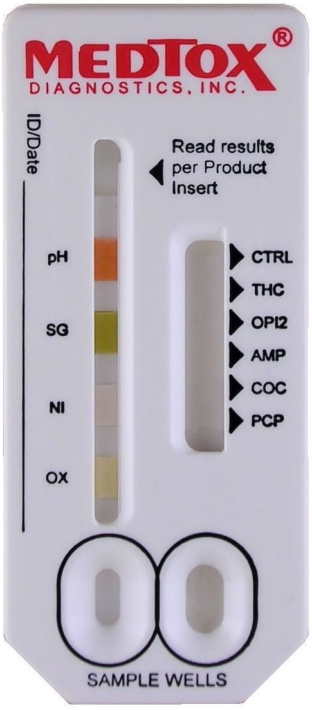
MEDTOX® DIAGNOSTICS, INC.

PROFILE®-II
PROFILE®-IIA
PROFILE-II ER®
VERDICT®-II

Training and Certification Program



www.medtoxdiagnostics.com
800-334-1116

Intended Use

The PROFILE®-II / VERDICT®-II Drugs of Abuse Test is a one-step immunochromatographic test for the rapid, qualitative detection of one or more of the following: Cannabinioids (THC), Opiates, Amphetamine, Cocaine, Phencyclidine, Tricyclic Antidepressants, Barbiturates, Methadone, Benzodiazepines, Methamphetamine/ 3,4 Methylenedioxymethamphetamine and Oxycodone in human urine. It is not for over-the-counter sale. The test detects drug classes at the following cutoff concentrations:

THC	Cannabinoids (11-nor-9-carboxy-Δ9-THC)	50 ng/mL
OPI2	Opiates (Morphine)	2000 ng/mL
OPI3	Opiates (Morphine)	300 ng/mL
AMP	Amphetamine (d-Amphetamine)	1000 ng/mL
COC	Cocaine (Benzoylecgonine)	300 ng/mL
PCP	Phencyclidine (Phencyclidine)	25 ng/mL
TCA	Tricyclic Antidepressants (Desipramine)	300 ng/mL
BAR	Barbiturates (Butalbital)	200 ng/mL
MTD	Methadone (Methadone)	300 ng/mL
BZO	Benzodiazepines (Nordiazepam)	300 ng/mL
MAMP	Methamphetamine (d-Methamphetamine)	1000 ng/mL
MDMA	3,4 Methylenedioxymethamphetamine	1500 ng/mL
OXY	Oxycodone (Oxycodone)	100 ng/mL

The PROFILE®-II / VERDICT®-II 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), High Performance Liquid Chromatography (HPLC) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any Drug of Abuse test result, particularly when preliminary positive results are obtained.

Product Quality

- During manufacturing, the PROFILE® and VERDICT® 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.
- 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 PROFILE® and VERDICT® 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.

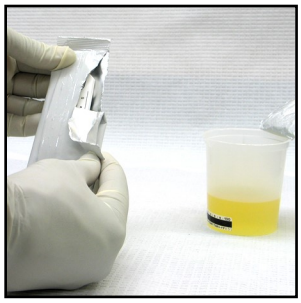
Sample Preparation

- If urine specimens have been stored at refrigerated temperatures, the urine must be allowed to warm to room temperature prior to testing. No preservative should be added to the urine specimen.
- Stored urine specimens should be mixed prior to testing. Mixing can be accomplished by gently swirling the collection cup.

Instructions

1. Device must be at room temperature (18-25˚C / 64-77˚F) before opening. If stored cooler than this, allow ample time to warm up to room temperature before use. Do not store above 77˚F.

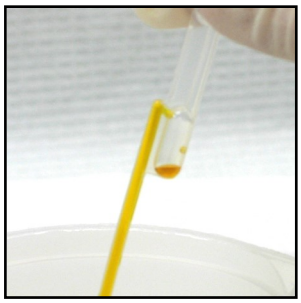
2. Collect the urine sample in a clean, dry container. A volume of 45 mL is more than sufficient.



3. Remove the device from foil pouch. One pouch is needed per sample. Label device with sample identification.

   You may notice a reddish-purple color in sample well. This is normal, do not discard the test.

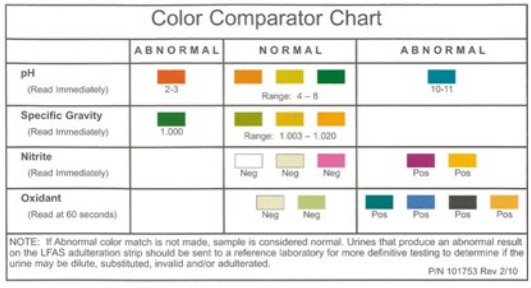
4. Squeeze the upper bulb of the pipette and lower the stem into the urine sample.



5. Release the bulb to fill the stem of the pipette. Excess urine will flow into the lower bulb.

6. Squeeze the upper bulb and empty all the urine in the stem into the sample well. Excess urine will remain in the lower bulb.

   Repeat steps 4-6 for all sample wells.



Color Comparator Chart

	ABNORMAL	NORMAL	ABNORMAL
pH (Read Immediately)	2-3	Range: 4 – 8	10-11
Specific Gravity (Read Immediately)	1.000	Range: 1.003 – 1.020	
Nitrite (Read Immediately)		Neg Neg Neg	Pos Pos
Oxidant (Read at 60 seconds)		Neg Neg	Pos Pos Pos Pos

NOTE: If Abnormal color match is not made, sample is considered normal. 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.

P/N 101753 Rev 2/10

7. If Lateral Flow Adulterant Strip (LFAS) is present, see the Color Comparator chart for read times of the strip and interpretation of LFAS results.

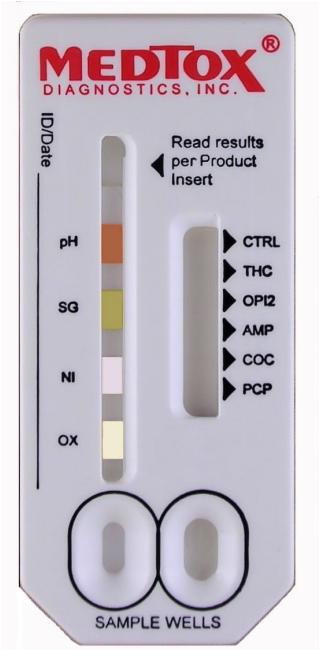
   LFAS strip, if present, is for forensic/toxicology use only.

NOTE: 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.

8. **Read results at 5 minutes** or within 15 minutes of the sample application**.** If Oxycodone (OXY) is one of the drug tests on the device you are using, the OXY results should be read at 5 minutes.

   NOTE: **Line intensity** may vary. The presence of any reddish-purple line, whether faint or broken, is to be interpreted as a negative

Reading and Interpreting the Adulterant Strip



The Lateral Flow Adulterant Strip (LFAS) 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 pipetting urine into the sample wells, you may begin to read the Adulterant Strip (if applicable).

Use the Color Comparator Chart that accompanies the test kit to assist in reading Adulterant Strip results.

The pH, Specific Gravity (SG), and Nitrite (NI) can be read immediately after they are wetted.

The Oxidant pad (OX) 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.

Color Comparator Chart

	ABNORMAL	NORMAL	ABNORMAL
pH (Read Immediately)	2-3	Range: 4 – 8	10-11
Specific Gravity (Read Immediately)	1.000	Range: 1.003 – 1.020	
Nitrite (Read Immediately)		Neg Neg Neg	Pos Pos
Oxidant (Read at 60 seconds)		Neg Neg	Pos Pos Pos Pos

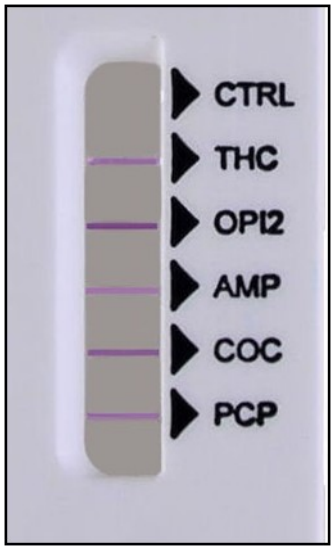
NOTE: If Abnormal color match is not made, sample is considered normal. Urines that produce an abnormal result on the LFAS adulteration strip should be sent to a reference laboratory for more definitive testing to determine if the urine may be dilute, substituted, invalid and/or adulterated.

P/N 101753 Rev 2/10

Reading Test Results

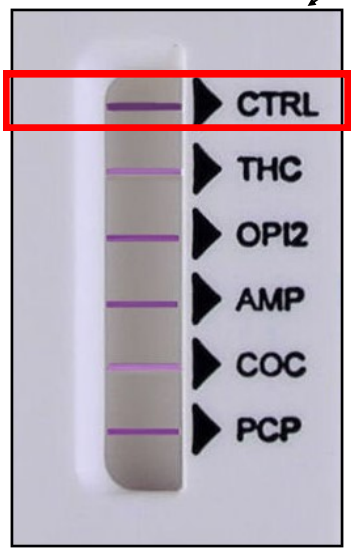
(5 Minutes)

VALID TEST:
A reddish-purple line must appear in the "CTRL" area of the test strip for the tests on the strip to be Valid.



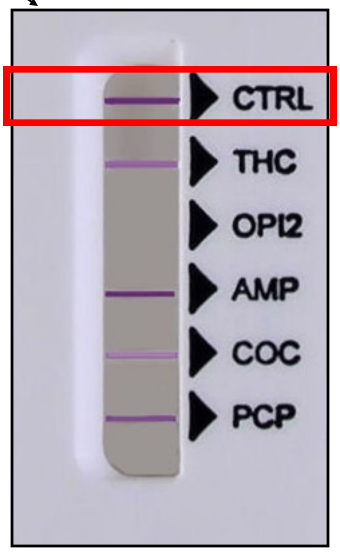
INVALID TEST:
If no control line "CTRL" is present on a test strip the test is invalid. Retest the urine with a new device.

The control line must be present for the test strip to be valid.



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

Example above: All five test results are negative, the control lines are present, and the tests are valid.



NON-NEGATIVE:
(Preliminary Positive)
The absence of a line in the test area is a preliminary positive result.

Example above: OPI2 (Opiates) test is a preliminary positive. All Tests are Valid.

Non-Negative (Preliminary Positive) results can be read after 5 minutes **but not longer than 15 minutes**.

NOTE: For devices with Oxycodone test (OXY), results must be read at 5 minutes.

Interpreting Test Results

- If you are unsure of the test results, send the specimen to a reference laboratory for confirmation. Any reddish-purple line (even a faint or broken line regardless of the color intensity) visible at 5 minutes in the test area (along with a valid control) indicates a negative test result.
- A NEGATIVE test result for a specific drug indicates that the sample does not contain the drug/drug metabolite above the cutoff level. Cutoff levels are found in the Intended Use section (Page 1) of this training document.
- A NON-NEGATIVE (Preliminary 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. Preliminary Positive samples or those with abnormal adulterant strip results should be sent to a reference laboratory for more definitive testing. Confirmatory testing should be done to Limit of Detection or lower Limit of Quantification (LOD or LOQ) using expanded panels that encompass a wider range of cross reactant drugs—see individual section of product insert for related cross reactants.

Limitations of Procedure

- The PROFILE® and VERDICT® Drugs of Abuse Tests are only for use with unadulterated human urine samples. Urine samples which are either extremely acidic (below pH 4.0) or basic (above 9.0) may produce erroneous results.
- A non-negative (preliminary 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 results interpreted after 15 minutes may not be consistent with the original result obtained at 5 minutes.
- Oxycodone results should be read at 5 minutes. Reading Oxycodone results after 5 minutes may not be consistent with the original result obtained at 5 minutes.
- The PROFILE® and VERDICT® Drugs of Abuse Tests were 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.

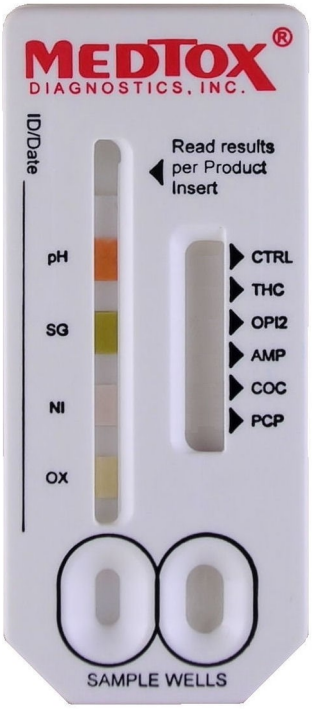
You have now completed the PROFILE®-II, PROFILE®-IIA, PROFILE-II ER® and VERDICT®-II Training Program. To achieve certification as a Tester for this device, you must complete the accompanying Certification Quiz with a score of 80% or higher.

For complete product information refer to the current version of the PROFILE®-II / PROFILE®-IIA / PROFILE-II ER® package insert and VERDICT®-II package insert available at www.medtoxdiagnostics.com/Resources or contact Technical Support at 1-877-643-5703 or TechServices@medtoxdiagnostics.com.

MEDTOX®
DIAGNOSTICS, INC.

PROFILE®-II
PROFILE®-IIA
PROFILE-II ER®
VERDICT®-II

Certification Quiz



www.medtoxdiagnostics.com
800-334-1116

PROFILE®-II, PROFILE®-IIA, PROFILE-II ER®, & VERDICT®-II 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. PROFILE® and VERDICT® devices should be stored at 36-77˚F (2-25˚C).

   A. True
   B. False

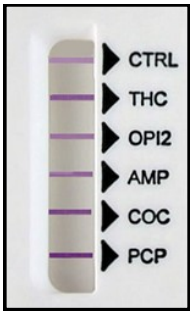
2. After allowing five minutes for test and control lines to develop, if one or more control lines are missing on the device:

   A. The tests on the strip/strips with missing control lines are invalid and sample should be rerun on a new device.
   B. The tests on the strip/strips with missing control lines are valid
   C. Missing control lines have no impact on the validity of the tests.

3. 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

4. Interpret the following results: ⟶

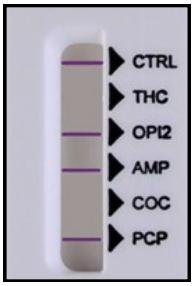


   A. Non-Negative (preliminary positive) for AMP
   B. Negative for all Drugs and the tests are valid
   C. Non-Negative (preliminary positive) for THC
   D. Non-Negative (preliminary positive) for OPI2

5. 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

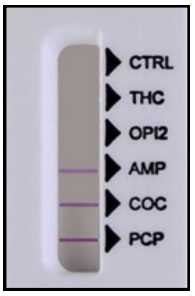
6. Interpret the following results: ⟶



   A. Results are invalid
   B. Non-Negative (preliminary positive) for THC and COC
   C. Non-Negative (preliminary positive) for OPI2, AMP, and PCP
   D. Negative for all drugs

For complete product information refer to the current version of the PROFILE®-II / PROFILE®-IIA / PROFILE-II ER® package insert and VERDICT®-II package insert available at www.medtoxdiagnostics.com/Resources or contact Technical Support at 1-877-643-5703 or TechServices@medtoxdiagnostics.com.

7. Interpret the following results: ⟶



   A. All test results are invalid
   B. Non-Negative (preliminary positive) for THC, OPI2
   C. Non-Negative (preliminary positive) for AMP, COC, PCP
   D. Invalid results for THC, OPI2

8. All test results should be read:

   A. Before 5 minutes
   B. Between 5 and 15 minutes (except OXY at 5 min)
   C. After 15 minutes

9. If urine has been stored, the urine sample should be mixed prior to testing. If urine sample was refrigerated, bring to room temperature before testing.

   A. True
   B. False

10. The Lateral Flow Adulteration Strip (LFAS) should be read after 15 minutes and following the interpretation of the drug results.

   A. True
   B. False

11. On the Lateral Flow Adulteration Strip (LFAS), the oxidant results can be read immediately with the pH, Specific Gravity, and Nitrites.

   A. True
   B. False

12. Too much or too little urine dispensed from the pipette into the test well of the device can cause incorrect results.

   A. True
   B. False

13. Because the reading and interpretation of the results are time dependent, it is recommended that a timer or timing device be used.

   A. True
   B. False

14. PROFILE® and VERDICT® 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

15. If you are unsure of the test results, send the specimen to a reference laboratory for confirmation or additional testing.

   A. True
   B. False

For complete product information refer to the current version of the PROFILE®-II / PROFILE®-IIA / PROFILE-II ER® package insert and VERDICT®-II package insert available at www.medtoxdiagnostics.com/Resources or contact Technical Support at 1-877-643-5703 or TechServices@medtoxdiagnostics.com.

PROFILE®-II, PROFILE®-IIA, PROFILE-II ER®, & VERDICT®-II

Certification Quiz Answer Sheet
Enter your answers in the spaces below, fill in your name and other requested information, and email/fax your answer sheet to MEDTOX Diagnostics. To receive a Certificate of Achievement, participants must achieve a score of at least 80% or retake the quiz until an acceptable result is achieved.

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

Name (please print): _____

Company Name: _____

Address: _____

City, State, Zip: _____

Telephone: _____

Fax: _____

Email: _____

Email Completed Answer Sheet To: customerservice@medtoxdiagnostics.com
or Fax Completed Answer Sheet To: 1-336-227-7302

If you have questions, please call 800-334-1116 or email customerservice@medtoxdiagnostics.com