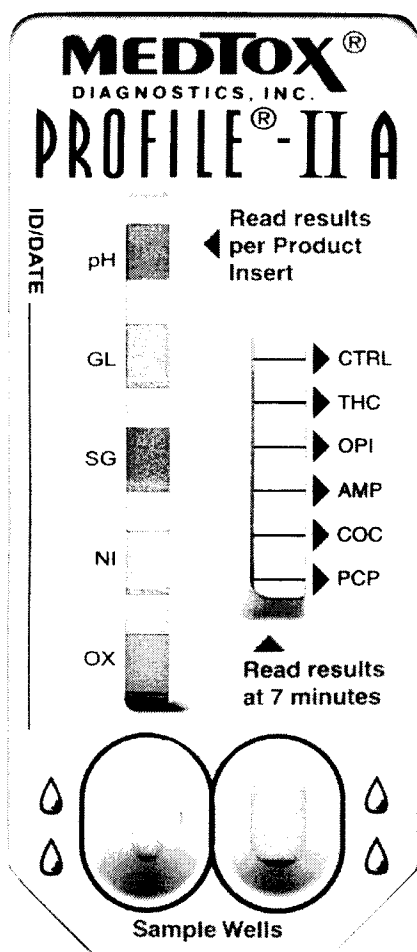


# PROFILE<sup>®</sup>-IIA



## TRAINING & CERTIFICATION PROGRAM

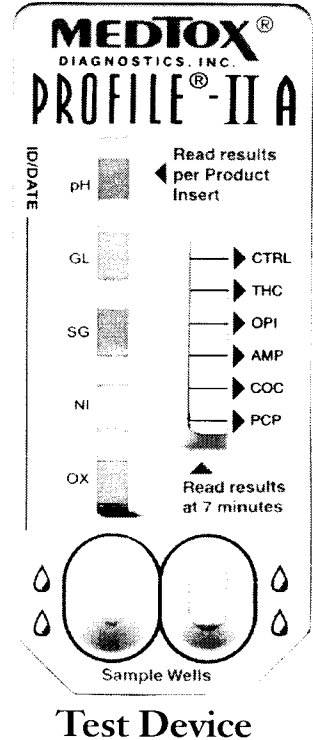
*Presented by:*

**MEDTOX<sup>®</sup>**

# MEDTOX PROFILE-IIA Device

## Concept

- One company (MEDTOX Scientific) will provide all aspects of the on-site testing system.
- Evaluate urine prior to DAU testing for Oxidants, Nitrites, Glutaraldehyde, Specific Gravity, and pH values.
- Liability coverage for MEDTOX confirmed positive test results. The System is legally defensible when followed properly.
- Re-screening and, if necessary, GC/MS confirmation of non-negative specimens by MEDTOX's SAMHSA certified lab.
- Results are "captured" in a centralized database and electronically transmitted to the designated party.
- MEDTOX trains and certifies collectors/testers.



## Intended Use

Profile-IIA is a one-step immunochromatographic test for the rapid qualitative detection of cannabinoids (THC), cocaine, opiates, amphetamines and phencyclidine (PCP) in human urine. The test detects the major metabolites of these drugs at the SAMHSA recommended cutoff concentrations. The device also contains a Lateral Flow (LatFlo™) Adulterant Strip (LFAS) which is a one-step qualitative screening assay for the detection of pH - Hydrogen Ion Concentration, GL - Glutaraldehyde, SG - Specific Gravity (sample dilution), NI - Nitrites, OX - Oxidants (bleach, chromates) in human urine. The LFAS strip is only for Forensic/Toxicology use and not for in-vitro diagnostics application. This product is intended for use under medical supervision in hospitals, physicians offices, health clinics, and drug treatment/counseling centers. It is not for over-the-counter sale.

The PROFILE-IIA LatFlo Test Device 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. Laboratory confirmation with mass spectrometry is the preferred confirmatory method (GC/MS). As always, clinical consideration and professional judgment should be applied to any drugs-of-abuse test result, particularly when preliminary positive results are used.

# PROFILE-IIA Test System

## CONTENTS

- PROFILE-IIA LatFlo Test System contains:
  - FDA-cleared PROFILE-II five-panel test, lateral flow adulterant strip, and a pipette in foil package.
  - Color Comparator Chart
  - Collection Cup
  - Split specimen urine transfer tubes
  - Specimen biohazard bag
- Package insert
- Customized on-site chain of custody form
- Airborne Express labels and shipping supplies

## PRECAUTIONS

- PROFILE-IIA test devices should be stored at 35-77° (2-25°C) and brought to room temperature prior to use. Refrigerate kits prior to use if room or ambient temperatures could exceed 77°F.
- Dilution/adulteration may produce inaccurate test results on the PROFILE-II strip.
- Do not use test after Expiration Date on package label is exceeded.
- Do not freeze test kits.
- PROFILE-II provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. (GC/MS is the preferred confirmatory method.)
- Urine specimens and materials coming into contact with urine should be handled and disposed of appropriately (see package insert).
- Avoid cross-contamination of urine samples by using a new urine specimen container and pipette for each urine sample
- PROFILE-IIA test devices should remain in original sealed foil package until ready to use. If pouch integrity is damaged, do not use.
- The PROFILE-II test strip is for in vitro diagnostic use only. The LFAS strip is only for Forensic/Toxicology use and not for in vitro diagnostic applications.
- For the PROFILE-II strip, if any lines formed are outside the arrow indicated by the drug name, the test is invalid.
- If urine is stored under refrigeration, it must be brought to ambient temperature and mixed well to assure a homogenous sample prior to testing.
- Do not store urine under refrigeration for more than one day. Urine may be frozen for longer storage.

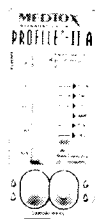
# SPECIMEN COLLECTION PROCEDURE

1. Verify the donor's identity by photo identification or positive identification by employer's representative.
2. Complete **Step 1** of the chain of custody form.
3. Have the donor complete **Step 7** on copy 4 of the chain of custody form.
4. The donor must leave outer garments (coats, coveralls, hats) and personal belongings (purses, briefcases) outside of the collection area. The donor may retain his wallet.
5. Instruct the donor to wash and dry their hands.
6. Open MEDTOX split specimen collection containers in the donor's presence.
7. Instruct the donor to provide at least 60 milliliters of urine into the calibrated collection container with temperature strip on it.
8. After obtaining the specimen from the donor, check the temperature of the sample and indicate in **Step 2** of the chain of custody form that the temperature has been checked and is within range.
9. Open the two urine transfer tubes in the donor's presence and pour at least 30 milliliters of urine into each. Secure the lids.
10. Place one security seal over the top and down the side of each bottle.
11. Have the donor initial and date the security seals that are attached to the side of the chain of custody form.
12. Begin **Step 3** on the chain of custody form by filling in line one with date, collector's name, and collector's signature.
13. Place the sealed specimens into the biohazard bag. Do not seal the bag.
14. Give the green copy of the chain of custody form to the donor. Place the remaining copies of the chain of custody form in the biohazard bag with the specimen.
15. The specimens are now secure for temporary storage.

# PROFILE-IIA TEST PROCEDURES

1. Remove chain of custody form and ONE specimen container from the biohazard bag. Remove foil sealed PROFILE-IIA test device.
2. Check the expiration date and record it and the lot number in **Step 2** on the chain of custody form.
3. Complete **Step 3** on the chain of custody form by filling in line two with date, tester's name, and tester's signature.
4. Obtain the Color Comparator chart specific for the lot of PROFILE-IIA devices being tested.
5. Open one foil sealed PROFILE-IIA test device.
6. Open the sealed specimen bottle. Squeeze end of pipette and insert into urine. Release end of pipette when full and remove.
7. Holding pipette at vertical angle, dispense exactly two (2) drops of urine into each of the sample wells.
8. For the LatFlo strip, allow the urine specimen to migrate down the test strip. Read the results for Nitrite, Specific Gravity, Glutaraldehyde, and pH immediately after the pads are wetted with the sample. Read the results for the Oxidant test pad one minute after the pads are wetted with the sample.
9. For the PROFILE-II strip, read the results at 7 minutes of sample application.
10. Complete the chain of custody form by filling in **Step 4** and annotating the results of the on-site test.
11. If the test result is negative, fax the top copy of the form to MEDTOX at 1-888-295-0466. If an MRO is listed, send the pink copy of the form to the MRO. If no MRO is listed, send this copy to the employer. Discard the specimen and keep the yellow copy for your records.
12. If the test result is non-negative, complete **Step 5** on the chain of custody form and fax the top copy to MEDTOX at 1-888-295-7559. Place the top copy of the form and the remaining sealed specimen into the biohazard bag for transport to MEDTOX via Airborne Express.

# READING THE TEST RESULTS PROFILE-II



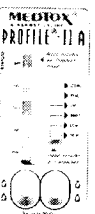
## NEGATIVE:

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 line of faint color intensity visible within 7 minutes indicates a negative result.



## NON-NEGATIVE:

The appearance of a reddish-purple control (CTRL) line and the absence of a line next to a specific drug name at 7 minutes indicates a preliminary positive test result for that specific drug.



## INVALID:

The absence of a reddish-purple Control (CTRL) line indicates the test is invalid. The urine sample should be retested on a new PROFILE-IIA device.

**LFAS Strip:** Visually compare the reagent test pads on the LFAS strip to the corresponding color blocks on the LFAS Color Comparator chart. Hold the device close to the LFAS Color Comparator chart. Carefully match the parameter pad colors on the LFAS strip with the color blocks on the LFAS Color Comparator chart. Record the results of each parameter test pad. Proper read times are critical for optimal results. The read time listed on the LFAS Color Comparator chart for each parameter test pad is to begin as soon as the parameter test pads have completely wetted. The lot number on the Color Comparator chart must match the lot number of the PROFILE-IIA device that is being utilized.

## INTERPRETATION OF TEST RESULTS

**PROFILE-II Strip:** A negative test result for a specific drug indicates that the sample does not contain the drug/drug metabolite above the cutoff level.

A positive test result for a specific drug indicates that the sample contains drug/drug metabolite at or above the cutoff level. It does not indicate the level of intoxication or the specific concentration of drug in the urine sample.

There are other possible results depending on the drug or combination of drugs present in the urine sample.

**LFAS Strip:** Results with the LatFlo reagent strip are obtained directly from the LatFlo Color Comparator chart by visual comparison. Urine specimens tested will be either 'normal or abnormal as indicated on the LatFlo Color Comparator chart. A normal specimen is considered not adulterated and an abnormal specimen is considered as a preliminary positive test result for adulteration. Abnormal specimens should be sent to a laboratory for further analysis.

# Chain-of-Custody Form, Negative

**MEDTOX FAX RESULT LINE: 888-295-0466**  
 On Site Screening Custody Form - **FAX THIS COPY**



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



**PA581152**

Employer:

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

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

Donor Social Security Number **987654321**

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

First Name

**DOE**

**JANE**

MRO

Referring Physician / Company

MRO: **JOHN SMITH**  
 STREET ADDRESS  
 CITY, STATE, ZIP CODE

**DONOR CONSENT** I certify that I provided my specimen to the collector, that the specimen container was sealed with a tamper-proof seal in my presence, and that the information provided on this form and on the label affixed to the specimen bottle is correct. I hereby give permission for the release of the results of these tests to my health care provider. In the case of screening for employment or pre-employment, I also authorize release of the results of these tests to my employer or prospective employer and / or their authorized health care professionals.

Signature

Month Day DATE Year

Account # **9999**

*Jane Doe*

**03152001**



**PA581152**

**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 **12 01 01** Specimen temperature  Yes, 90° - 100° F / 32° - 38° C  
 Lot # **12345** within range:  No, Record specimen temperature here

Collection Site Phone No. **7635551212**

**STEP 3** To be initiated by the **PERSON COLLECTING THE SPECIMEN** and **COMPLETED AS NECESSARY THEREAFTER:**

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.

DATE: Month Day Year  
**03152001**

RELEASED BY: Collector's Printed Name **JOHN SMITH**  
 Collector's Signature *John Smith*

RECEIVED BY: **TEMPORARY STORAGE**

PURPOSE OF CHANGE: Temporary Storage

Month Day Year  
**03152001** **TEMPORARY STORAGE**

Tester's Printed Name **JOHN SMITH**  
 Tester's Signature *John Smith*

Perform On-Site Test

**STEP 4** To be completed by person conducting on-site drug test only

**RESULTS OF ON-SITE SCREEN TEST:**  **NEGATIVE**  **NON-NEGATIVE: REQUIRES ADDITIONAL TESTING**

REMARKS CONCERNING COLLECTION / TEST

**45991**

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

TESTED  12



**STEP 5** Complete Step 5 ONLY if the on-site test is non-negative.

DATE: Month Day Year

RELEASED BY PRINTED NAME / SIGNATURE  
 Tester's Printed Name  
 Tester's Signature

RECEIVED BY PRINTED NAME / SIGNATURE  
**COURIER**

PURPOSE OF CHANGE: For Transport to MEDTOX

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

DATE: Month Day Year

RELEASED BY PRINTED NAME / SIGNATURE  
**COURIER**

RECEIVED BY PRINTED NAME / SIGNATURE  
 Received by Printed Name  
 Received by Signature

PURPOSE OF CHANGE:  **SEAL INTACT**  
 For Accessioning at MEDTOX

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE:

**NEGATIVE**  **POSITIVE**, for the following:  **CANNABINOIDS** as Carboxy-THC  **COCAINE METABOLITES** as Benzoylcegonine  **PHENCYCLIDINE**  
 **OPIATES:**  codeine  morphine  **AMPHETAMINES:**  amphetamine  methamphetamine  
 **TEST NOT PERFORMED**  **SPECIMEN INTEGRITY RESULTS OUTSIDE NORMAL RANGE**

I certify that the specimen identified by this accession number has been examined upon receipt for proper identification and chain of custody. I have reviewed immunoassay and confirmation data and the results set forth are for the specimen indicated.

Harry G. McCoy Pharm.D.  Andrew Kroll, B.A.  Ann Sullivan, B.S. MT (ASCP)  
 David A. Breutzmann, M.S., MT (ASCP)  Susuia Williamson B.S., MT (ASCP)  Other  
 Jennifer A. Collins, Ph.D.  Barbara S. Mayer, MT (ASCP)  
 Mitchell LeBard, B.S.  Jasbir Singh, Ph.D.  
 Robert Sheeran, M.S., MT (ASCP)

Signature

Date (Mo., Day, Yr.)

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

100771 (8/00)

# Chain-of-Custody Form, Non-Negative

**MEDTOX FAX RESULT LINE: 888-295-0466**  
 On Site Screening Custody Form - **FAX THIS COPY**



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



**PA581150**

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

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

Donor Social Security Number **1 2 3 4 5 6 7 8 9**

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

First Name

**DOE**

**JOHN**

Referring Physician / Company

MRO **JOHN SMITH**  
 STREET ADDRESS  
 CITY, STATE, ZIP CODE

**DONOR CONSENT** I certify that I provided my specimen to the collector, that the specimen container was sealed with a tamper-proof seal in my presence, and that the information provided on this form and on the label affixed to the specimen bottle is correct. I hereby give permission for the release of the results of these tests to my health care provider. In the case of screening for employment or pre-employment, I also authorize release of the results of these tests to my employer or prospective employer and / or their authorized health care professionals.

Signature

Month Day DATE Year

Account # **9999**

*John Doe*

**02 15 2001**



**PA581150**

**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 **12 31 01** Specimen temperature  Yes, 90° - 100°F / 32 - 38° C.  
 Lot # **6789** within range:  No, Record specimen temperature here

Collection Site Phone No. **555 627 9438**

**STEP 3** To be initiated by the **PERSON COLLECTING THE SPECIMEN** and **COMPLETED AS NECESSARY THEREAFTER:**  
 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.

DATE: Month Day Year

RELEASED BY:

RECEIVED BY:

PURPOSE OF CHANGE

**02 15 2001**

Collector's Printed Name **Bill Smith**  
 Collector's Signature *Bill Smith*

**TEMPORARY STORAGE**

Temporary Storage

**02 15 2001**

**TEMPORARY STORAGE**

Tester's Printed Name **Bill Smith**  
 Tester's Signature *Bill Smith*

Perform On-Site Test

**STEP 4** To be completed by person conducting on-site drug test only  
**RESULTS OF ON-SITE SCREEN TEST:**  **NEGATIVE**  **NON-NEGATIVE: REQUIRES ADDITIONAL TESTING**

REMARKS CONCERNING COLLECTION / TEST

**45991**

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

ORDERED (S)  **12**



**STEP 5** Complete Step 5 ONLY if the on-site test is non-negative.

DATE: Month Day Year

RELEASED BY PRINTED NAME / SIGNATURE

RECEIVED BY PRINTED NAME / SIGNATURE

PURPOSE OF CHANGE

**02 15 2001**

Tester's Printed Name **Bill Smith**  
 Tester's Signature *Bill Smith*

**COURIER**

For Transport to MEDTOX

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

DATE: Month Day Year

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

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE:

**NEGATIVE**  **POSITIVE**, for the following:  **CANNABINOIDS** as Carboxy-THC  **COCAINE METABOLITES** as Benzoylcegonine  **PHENCYCLIDINE**

**TEST NOT PERFORMED**  **SPECIMEN INTEGRITY RESULTS OUTSIDE NORMAL RANGE**  **OPIATES:**  codeine  morphine  **AMPHETAMINES:**  amphetamine  methamphetamine

I certify that the specimen identified by this accession number has been examined upon receipt for proper identification and chain of custody. I have reviewed immunoassay and confirmation data and the results set forth are for the specimen indicated.

- Harry G. McCoy Pharm.D.
- David A. Breutzmann, M.S., MT (ASCP)
- Jennifer A. Collins, Ph.D.
- Mitchell LeBar, B.S.
- Andrew Kroll, B.A.
- Susula Williamson B.S., MT (ASCP)
- Barbara S. Mayer, MT (ASCP)
- Jasbir Singh, Ph.D.
- Robert Sheeran, M.S., MT (ASCP)
- Ann Sullivan, B.S. MT (ASCP)
- Other

Signature

Date (Mo., Day, Yr.)

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

100771 (8/00)

# Chain-of-Custody Form, MRO Copy

**MEDTOX FAX RESULT LINE: 888-295-0466**  
 On Site Screening Custody Form - **FAX THIS COPY**

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



**PA581149**

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

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

Donor Social Security Number 1 2 3 4 5 6 7 8 9

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

First Name

DOE

JOHN

Referring Physician / Company

MRO: JOHN SMITH  
 STREET ADDRESS  
 CITY, STATE, ZIP CODE

**DONOR CONSENT** I certify that I provided my specimen to the collector, that the specimen container was sealed with a tamper-proof seal in my presence, and that the information provided on this form and on the label affixed to the specimen bottle is correct. I hereby give permission for the release of the results of these tests to my health care provider. In the case of screening for employment or pre-employment, I also authorize release of the results of these tests to my employer or prospective employer and / or their authorized health care professionals.

Signature

Month Day DATE Year

John Doe

02 15 2001

Account # 9999



**PA581149**

**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 12 31 01

Specimen temperature  Yes, 90° - 100°F / 32 - 38° C

Lot # 6789

within range:  No, Record specimen temperature here

Collection Site Phone No. 555 6279438

**STEP 3** To be initiated by the **PERSON COLLECTING THE SPECIMEN** and **COMPLETED AS NECESSARY THEREAFTER:**  
 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.

DATE: Month Day Year

RELEASED BY:

RECEIVED BY:

PURPOSE OF CHANGE

02 15 2001

Collector's Printed Name Bill Smith  
 Collector's Signature Bill Smith

**TEMPORARY STORAGE**

Temporary Storage

02 15 2001

**TEMPORARY STORAGE**

Tester's Printed Name Bill Smith  
 Tester's Signature Bill Smith

Perform On-Site Test

**STEP 4** To be completed by person conducting on-site drug test only  
**RESULTS OF ON-SITE SCREEN TEST:**  **NEGATIVE**  **NON-NEGATIVE: REQUIRES ADDITIONAL TESTING**

REMARKS CONCERNING COLLECTION / TEST

**45991**

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

12



**STEP 5** Complete Step 5 ONLY if the on-site test is non-negative.

DATE: Month Day Year

RELEASED BY PRINTED NAME / SIGNATURE

RECEIVED BY PRINTED NAME / SIGNATURE

PURPOSE OF CHANGE

02 15 2001

Tester's Printed Name Bill Smith  
 Tester's Signature Bill Smith

**COURIER**

For Transport to MEDTOX

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

DATE: Month Day Year

RELEASED BY PRINTED NAME / SIGNATURE

RECEIVED BY PRINTED NAME / SIGNATURE

PURPOSE OF CHANGE

SEAL INTACT

Month	Day	Year

**COURIER**

Received by Printed Name

For Accessioning at MEDTOX

Received by Signature

**STEP 7** To be completed by **Donor** Donor Name John Doe Donor Address 1234 Fifth Ave  
 City Anywhere State UT Zip 54321 Home Phone # (555) 123-4567 Work Phone # (555) 456-1237  
 Date of Birth 1/1/55  
 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.

**STEP 8** 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 Performed  Test Cancelled

REMARKS:

(PRINT) Medical Review Officer's Name (First, MI, Last)

Signature of Medical Review Officer

Date (Mo., Day, Yr.)

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

100771 (8/00)

# LIMITATIONS OF PROCEDURES

## PROFILE-II:

- PROFILE-II is only for use with unadulterated human urine samples.
- A positive result for any drug(s) in PROFILE-II does not indicate or measure intoxication. It only indicates the presence of specific drugs(s) in the urine specimen.
- Test results interpreted after 7 minutes may not be consistent with the original result obtained at the 7 minute reading. Disregard any results obtained after 7 minutes.
- Certain medications containing opiates or opiate derivatives, or amphetamines may produce a positive result in any chemical or immunological assay. Additionally, foods and tea containing poppy products, or prolonged passive inhalation of THC, may produce a positive result. Package insert contains additional information.
- There is a possibility that other substances and/or factors not listed above, e.g. technical or procedural errors, may interfere with the test and cause false results.
- Some result lines will be more faint than others. **Any indication of a line represents a negative result.**

**LFAS Strip:** The object of the tests for adulteration is to discover deviations in human urine samples, such as dilution or the addition of drug-test interfering substances. The list of limitations below includes those compounds or physical properties that may affect the test. Medications may cause abnormal results due to discoloration of the urine, and consequently mask the reagent pad color development.

**Oxidant:** Larger amounts of ascorbic acid that may be present in urine after a high intake of vitamin C (vitamin tablets, antibiotics, or fruit juices) can lead to lower or falsely negative results. Nitrates at very high concentrations (10mg/ml) will produce a green/black color change on the Oxidant pad. The presence of blood cells in the urine may cause the oxidant pad to turn green.

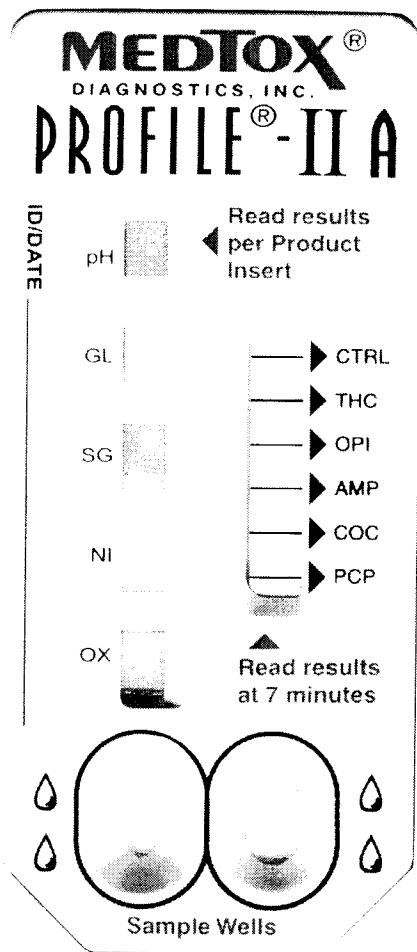
**Nitrite:** False positive results can be caused by the presence of diagnostic or therapeutic dyes in the urine. Very high concentrations of oxidant (80% bleach) will produce a brown color change on the Nitrite pad.

**Glutaraldehyde:** Phenylketones in higher concentrations interfere with the test, and will produce variable colors. Pthalein compounds interfere by producing a red coloration.

*You have now completed the PROFILE-IIA training program.*

*To achieve certification as a tester with this device, you must successfully complete the following fifteen 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 us at 1-888-557-2590.*

# PROFILE<sup>®</sup>-IIA



## CERTIFICATION QUIZ

*Presented by:*

**MEDTOX<sup>®</sup>**

# PROFILE<sup>®</sup>-IIA 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.

1) PROFILE-IIA tests a single urine sample for:

- A) THC, cocaine, barbiturates, adulterants
- B) THC, cocaine, opiates, methadone, PCP
- C) THC, cocaine, barbiturates, amphetamines, PCP, adulterants
- D) THC, cocaine, opiates, amphetamines, PCP, adulterants

2) The entire test is INVALID if:

- A) no control (CTRL) line forms in the window
- B) the urine sample smells bad
- C) (CTRL) line only forms
- D) A and C only

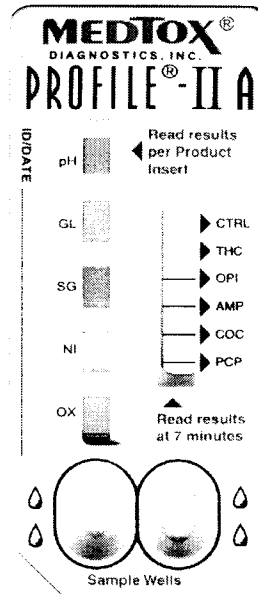
3) PROFILE-IIA devices should be stored at:

- A) 25 - 57°F
- B) 35 - 77°F
- C) 2 - 25°C
- D) A and B only
- E) B and C only

4) PROFILE<sup>®</sup>-IIA provides a:

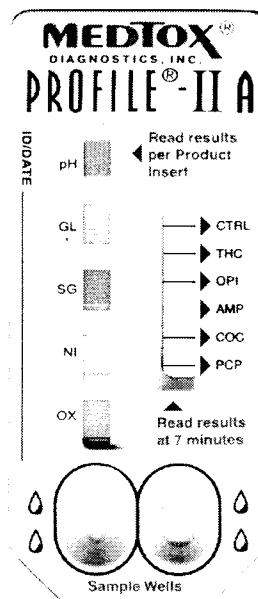
- A) confirmed analytical result
- B) quantitative analytical result
- C) preliminary test result
- D) qualitative test result
- E) C and D only

5) Interpret the following test:



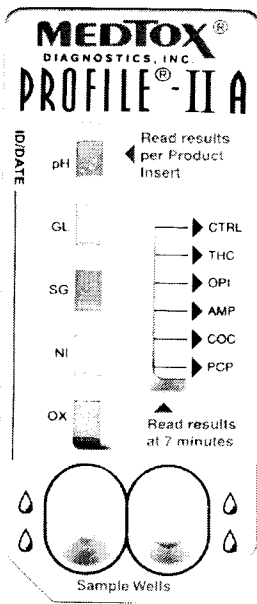
- A) negative for all 5 drugs
- B) valid test
- C) invalid test
- D) non-negative for THC
- E) A and B only

6) Interpret the following test:



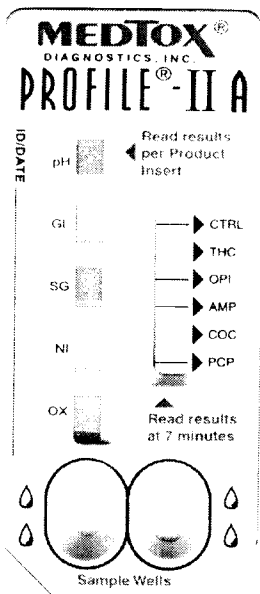
- A) non-negative for amphetamines
- B) negative for all 5 drugs
- C) valid test
- D) invalid test
- E) A and C only

7) Interpret the following test:



- A) non-negative for THC, PCP
- B) negative for THC, PCP
- C) negative for all 5 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 line (CTRL):

- 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®-IIA 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) between 5 and 7 minutes after the test is completed
- D) within 1 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 CTRL 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) LatFlo results are read by:

- A) looking for any change in color
- B) carefully matching the parameter pad colors on strip to color comparator chart
- C) looking for any change in color as soon as possible
- D) following proper read times for optimal results
- E) B and D only

**14) The following information is required on the chain-of-custody form:**

- A) Donor Identification Number (Social Security Number, Employee Number, etc.)
- B) Date of collection
- C) Specimen temperature in or out of stated range
- D) Name of collector and tester
- E) All of the above

**15) When the donor presents the urine sample to the collector:**

- A) Donor must leave the facility prior to dividing the sample into collection containers.
- B) Specimen bottles will already have been opened by the collector and the collector will be ready to split the sample into the two bottles.
- C) Collector should provide the donor with his/her copy of the chain-of-custody form.
- D) Collector should open both specimen bottles in full view of the donor and pour at least 30 ml into each from the original collection container.
- E) C and D

# PROFILE®IIA

## Certification Answer Sheet

Enter your answers in the spaces below; fill in your name and other requested information; and send your answers to MEDTOX. A Certificate of Achievement will be sent to you if you receive a score 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): \_\_\_\_\_

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