# EZ-SCREEN® CUP

Package Insert-II


## Training and Certification Program
## Presented by:

MEDTOX®

**www.medtox.com**
**866-593-0160**

## Concept
MEDTOX trains and certifies collectors.

## 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, Cocaine, Methamphetamine, Methadone, Opiates, Oxycodone, Phencyclidine, and THC (Cannabinioids) in human urine. The EZ-SCREEN® Cup is not for over-the-counter sale.

EZ-SCREEN® Cup detects drug classes at the following cutoff concentrations:

| Test ID | Drug Class (calibrator) | Cutoff |
|---|---|---|
| AM | Amphetamine (d-Amphetamine) | 1000 ng/mL |
| BA | Barbiturates (Butalbital) | 200 ng/mL |
| BZ | Benzodiazepines (Nordiazepam) | 300 ng/mL |
| CO | Cocaine (Benzoylecgonine) | 300 ng/mL |
| mA | Methamphetamine (d-Methamphetamine) | 1000 ng/mL |
| MT | Methadone (Methadone) | 300 ng/mL |
| OP | Opiates (Morphine) | 2000 ng/mL |
| OX | Oxycodone (Oxycodone) | 100 ng/mL |
| PC | Phencyclidine (Phencyclidine) | 25 ng/mL |
| TH | Cannabinoids (11-nor-9-carboxy-$\Delta^9$-THC) | 50 ng/mL |

The EZ-SCREEN® 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.

## Product Quality

- During formulation and 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.
- 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® 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.

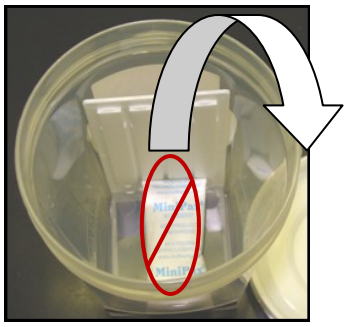
## Sample Preparation

- 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.

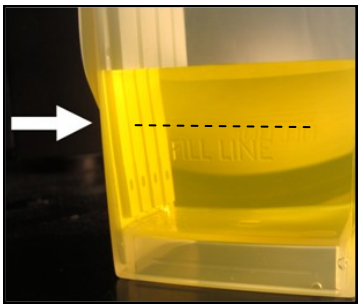
## Instructions

1. Bring pouched device to room temperature 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.

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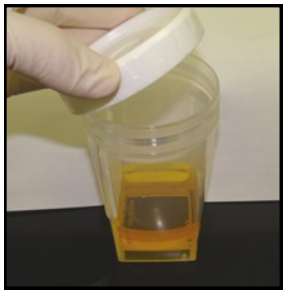
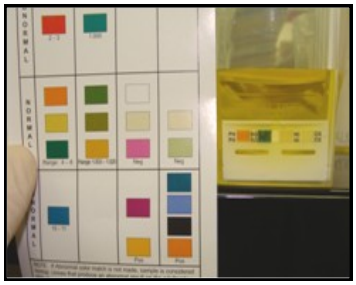


5. Tighten lid onto the cup.

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.

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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.

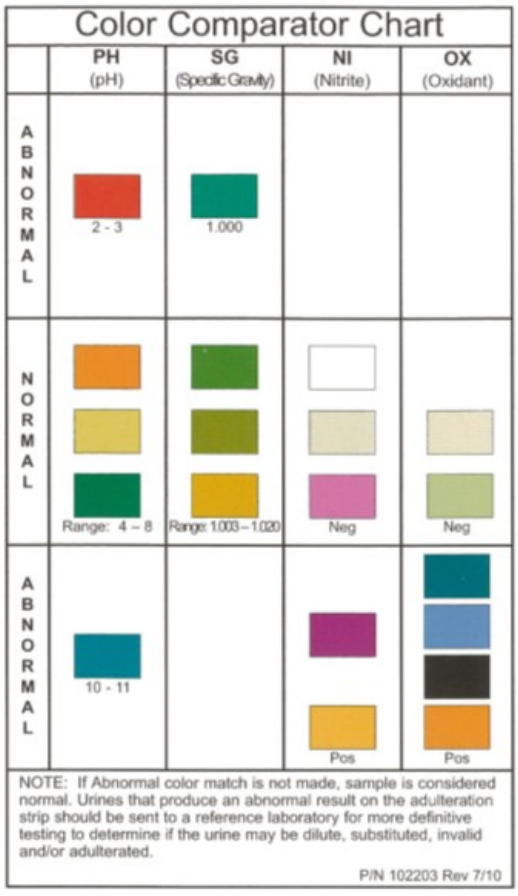
Shortly after voiding into the specimen cup, the test pads will be activated (wetted) as urine flows onto the adulterant strip. At this point you may begin to read the Adulterant Strip.

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.

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.



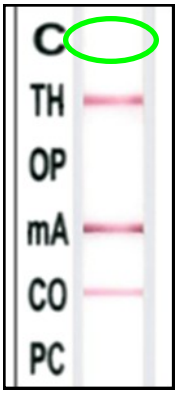
## Reading Test Results
**(5 Minutes)**

EZ-SCREEN® Cup Drugs of Abuse Tests may include 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

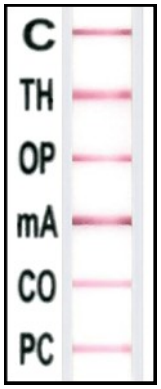

**VALID TEST:**
A reddish-purple line must appear in the "C" area of the test strip for that test to be valid.

**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.



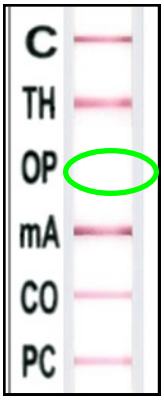

**NEGATIVE:**
Any reddish-purple line (even a faint or broken line) visible at 5 min. in both the test area and the control (C) line is a negative result.

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

- If you are unsure of the test results, send the specimen to a reference laboratory for confirmation. Any reddish-purple line (regardless of the color intensity) visible at 5 minutes 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 System 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 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® 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® Cup Package Insert-II 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**

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

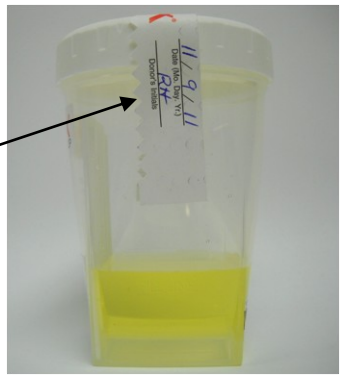
1. Ensure that the lid to the specimen cup is tightly sealed to prevent leakage during transport.


2. Fill out Chain-of-Custody form and attach Chain-of-Custody seal. (*see pages 8-11 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.



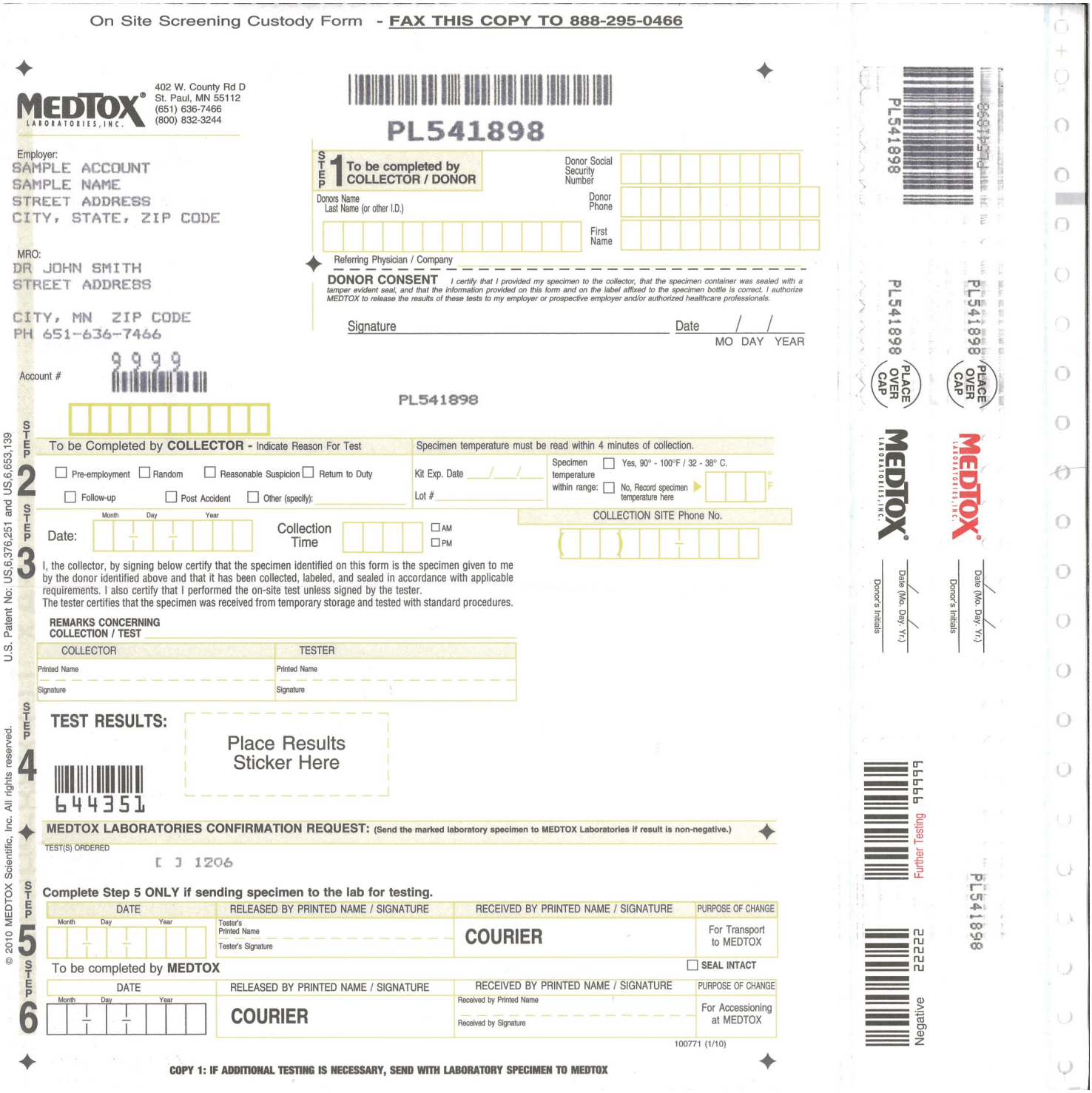
3. Donor should initial and date the seal in space provided before applying the seal to the container.

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, Seals Intact



On Site Screening Custody Form - FAX THIS COPY TO 888-295-0466

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

PL541898

Employer:
SAMPLE ACCOUNT
SAMPLE NAME
STREET ADDRESS
CITY, STATE, ZIP CODE

MRO:
DR JOHN SMITH
STREET ADDRESS

CITY, MN ZIP CODE
PH 651-636-7466

Account # 9999

STEP 1 To be completed by COLLECTOR / DONOR

Donors Name Last Name (or other I.D.)

Donor Social Security Number

Donor Phone

First Name

Referring Physician / Company

DONOR CONSENT I certify that I provided my specimen to the collector, that the specimen container was sealed with a tamper evident seal, and that the information provided on this form and on the label affixed to the specimen bottle is correct. I authorize MEDTOX to release the results of these tests to my employer or prospective employer and/or authorized healthcare professionals.

Signature _____ Date / / MO DAY YEAR

PL541898

STEP 2 To be Completed by COLLECTOR - Indicate Reason For Test

☐ Pre-employment ☐ Random ☐ Reasonable Suspicion ☐ Return to Duty
☐ Follow-up ☐ Post Accident ☐ Other (specify):

Kit Exp. Date ___/___/___
Lot # _____

Specimen temperature must be read within 4 minutes of collection.
Specimen temperature within range: ☐ Yes, 90° - 100°F / 32 - 38° C. ☐ No, Record specimen temperature here °F

STEP 3 Date: Month Day Year

Collection Time ☐ AM ☐ PM

COLLECTION SITE Phone No. ( ) -

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 unless signed by the tester.
The tester certifies that the specimen was received from temporary storage and tested with standard procedures.

REMARKS CONCERNING COLLECTION / TEST

| COLLECTOR | TESTER |
|---|---|
| Printed Name | Printed Name |
| Signature | Signature |

STEP 4 TEST RESULTS:

Place Results Sticker Here

644351

MEDTOX LABORATORIES CONFIRMATION REQUEST: (Send the marked laboratory specimen to MEDTOX Laboratories if result is non-negative.)

TEST(S) ORDERED

[ ] 1206

STEP 5 Complete Step 5 ONLY if sending specimen to the lab for testing.

| DATE | RELEASED BY PRINTED NAME / SIGNATURE | RECEIVED BY PRINTED NAME / SIGNATURE | PURPOSE OF CHANGE |
|---|---|---|---|
| Month Day Year | Tester's Printed Name / Tester's Signature | COURIER | For Transport to MEDTOX |

To be completed by MEDTOX ☐ SEAL INTACT

STEP 6

| DATE | RELEASED BY PRINTED NAME / SIGNATURE | RECEIVED BY PRINTED NAME / SIGNATURE | PURPOSE OF CHANGE |
|---|---|---|---|
| Month Day Year | COURIER | Received by Printed Name / Received by Signature | For Accessioning at MEDTOX |

100771 (1/10)

COPY 1: IF ADDITIONAL TESTING IS NECESSARY, SEND WITH LABORATORY SPECIMEN TO MEDTOX

PLACE OVER CAP

MEDTOX® LABORATORIES, INC.

Donor's Initials

Date (Mo. Day. Yr.)

99999 Further Testing

22222 Negative

PL541898

U.S. Patent No: US,6,376,251 and US,6,653,139

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Contact your confirmation laboratory to obtain the proper collection and shipping supplies.

## Chain-of-Custody Form, Negative

On Site Screening Custody Form - **FAX THIS COPY TO 888-295-0466**

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

PL541898

Employer:
SAMPLE ACCOUNT
SAMPLE NAME
STREET ADDRESS
CITY, STATE, ZIP CODE

MRO:
DR JOHN SMITH
STREET ADDRESS

CITY, MN ZIP CODE
PH 651-636-7466

Account # 9999

PL541898

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

Donors Name Last Name (or other I.D.): DOE
First Name: JANE
Donor Social Security Number: 987654321
Donor Phone: 5555454545

Referring Physician / Company

**DONOR CONSENT** *I certify that I provided my specimen to the collector, that the specimen container was sealed with a tamper evident seal, and that the information provided on this form and on the label affixed to the specimen bottle is correct. I authorize MEDTOX to release the results of these tests to my employer or prospective employer and/or authorized healthcare professionals.*

Signature Jane Doe Date 11/9/11 (MO DAY YEAR)

**STEP 2** To be Completed by **COLLECTOR** - Indicate Reason For Test

☒ Pre-employment ☐ Random ☐ Reasonable Suspicion ☐ Return to Duty
☐ Follow-up ☐ Post Accident ☐ Other (specify):

Specimen temperature must be read within 4 minutes of collection.

Kit Exp. Date 10/31/12
Lot # 12345

Specimen temperature within range: ☒ Yes, 90° - 100°F / 32 - 38° C. ☐ No, Record specimen temperature here °F

**STEP 3** Date: Month 11 Day 09 Year 2011

Collection Time 1030 ☒ AM ☐ PM

COLLECTION SITE Phone No. 8883242468

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 unless signed by the tester.
The tester certifies that the specimen was received from temporary storage and tested with standard procedures.

REMARKS CONCERNING COLLECTION / TEST

| COLLECTOR | TESTER |
|---|---|
| Printed Name JOHN SMITH | Printed Name |
| Signature John Smith | Signature |

**STEP 4** TEST RESULTS:

644351

Negative 22222

**MEDTOX LABORATORIES CONFIRMATION REQUEST:** (Send the marked laboratory specimen to MEDTOX Laboratories if result is non-negative.)

TEST(S) ORDERED

[ ] 1206

**STEP 5** Complete Step 5 ONLY if sending specimen to the lab for testing.

| DATE (Month Day Year) | RELEASED BY PRINTED NAME / SIGNATURE | RECEIVED BY PRINTED NAME / SIGNATURE | PURPOSE OF CHANGE |
|---|---|---|---|
| | Tester's Printed Name / Tester's Signature | COURIER | For Transport to MEDTOX |

To be completed by **MEDTOX** ☐ SEAL INTACT

**STEP 6**

| DATE (Month Day Year) | RELEASED BY PRINTED NAME / SIGNATURE | RECEIVED BY PRINTED NAME / SIGNATURE | PURPOSE OF CHANGE |
|---|---|---|---|
| | COURIER | Received by Printed Name / Received by Signature | For Accessioning at MEDTOX |

100771 (1/10)

**COPY 1: IF ADDITIONAL TESTING IS NECESSARY, SEND WITH LABORATORY SPECIMEN TO MEDTOX**

U.S. Patent No: US,6,376,251 and US,6,653,139
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## Chain-of-Custody Form, Further Testing

On Site Screening Custody Form - **FAX THIS COPY TO 888-295-0466**

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

PL541898

Employer:
SAMPLE ACCOUNT
SAMPLE NAME
STREET ADDRESS
CITY, STATE, ZIP CODE

MRO:
DR JOHN SMITH
STREET ADDRESS

CITY, MN ZIP CODE
PH 651-636-7466

Account # 9999

PL541898

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

Donors Name Last Name (or other I.D.): DOE
First Name: JANE
Donor Social Security Number: 987654321
Donor Phone: 5555454545
Referring Physician / Company:

**DONOR CONSENT** *I certify that I provided my specimen to the collector, that the specimen container was sealed with a tamper evident seal, and that the information provided on this form and on the label affixed to the specimen bottle is correct. I authorize MEDTOX to release the results of these tests to my employer or prospective employer and/or authorized healthcare professionals.*

Signature Jane Doe Date 11/9/11 (MO DAY YEAR)

**STEP 2** To be Completed by **COLLECTOR** - Indicate Reason For Test

Specimen temperature must be read within 4 minutes of collection.

☒ Pre-employment ☐ Random ☐ Reasonable Suspicion ☐ Return to Duty
☐ Follow-up ☐ Post Accident ☐ Other (specify):

Kit Exp. Date 10/31/12
Lot # 12345

Specimen temperature within range: ☒ Yes, 90° - 100°F / 32 - 38° C. ☐ No, Record specimen temperature here °F

**STEP 3** Date: Month Day Year 11092011 Collection Time 1030 ☒ AM ☐ PM

COLLECTION SITE Phone No. 8883242468

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 unless signed by the tester.
The tester certifies that the specimen was received from temporary storage and tested with standard procedures.

REMARKS CONCERNING COLLECTION / TEST

| COLLECTOR | TESTER |
|---|---|
| Printed Name JOHN SMITH | Printed Name |
| Signature John Smith | Signature |

**STEP 4** TEST RESULTS:

644351

Further Testing 99999

**MEDTOX LABORATORIES CONFIRMATION REQUEST:** (Send the marked laboratory specimen to MEDTOX Laboratories if result is non-negative.)

TEST(S) ORDERED
[X] 1206

**STEP 5** Complete Step 5 ONLY if sending specimen to the lab for testing.

| DATE (Month Day Year) | RELEASED BY PRINTED NAME / SIGNATURE | RECEIVED BY PRINTED NAME / SIGNATURE | PURPOSE OF CHANGE |
|---|---|---|---|
| 11092011 | Tester's Printed Name JOHN SMITH<br>Tester's Signature John Smith | COURIER | For Transport to MEDTOX |

☐ SEAL INTACT

**STEP 6** To be completed by **MEDTOX**

| DATE (Month Day Year) | RELEASED BY PRINTED NAME / SIGNATURE | RECEIVED BY PRINTED NAME / SIGNATURE | PURPOSE OF CHANGE |
|---|---|---|---|
| | COURIER | Received by Printed Name<br>Received by Signature | For Accessioning at MEDTOX |

100771 (1/10)

**COPY 1: IF ADDITIONAL TESTING IS NECESSARY, SEND WITH LABORATORY SPECIMEN TO MEDTOX**

U.S. Patent No: US,6,376,251 and US,6,653,139
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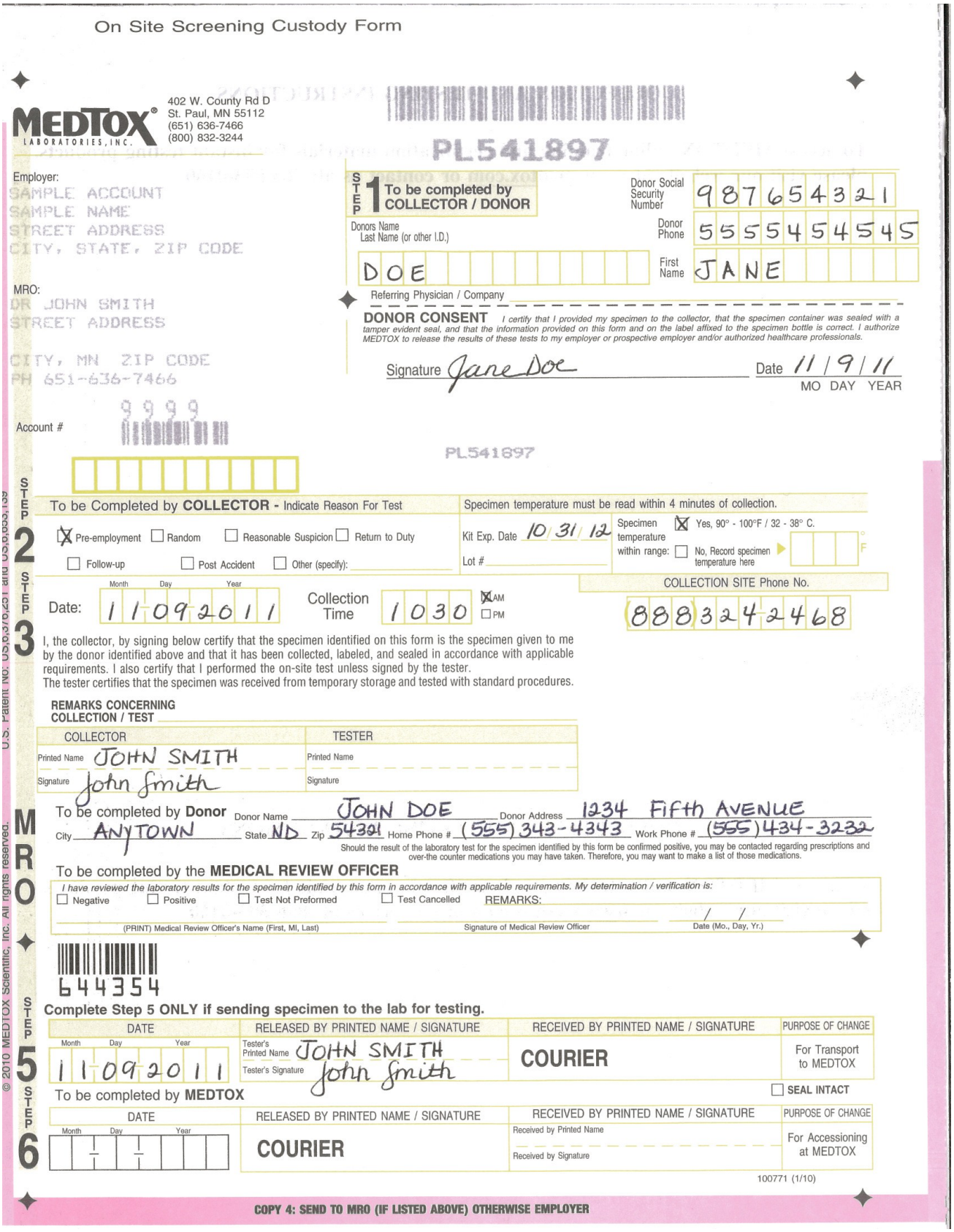
## Chain-of-Custody Form, MRO



On Site Screening Custody Form

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

PL541897

Employer:
SAMPLE ACCOUNT
SAMPLE NAME
STREET ADDRESS
CITY, STATE, ZIP CODE

MRO:
DR JOHN SMITH
STREET ADDRESS
CITY, MN ZIP CODE
PH 651-636-7466

Account # 9999

STEP 1 To be completed by COLLECTOR / DONOR

Donors Name Last Name (or other I.D.): DOE
First Name: JANE
Donor Social Security Number: 987654321
Donor Phone: 5555454545
Referring Physician / Company:

DONOR CONSENT *I certify that I provided my specimen to the collector, that the specimen container was sealed with a tamper evident seal, and that the information provided on this form and on the label affixed to the specimen bottle is correct. I authorize MEDTOX to release the results of these tests to my employer or prospective employer and/or authorized healthcare professionals.*

Signature Jane Doe Date 11/9/11 (MO DAY YEAR)

PL541897

STEP 2 To be Completed by COLLECTOR - Indicate Reason For Test

Specimen temperature must be read within 4 minutes of collection.

☒ Pre-employment ☐ Random ☐ Reasonable Suspicion ☐ Return to Duty
☐ Follow-up ☐ Post Accident ☐ Other (specify):

Kit Exp. Date 10/31/12
Lot #
Specimen temperature within range: ☒ Yes, 90° - 100°F / 32 - 38° C. ☐ No, Record specimen temperature here °F

STEP 3 Date (Month Day Year): 11092011 Collection Time: 1030 ☒ AM ☐ PM

COLLECTION SITE Phone No.: 8883242468

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 unless signed by the tester.
The tester certifies that the specimen was received from temporary storage and tested with standard procedures.

REMARKS CONCERNING COLLECTION / TEST

| COLLECTOR | TESTER |
|---|---|
| Printed Name JOHN SMITH | Printed Name |
| Signature John Smith | Signature |

MRO

To be completed by Donor
Donor Name JOHN DOE Donor Address 1234 Fifth AVENUE
City ANYTOWN State ND Zip 54321 Home Phone # (555)343-4343 Work Phone # (555)434-3232

Should the result of the laboratory test for the specimen identified by this form be confirmed positive, you may be contacted regarding prescriptions and over-the counter medications you may have taken. Therefore, you may want to make a list of those medications.

To be completed by the MEDICAL REVIEW OFFICER

*I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable requirements. My determination / verification is:*
☐ Negative ☐ Positive ☐ Test Not Preformed ☐ Test Cancelled REMARKS:

(PRINT) Medical Review Officer's Name (First, MI, Last) Signature of Medical Review Officer Date (Mo., Day, Yr.) / /

644354

STEP 5 Complete Step 5 ONLY if sending specimen to the lab for testing.

| DATE (Month Day Year) | RELEASED BY PRINTED NAME / SIGNATURE | RECEIVED BY PRINTED NAME / SIGNATURE | PURPOSE OF CHANGE |
|---|---|---|---|
| 11092011 | Tester's Printed Name JOHN SMITH<br>Tester's Signature John Smith | COURIER | For Transport to MEDTOX |

☐ SEAL INTACT

STEP 6 To be completed by MEDTOX

| DATE (Month Day Year) | RELEASED BY PRINTED NAME / SIGNATURE | RECEIVED BY PRINTED NAME / SIGNATURE | PURPOSE OF CHANGE |
|---|---|---|---|
| / / | COURIER | Received by Printed Name<br>Received by Signature | For Accessioning at MEDTOX |

100771 (1/10)

COPY 4: SEND TO MRO (IF LISTED ABOVE) OTHERWISE EMPLOYER

U.S. Patent No. US 6,375,612 and US 6,893,139
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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.

# EZ-SCREEN® CUP

Package Insert-II


## Troubleshooting Guide
## Presented by:

MEDTOX®

**www.medtox.com**
**866-593-0160**

# 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-II


## Certification Quiz
## Presented by:

MEDTOX®

**www.medtox.com**
**866-593-0160**

# 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. The EZ-SCREEN® 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:

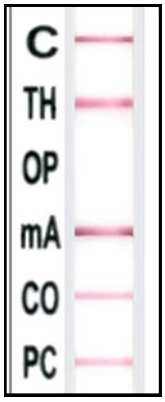
   A. No control (C) line is present on one or more strips
   B. The urine is yellow and looks concentrated
   C. Control (C) lines are present
   D. The urine is pale, colorless, and looks dilute

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: →

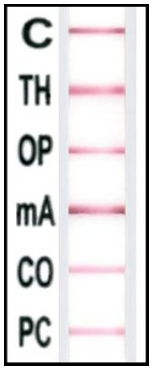
   A. Non-Negative (presumptive positive) for OP and the test is valid
   B. Non-Negative (presumptive positive) for TH, mA, CO, and PC
   C. Invalid and test should be repeated
   D. Non-Negative (presumptive positive) for OP and the test is invalid



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

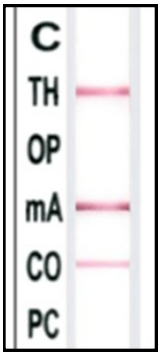
   A. True
   B. False

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® 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® 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® 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® 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 and then poured into an EZ-SCREEN® Cup may produce erroneous results.

    A. True
    B. False

# EZ-SCREEN® 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, a score of 80% or higher must be obtained (16 out of 20 or better).

| | | |
|---|---|---|
| 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: 1-888-378-7265
Or email answers to: profiletraining@medtox.com

Or Mail to: MEDTOX Laboratories, Inc.
Attn: EZ-SCREEN® Cup Certification
402 West County Road D
Saint Paul, MN 55112

Please call 866-593-0160 with any questions or email profiletraining@medtox.com.

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