

# *PROFILE<sup>®</sup> -II ER*

## TRAINING AND CERTIFICATION PROGRAM



Presented by:

**MEDTOX<sup>®</sup>**

## CONCEPT

- MEDTOX trains and certifies testers.



## INTENDED USE

The PROFILE<sup>®</sup>-II ER device is a one-step immunochromatographic test for the rapid qualitative detection of cannabinoids (THC), cocaine, opiates, phencylidine, amphetamines, tri-cyclic antidepressants, barbiturates, methadone and benzodiazepines in human urine. This product is intended for use under medical supervision in hospitals, physician offices, health clinics, occupational clinics, and drug treatment/counseling centers. It is not for over-the-counter sale.

The PROFILE<sup>®</sup>-II ER test device provides only a preliminary, qualitative, analytical test result. Non-negative screening only results should not be used for employment purposes. A more specific alternate chemical method must be used in order to obtain a confirmed, quantitative 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.

# PROFILE<sup>®</sup> -II ER

## PRECAUTIONS

- PROFILE<sup>®</sup> -II ER test devices should be stored at 35° - 77° F (2° - 25° C). The devices should be refrigerated if room temperature could exceed 77° F. Devices that have been stored in refrigeration must be brought to room temperature prior to use.
- Dilution or adulteration may produce inaccurate test results.
- Do not use the device after the Expiration Date on package label is exceeded.
- Do not freeze PROFILE<sup>®</sup> -II ER test devices.
- PROFILE<sup>®</sup> -II ER 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. 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).
- Use a new pipette for each urine sample.
- PROFILE<sup>®</sup> -II ER test devices should remain in original sealed foil package until ready to use. If pouch integrity is damaged, do not use.
- The PROFILE<sup>®</sup> -II ER test device is for in-vitro diagnostic use only.
- 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.
- Do not read test results after fifteen minutes have elapsed.

## **PROFILE<sup>®</sup>-II ER TEST PROCEDURES**

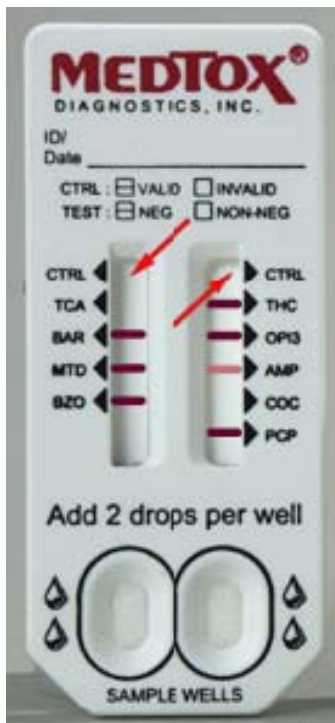
There are two test strips on the PROFILE<sup>®</sup>-II ER device. Each test strip requires 100 µl of urine be added to each of the Sample Wells to activate the testing procedure. Pipette 100 µl of urine into the first sample well to determine the preliminary results of the THC, opiate, amphetamine, cocaine, and phencyclidine screen. Finally, pipette 100 µl of urine into the second sample well to determine preliminary results of TCA, barbiturate, methadone, and benzodiazepine. Each test 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.

- Step 1      Hold the 100 µl sample pipette by the upper bulb.
  
- Step 2      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 3      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. Apply 100 µl of sample ONE time into EACH sample well.
  
- Step 4      Read the test results at 5 to 15 minutes after sample application. Do not wait over 15 minutes.

## INTERPRETING PROFILE<sup>®</sup>-II TEST RESULTS

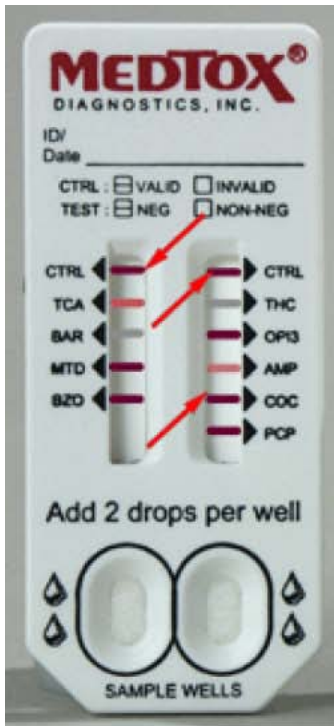
If you are unsure of the test results, send the specimen to MEDTOX for confirmation. Any line of faint color intensity visible after at least 5 minutes and at a maximum of 15 minutes indicates a negative test result.

***WHEN IN DOUBT – SEND IT OUT!***



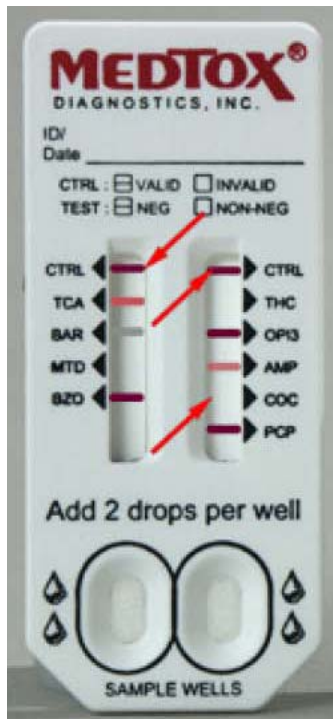
### INVALID TEST

The absence of a reddish-purple Control (CTRL) line indicates the test is invalid. The urine sample should be retested on a new PROFILE<sup>®</sup>-II ER test device.



## 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 line that is broken or of faint color intensity, that is visible within 15 minutes, indicates a negative test result.



## NON-NEGATIVE

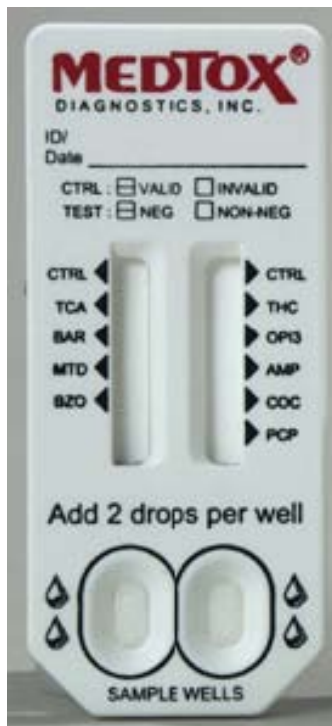
The appearance of a reddish-purple Control (CTRL) line and the absence of a line next to a specific drug name indicates a preliminary positive test result for that drug.

## LIMITATIONS OF PROCEDURE

- PROFILE<sup>®</sup>-II ER is only for use with unadulterated human urine.
- A non-negative result for any drug(s) in PROFILE<sup>®</sup>-II ER does not indicate or measure intoxication; it only indicates the presence of specific drugs in the urine specimen.
- Test results interpreted after 15 minutes may not be consistent with the original result obtained at the 5 to 15 minute reading. Disregard any results obtained after 15 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. The Product 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.

***You have now completed the PROFILE<sup>®</sup>-II ER training program. To achieve certification as a tester with this device, you must successfully complete the following fifteen question 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 1-800-832-3244.***

# PROFILE<sup>®</sup>-II ER



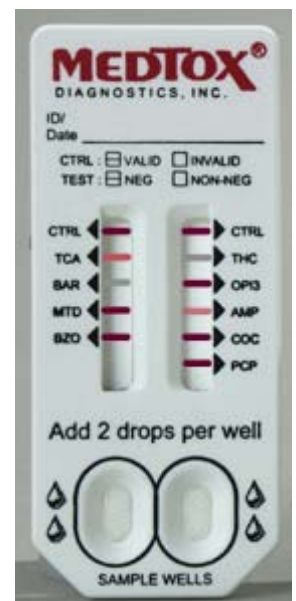
## Certification Quiz



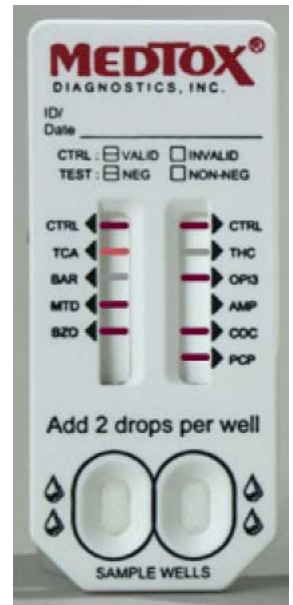
# PROFILE<sup>®</sup>-II ER CERTIFICATION QUIZ

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 certificate of achievement, fax your answer sheet to MEDTOX at 877-838-0029.

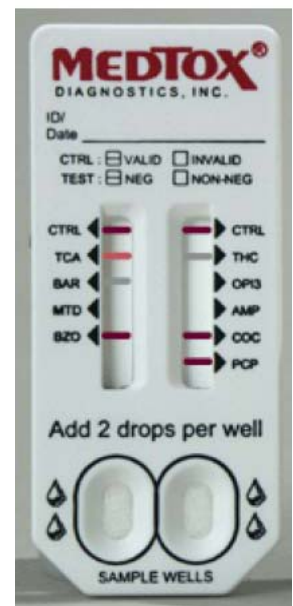
1. The entire test is invalid if:
  - A) no control (CTRL) line forms in the window
  - B) the urine sample smells bad
  - C) control (CTRL) line only forms
  - D) A and C only
  
2. PROFILE<sup>®</sup>-II ER devices should be stored at:
  - A) 25° – 57° F
  - B) 35° – 77° F
  - C) 2° – 25° C
  - D) A and B only
  - E) B and C only
  
3. PROFILE<sup>®</sup>-II ER provides a:
  - A) confirmed analytical result
  - B) quantitative analytical result
  - C) preliminary test result
  - D) qualitative test result
  - E) C and D only
  
4. Interpret the following test:
  - A) negative for all nine drugs
  - B) valid test
  - C) invalid test
  - D) non-negative for THC
  - E) A and B only



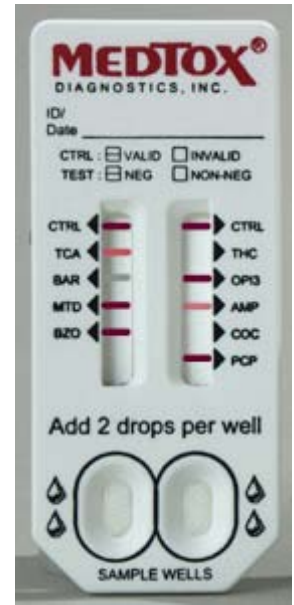
5. Interpret the following test:
- A) non-negative for amphetamines
  - B) negative for all seven drugs
  - C) valid test
  - D) invalid test
  - E) A and C only



6. 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, MTD
  - E) invalid test



7. 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



8. 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
9. 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
10. 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

# PROFILE<sup>®</sup>-II ER

## 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 1-651-286-6264. A Certificate of Achievement will be faxed to you if you receive a score of 80% or higher.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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