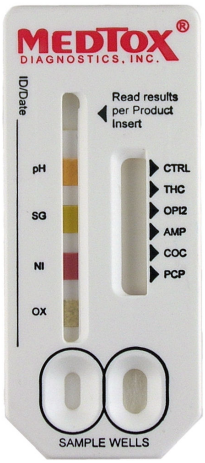
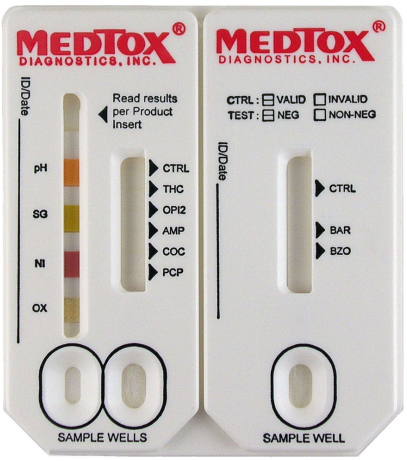
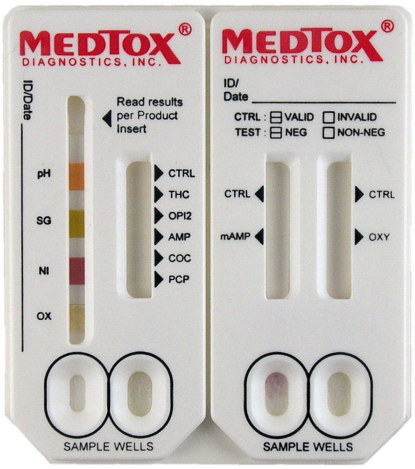
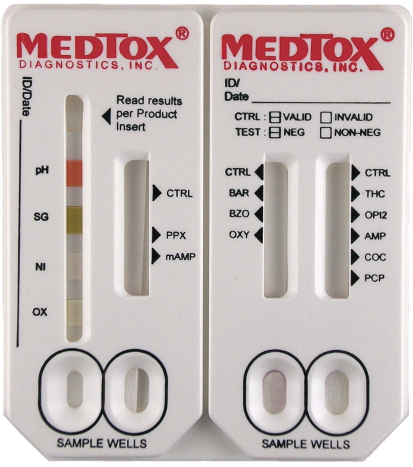
PROFILE® - II and PROFILE® - IIA with Paper Chain-of-Custody Forms









Training and Certification Program
Presented by:

MEDTOX®

www.medtox.com
888-324-2468

Intended Use

The PROFILE® -II Drugs of Abuse Test is a one-step immunochromatographic test for the rapid, qualitative detection of one or more of the following: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methamphetamine/ 3,4 Methylenedioxymethamphetamines, Opiates, Oxycodone, Phencylidine, Propoxyphene and THC (Cannabinoids) in human urine. It is not for over the counter sale. (Specific configurations listed below.) Some product configurations include a Lateral Flow Adulteration panel (LFAS).

PROFILE® -II / PROFILE® -IIA Panel Configurations

PROFILE® -IIA 5 Panel
Detects the major metabolites of these drugs: Cannabinoids (11-nor-9-carboxy-Δ^9-THC). Cocaine (Benzoylecgonine), Opiates (Morphine-Codeine), Amphetamines (d-Amphetamine), and Phencyclidine and LFAS.

PROFILE® -IIA 7 Panel
Detects the major metabolites of these drugs: Cannabinoids (11-nor-9-carboxy-Δ^9-THC), Cocaine (Benzoylecgonine), Opiates (Morphine-Codeine), Amphetamines (d-Amphetamine), Phencyclidine, Barbiturates (Phenobarbital), and Benzodiazepines (nordiazepam) and LFAS.

PROFILE® -IIA 7 Panel
Detects the major metabolites of these drugs: Cannabinoids (11-nor-9-carboxy-Δ^9-THC), Cocaine (Benzoylecgonine), Opiates (Morphine-Codeine), Amphetamines (d-Amphetamine), Phencyclidine, Methamphetamine (mAMP), Oxycodone, and LFAS.

PROFILE® -IIA 10 Panel
Detects the major metabolites of these drugs: Cannabinoids (11-nor-9-carboxy-Δ^9-THC), Cocaine (Benzoylecgonine), Opiates (Morphine-Codeine), Amphetamines (d-Amphetamine), Phencyclidine, Barbiturates (Phenobarbital), and Benzodiazepines (nordiazepam), Propoxyphene, and Methamphetamine (mAMP), Oxycodone and LFAS.

The test detects drug classes at the following cutoff concentrations:

AMP	Amphetamine (d-Amphetamine)	1000 ng/ml
BAR	Barbiturates (Butalbital)	200 ng/ml
BZO	Benzodiazepines (Nordiazepam)	300 ng/ml
COC	Cocaine (Benzoylecgonine)	300 ng/ml
MAMP	Methamphetamine (d-methamphetamine)	1000 ng/ml
MDMA	3,4 Methylenedioxymethamphetamine (Ecstasy)	1500 ng/ml
OPI	Opiates (Codeine/Morphine)	2000 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
THC	Cannabinoids (11-nor-9-carboxy-Δ^9-THC)	50 ng/ml

LFAS *- Test devices contain a membrane strip laminated with adulterant test pads, testing for the presence of* ***Oxidants*** *and* ***Nitrites****, as well as determining approximate values of* ***pH*** *and* ***Specific Gravity****.*

The PROFILE® -II/PROFILE® -IIA 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) or High Performance Liquid Chromatography (HPLC) or Liquid Chromatography/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Kit Contents:

The PROFILE® -II Drugs of Abuse Test System kit contains 25 test system bags and one instructional Quick Start guide. Product inserts are available at http://www.medtox.com/ProductTraining.aspx.

Test System Contents:

1. One test device and pipette in a foil package.
    A. The test strips each contain a membrane coated with drug conjugate and a pad coated with antibody dye complexes in a protein matrix.
    B. LFAS test devices contain a membrane strip laminated with adulterant test pads for testing the presence of Oxidants and Nitrites, as well as determining approximate values of Specific Gravity and pH in human urine.
2. Collection cup with temperature strip attached.
3. Split specimen urine transfer tubes.
4. One color comparator chart (for LFAS test devices).
5. Specimen biohazard bag.
6. UPS shipping supplies (lab pack, Saturday stickers and window pouch). To print your own UPS airbills, go to http://medtox.upsrow.com.
7. Customized onsite chain-of-custody forms.
8. Package insert.

Precautions:

1. Urine specimens and all materials coming in contact with them should be handled and disposed of as if infectious and capable of transmitting infection. Never pipette by mouth and avoid contact with broken skin.
2. Avoid cross-contamination of urine samples by using a new urine specimen container for each urine sample.
3. The device should remain in its original sealed foil pouch until ready to use. If the pouch is damaged, do not use the test.
4. Test kits should be stored at 36-77°F (2-25°C) and should be refrigerated if temperature exceeds 77°F (25°C).
5. If devices have been stored refrigerated, bring to ambient temperature (18-25°C / 64-77°F) prior to opening foil pouch.
6. Do not use tests after the expiration date printed on the package label.
7. The drug screen portion of the device is for in-vitro diagnostic use only. The LFAS strip is for forensic/toxicology use only.
8. PROFILE® -II provides only a preliminary, qualitative, analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Mass Spectrometry is the preferred confirmatory method (i.e. GC/MS or LC/MS/MS).
9. Adulteration may produce inaccurate test results.
10. Use a new pipette for each urine sample.
11. PROFILE® -II test device is for in-vitro diagnostic use only.
12. Do not overfill the sample well. Using more than 100 µl of urine in each sample well can cause over-saturation and may produce inaccurate results.

Specimen Collection Procedures:

Step 1 - Verify donor's identity. Donor must provide a photo I.D. or be positively identified by employer's representative.

Step 2 - Begin Step 1 of chain-of-custody form by having the donor write in their name and social security number/ employee id number. Then have the donor complete the MRO section on copy 4 of the chain-of-custody form.

Step 3 - Donor's outer garments and personal belongings are to be left outside collection area. Wallet may be retained.

Step 4 - Collector inspects the contents of the donor's pockets.

Step 5 - Instruct donor to wash his hands prior to the collection.

Step 6 - Open a MEDTOX test system bag and split specimen collection kit in the presence of the donor.

Step 7 - Instruct donor to provide at least 60 milliliters of urine into the calibrated collection container with temperature strip.

Step 8 - Check the temperature of the sample within four minutes. Acceptable range is 90° - 100° F (32° - 38° C). Record results in Step 2 on the chain-of-custody form.

Step 9 - Inspect the sample for unusual odor, presence of foreign objects or material, or other signs of tampering (e.g. blue dye in specimen, smell of bleach).

Step 10 - In full view of donor; both specimen transfer tubes are opened.

Step 11 - Pour at least 30 milliliters of urine into each specimen transfer tube and secure lids.

Step 12 - Place a security seal over the top and down the side of each urine transfer tube. Have the donor initial each security seal. Collector dates each seal.

Step 13 - Complete Step 1 of chain-of-custody form by having donor sign the consent statement.

Step 14 - Collector completes Step 3 by dating, printing and signing their name.

Step 15 - Place the sealed specimens in the back pocket of the biohazard bag. Place all copies of the chain-of-custody form, except the green donor copy, into the front pocket of the biohazard bag. DO NOT SEAL THE BAG.

Step 16 - Give the donor their copy of the chain-of-custody form. The collector procedure is now complete and the donor may leave the collection facility.

Step 17 - The specimens are now secure for temporary storage.

PROFILE® -II Test Procedures

There are up to three drug test strips and lateral flow adulteration strip (on LFAS test devices) on the PROFILE®-II / PROFILE®-IIA devices. Each drug strip has a control (CTRL), which determines that the proper amount of urine has been used. The control line must form to have a valid result for that drug strip.

Step 1 - Remove chain-of-custody form and one specimen from the biohazard bag.

Step 2 - Remove foil sealed PROFILE®-II test device. Check the expiration date, record it and the lot number in Step 2 on the chain-of-custody form.

Step 3 - Complete Step 3 of the chain-of-custody form by writing in the tester's name and obtaining their signature. (Only required if the tester and the collector of the sample are not the same individual.)

Step 4 - Open one foil sealed device for the test to be performed.

Step 5 - Hold the 100 µl sample pipette by the upper bulb.

Step 6 - Open the sealed specimen bottle. Lower the pipette stem into the urine sample. Squeeze the upper bulb then release it slowly. (This motion will draw 100 µl of urine into the stem.) The urine sample should reach the top of the stem, and overflow slightly into the middle bulb. If not, repeat this process.

Step 7 - Dispense the 100 µl sample into the sample well by squeezing the upper bulb. This will empty the stem delivering the entire contents into the sample well. Excess urine will remain in the overflow bulb. Apply 100 µl of sample ONE time into EACH sample well.

Step 8 - Read pH, Specific Gravity, and Nitrites as soon as color changes on LFAS strip. Read oxidant at 60 seconds.

Step 9 - Read the test at 5 minutes after sample application. Test results read after 5 minutes may not be consistent with those at 5 minutes.

Step 10 - Complete the chain-of-custody form by removing the appropriate negative/further testing sticker and placing it onto the results sticker box in Step 4. (If applicable, turn to Copy 2 and annotate the results in the boxes provided.)

Step 11 - If the test result is NEGATIVE:

- Fax the top copy of the chain-of-custody form to the MEDTOX Fax Result Line at 1-888-295-0466. (No cover page is necessary.)
- Send the MRO copy (pink) to the MRO, if one is designated.
- Discard the specimen and file the chain-of-custody form for your records.

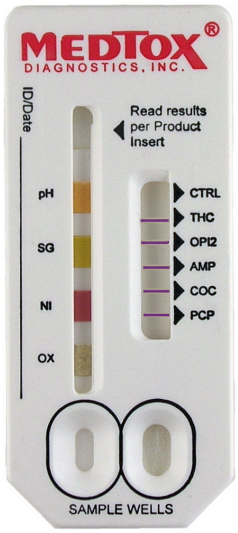
If the test needs FURTHER TESTING (NON-NEGATIVE), or results are Abnormal:

- Place the top copy of the chain-of-custody form and the remaining sealed sample into the biohazard bag and transport to MEDTOX overnight via UPS. Apply Saturday deliver sticker to shipments being picked up on Fridays.
- Send Copy 4 (pink) to the MRO, if one is designated, otherwise send it to the employer.
- Discard the remaining unsealed specimen and file the clinic copy (yellow).

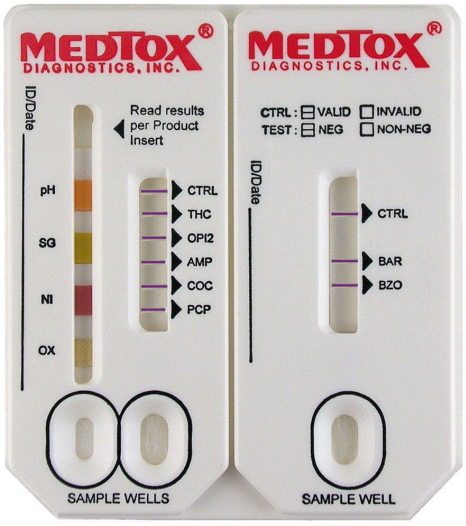
Interpreting PROFILE® -II Test Results

WHEN IN DOUBT - SEND IT OUT!

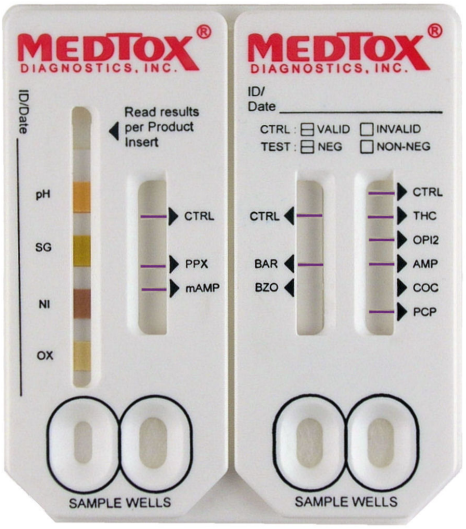
INVALID TEST
The absence of a reddish-purple Control (CTRL) line indicates the test is invalid. The urine sample should be retested on a new device. If the second test is also invalid, send the urine sample to a reference laboratory for additional testing.



NEGATIVE TEST
The appearance of both a reddish-purple Control (CTRL) line and a specific drug line indicates a negative test result. The color intensities of the Control line and a specific drug line may not be equal; any reddish-purple line visible at 5 minutes indicates a negative test result. Line intensity will vary from test to test.



NON-NEGATIVE TEST
The appearance of both a reddish-purple Control (CTRL) line and the absence of a line next to a specific drug name at 5 minutes indicates a preliminary positive test result for that drug. Occasionally a white line (line lighter than the background of the strip) may appear next to a specific drug name. This indicates a preliminary positive test result from the drug. In this example the COC and BZO tests are valid preliminary positives.



LFAS Test:
Urines that produce an abnormal result on the LFAS 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.

Chain-of-Custody Form, 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

PJ399677

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

PJ399677

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

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

Lot #

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

COLLECTION SITE Phone No. ( ) -

STEP 3 Date: Month Day Year

Collection Time ☐ AM ☐ PM

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:**

644351

Place Results Sticker Here

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

STEP 6 To be completed by **MEDTOX** ☐ SEAL INTACT

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 (8/08)

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

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

SPECIMEN ID NO. PJ399677

SPECIMEN ID NO. PJ399677

PLACE OVER CAP MEDTOX LABORATORIES, INC.

PLACE OVER CAP MEDTOX LABORATORIES, INC.

Donor's Initials Date (Mo. Day, Yr.)

Donor's Initials Date (Mo. Day, Yr.)

99999 Further Testing

PJ399677

22222 Negative

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

PJ399673

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

Donor Social Security Number: 987654321
Donor Phone: 5554736241
Donors Name Last Name (or other I.D.): DOE
First Name: JANE
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 2 / 24 / 09 (MO DAY YEAR)

PJ399673

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 10
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): 02 24 2009
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

STEP 6 To be completed by **MEDTOX** ☐ SEAL INTACT

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 (8/08)

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

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

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

PJ399671

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

Donor Social Security Number: 123456789
Donors Name Last Name (or other I.D.): DOE
First Name: JOHN
Donor Phone: 5556986139
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 John Doe Date 02/24/09 (MO DAY YEAR)

PJ399671

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 10
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): 02 24 2009
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
[ ] 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
02 24 2009	Tester's Printed Name JOHN SMITH Tester's Signature John Smith	COURIER	For Transport to MEDTOX

STEP 6 To be completed by **MEDTOX** ☐ SEAL INTACT

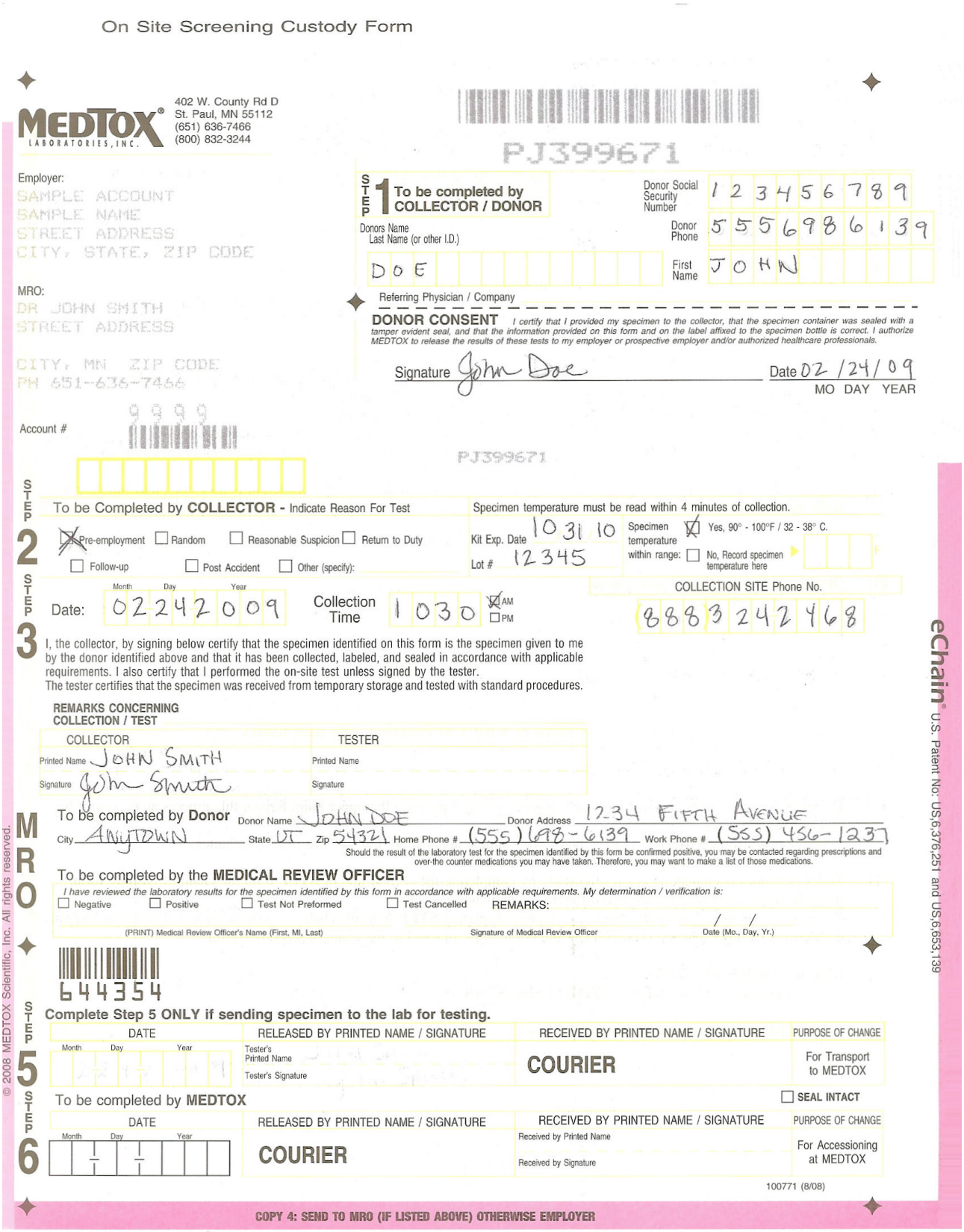
DATE (Month Day Year)	RELEASED BY PRINTED NAME / SIGNATURE	RECEIVED BY PRINTED NAME / SIGNATURE	PURPOSE OF CHANGE
/ /	COURIER	Received by Printed Name Received by Signature	For Accessioning at MEDTOX

100771 (8/08)

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

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

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

PJ399671

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: JOHN
Donor Social Security Number: 123456789
Donor Phone: 5556986139
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 John Doe Date 02/24/09 (MO DAY YEAR)

PJ399671

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 10
Lot # 12345
Specimen temperature within range: ☒ Yes, 90° - 100°F / 32 - 38° C. ☐ No, Record specimen temperature here

STEP 3 Date: Month 02 Day 24 Year 2009
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 UT Zip 54321 Home Phone # (555) 698-6139 Work Phone # (555) 456-1237
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	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

STEP 6 To be completed by MEDTOX ☐ SEAL INTACT

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 (8/08)

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

eChain® U.S. Patent No: US6,376,251 and US6,653,139

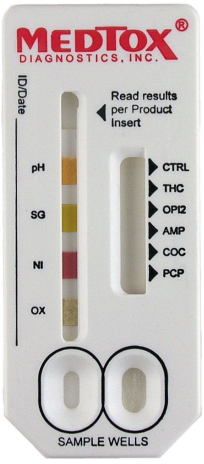
Limitations of Procedure

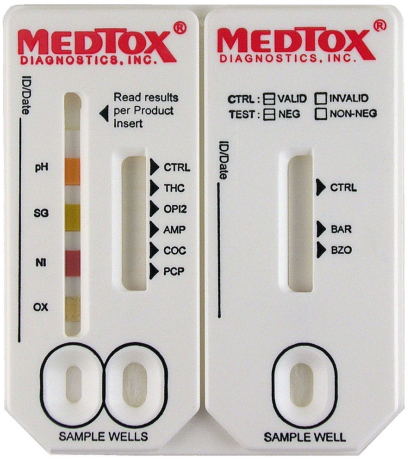
- The PROFILE® -II Drugs of Abuse Test System is only for use with unadulterated human urine samples. Urine samples which are either extremely acidic (below pH 4.0) or basic (above pH 9.0) may produce erroneous results.
- A non-negative (presumptive positive) test result for a specific drug indicates 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. Non-negative (presumptive positive) samples should be sent to a reference laboratory for more definitive testing.
- Test results interpreted after 5 minutes may not be reliable.
- The PROFILE® -II Drugs of Abuse Test System was not evaluated in point-of-collection settings.
- There is a possibility that other substances and/or factors, e.g. technical or procedural errors, may interfere with the test and cause false results.

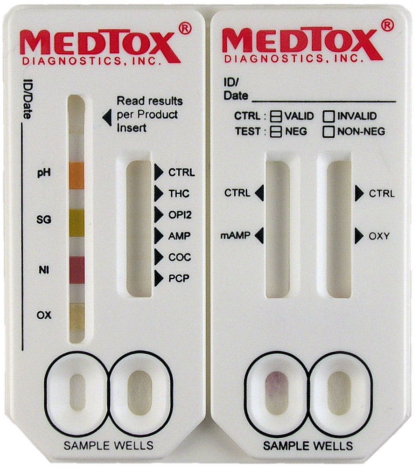
You have now completed the PROFILE® -II training program. To achieve certification as a tester with this device, you must successfully complete the following ten question certification quiz with a score of 80% or higher.

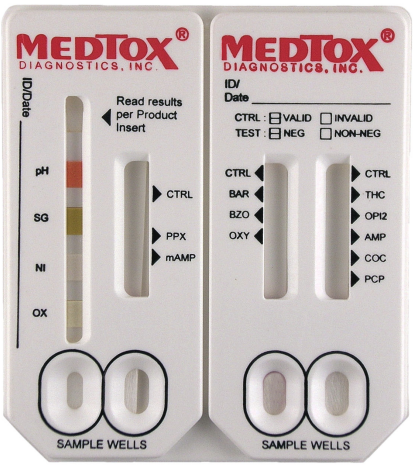
If you have any questions and would like to speak to a service representative, please call 888-324-2468 or email us at echain@medtox.com.

PROFILE® - II and PROFILE® - IIA with Paper Chain-of-Custody Forms









Certification Quiz
Presented by:

MEDTOX®

www.medtox.com
888-324-2468

PROFILE® -II CERTIFICATION QUIZ

After reading each question completely, choose the best answer. Record your answers on the answer sheet found at the end of the quiz. To receive a certification of achievement, fax your answer sheet to MEDTOX at 866-398-3783, or email to echain@medtox.com.

1. Depending on configuration, PROFILE® -II tests a single urine sample for:

    A. amphetamines, cocaine, opiates, PCP, THC
    B. amphetamines, barbiturates, benzodiazepines, cocaine, opiates, PCP, THC
    C. amphetamines, barbiturates, benzodiazepines, cocaine, methamphetamine , opiates, Oxycodone, PCP, propoxyphene, THC
    D. All of the above

2. The entire test is invalid if:

    A. No control (CTRL) line forms in the window
    B. The urine sample smells bad
    C. Control (CTRL) line only forms
    D. A and C only

3. PROFILE® -II devices should be stored at:

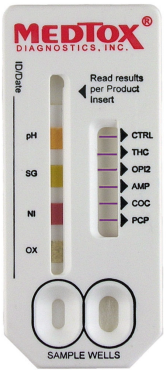
    A. 25° -57° F
    B. 36° -77° F
    C. 25° -77° F
    D. 35° -88° F
    E. 15° -57° F

4. PROFILE® -II provides a:

    A. Confirmed analytical result
    B. Quantitative analytical result
    C. Preliminary test result
    D. Qualitative test result
    E. C and D only

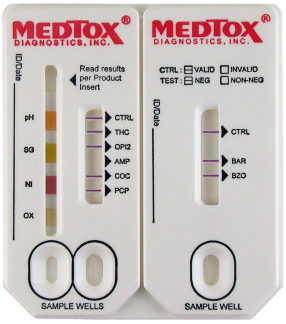
5. Interpret the following test:

    A. Negative for all five drugs
    B. Valid test
    C. Invalid test
    D. Non-negative for THC
    E. A and B only



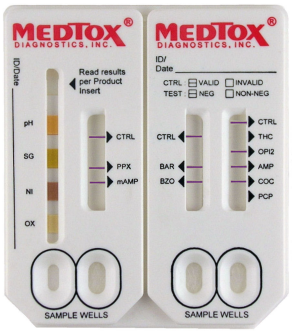
6. Interpret the following test:

   A. Non-Negative for amphetamines
   B. Negative for all seven drugs
   C. Valid test
   D. Invalid test
   E. A and C only



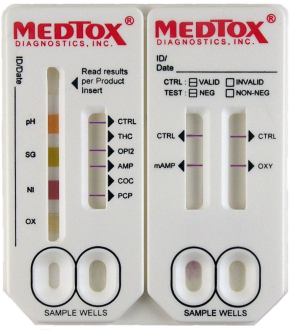
7. Interpret the following test:

   A. Non-Negative for THC, PCP
   B. Negative for THC, PCP
   C. Negative for all nine drugs
   D. Non-negative for OPI, AMP, COC
   E. Invalid test



8. Interpret the following test:

   A. Non-Negative for THC, COC
   B. Non-Negative for OPI, AMP, PCP
   C. Negative for OPI only
   D. Negative for THC, COC
   E. Invalid test



9. The control (CTRL) line:

    A. Should exhibit a reddish-purple line
    B. Should have no line appear
    C. Is used as a comparative indicator
    D. B and C only

10. PROFILE® -II test results may be safely interpreted:

    A. Immediately after the test is completed
    B. As soon as the control (CTRL) line appears in the window
    C. At 5 minutes
    D. Within one hour after the test is completed

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

    A. If the kit has not been opened
    B. Never
    C. Within one month after the expiration date
    D. Only if the kit has been frozen

12. Each test result should be:

    A. Separately and independently compared to the control line
    B. Separately and independently compared to the negative control line
    C. Separately and independently evaluated for the presence or absence of a line
    D. Compared to adjacent test lines

13. The following information is required on the chain-of-custody form:

    A. Donor identification number
    B. Date of collection
    C. Specimen temperature in or out of range
    D. Name of collector and tester
    E. All of the above

14. When the donor presents the urine sample to the collector:

    A. Donor must leave the facility prior to dividing the sample into the urine transfer tubes
    B. The collector will already have opened specimen transfer tubes and the collector will be ready to split the sample
    C. Collector should check the temperature of the sample and annotate it on the chain-of-custody form in Step 2
    D. Collector should open both urine transfer tubes in full view of the donor and pour at least 30 ml into each urine transfer tube from the original collection container
    E. Both C and D

15. The following statement is not true:

    A. Donor is instructed to wash hands prior to collection
    B. Donor is instructed to provide at least 60 ml of urine
    C. Donor initials and dates the security seals that have been affixed to the urine transfer tubes
    D. Donor is instructed that he cannot wear his coat inside the collection area
    E. Photo I.D. is not required if positive identification is provided by the employer's representative

PROFILE® -II

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 at 866-398-3783, or email to echain@medtox.com. A Certification of Achievement will be faxed to you if you receive a scored of 80% or higher.

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

Name (please print): _____

Company Name: _____

Address: _____

City, State, Zip : _____

Telephone: _____

Fax: _____

Email: _____

Or Mail to: MEDTOX Laboratories
Attn: PROFILE® Certification
402 West County Road D
Saint Paul, MN 55112

Or email answers to: echain@medtox.com

Please call 888-324-2468 with any questions, or email echain@medtox.com.

8.2009