup (non-EZ-SREEN<sup>®</sup> Cup) and then poured into an EZ-SCREEN<sup>®</sup> Cup may produce erroneous results.
- A. True
  - B. False



**EZ-SCREEN<sup>®</sup> CUP****Certification Quiz Answer Sheet**

Enter your answers in the spaces below, fill in your name and other requested information, and fax your answer sheet to MEDTOX. To receive a Certificate of Achievement via fax, participants must receive a 100% or retake the test until 100% is accomplished.

Question 1 \_\_\_\_\_

Question 8 \_\_\_\_\_

Question 15 \_\_\_\_\_

Question 2 \_\_\_\_\_

Question 9 \_\_\_\_\_

Question 16 \_\_\_\_\_

Question 3 \_\_\_\_\_

Question 10 \_\_\_\_\_

Question 17 \_\_\_\_\_

Question 4 \_\_\_\_\_

Question 11 \_\_\_\_\_

Question 18 \_\_\_\_\_

Question 5 \_\_\_\_\_

Question 12 \_\_\_\_\_

Question 19 \_\_\_\_\_

Question 6 \_\_\_\_\_

Question 13 \_\_\_\_\_

Question 20 \_\_\_\_\_

Question 7 \_\_\_\_\_

Question 14 \_\_\_\_\_

Name (please print): \_\_\_\_\_

Company Name: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Telephone: \_\_\_\_\_

Fax: \_\_\_\_\_

Email: \_\_\_\_\_

Fax Answer Sheet to: 1-866-232-1901

Or email answers to: [collsitedept@medtox.com](mailto:collsitedept@medtox.com)

Or Mail to: MEDTOX Laboratories, Inc.

Attn: EZ-SCREEN<sup>®</sup> Cup Insert-I Certification

402 West County Road D

Saint Paul, MN 55112

Please call 866-593-0160 with any questions or email [collsitedept@medtox.com](mailto:collsitedept@medtox.com).

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