



PROFILE®-II VISUAL PRODUCT INSERT

The PROFILE®-II VISUAL products are one-step qualitative screening assays for the detection of one or more of the following: Oxycodone, Propoxyphene, and Tricyclic Antidepressants or their metabolites in human urine.

1. INTENDED USE

The PROFILE®-II VISUAL Drugs of Abuse Test is a one-step immunochromatographic test for the rapid, qualitative detection of one or more of the following: Oxycodone, Propoxyphene, and Tricyclic Antidepressants in human urine. It is not for over-the-counter sale. The test detects drug classes at the following cutoff concentrations:

OXY	Oxycodone	100 ng/mL
PPX	Propoxyphene (Norpropoxyphene)	300 ng/mL
TCA	Tricyclic Antidepressants (Desipramine)	300 ng/mL

THE PROFILE®-II VISUAL 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.

2. SUMMARY AND EXPLANATION OF THE TEST

Qualitative PROFILE®-II VISUAL Drugs of Abuse screens utilize a one-step, solid-phase immunoassay technology to provide a very rapid test requiring no instrumentation. This test may be used to screen urine samples for one or more of the following drug classes prior to confirmatory testing:

Oxycodone (OXY) (Oxycontin®, Percodan, Percocet) is a semi synthetic narcotic analgesic that is prescribed for moderately severe pain. It is available in both standard and sustained release oral formulations. Oxycodone is metabolized to Oxymorphone and Noroxycodone.

Propoxyphene (PPX) is a narcotic analgesic. It's primary metabolite is norpropoxyphene.³

Tricyclic Antidepressants (TCA) are a group of structurally related prescription drugs that are used to manage depression.

Many factors influence the length of time required for drugs to be metabolized and excreted in the urine. A variety of factors influence the time period during which drug metabolites are detected in urine; the rate of urine production, the volume of fluid consumption, the amount of drug taken, the urine pH, and the length of time over which drug was consumed. Drinking large volumes of liquid or using diuretics to increase urine volume will lower the drug concentration in the urine and may decrease the detection period. Although the detection period for these drugs varies widely depending upon the compound taken, dose and route of administration and individual rates of metabolism, some general times have been established and are listed below.^{1-4, 6}

<u>Drug</u>	<u>Detection Period</u>
Oxycodone	1-3 days
Propoxyphene	Up to 1 week
Tricyclic Antidepressants	1-7 days

3. PRINCIPLES OF THE PROCEDURE

The PROFILE®-II VISUAL Drugs of Abuse Test is a one-step, competitive, membrane-based immunochromatographic assay. A single urine sample can be evaluated for the presence of each of the specified classes of drugs in a single device. The device consists of antibody-colloidal gold, drug-conjugates and a control line.

1. ANTIBODY-COLLOIDAL GOLD Mouse monoclonal drug antibodies were developed. Each antibody only binds drugs from the drug class tested. Antibody-colloidal gold solutions were prepared by absorbing each of the individual monoclonal antibodies to colloidal gold. The colloidal gold solutions were applied to the sample well pad in the drugs of abuse test.

2. DRUG-CONJUGATES Drug from the class tested was individually conjugated to bovine serum albumin (BSA) or IgG. Each drug conjugate was immobilized as a line at a labeled location on the membrane strip.

3. CONTROL LINE Each test strip has anti-mouse immunoglobulin antibody immobilized as a line on the membrane at the Control (CTRL) location on the device window. The anti-mouse immunoglobulin antibody can bind to any of the mouse antibodies coated on the colloidal gold.

The device can be used to detect specific classes of drugs in urine because drug(s) in the urine and the drug(s) conjugated to the protein compete to bind to the antibody-colloidal gold in a highly specific reaction. When the urine sample is placed in the sample well(s), the dried antibody-colloidal gold on the sample pad(s) dissolves and the urine wicks up the white strips carrying the reddish-purple antibody-colloidal gold as a solution with it.

Negative Samples

When no drug(s) is present in the urine sample, the reddish purple antibody-colloidal gold solutions migrate along the strip and bind to the respective drug conjugate(s) immobilized on the membrane. The binding of the antibody-colloidal gold to the drug conjugate generates an easily visible reddish-purple line at the labeled position on the strip. Negative results can be reported as soon as a line is visible, and a control line has formed (see below).

Positive Samples

When drug(s) is present in the urine sample the antibody-colloidal gold binds to the drug(s) before it migrates along the strip. When the antibody-colloidal gold binds to the drug(s) in the urine, it cannot bind to the drug conjugate immobilized on the membrane and no line is generated at the drug-specific location in the result window. Read positive results at 10 minutes. The control line should be present for the test to be valid. The test result after 10 minutes may not be consistent with the original reading.

Control Line

Each test strip has an internal procedural control. A line must form at the Control (CTRL) position in the result window to indicate that sufficient sample was used and that the reagents are migrating properly. If a Control line does not form, the test is invalid. A Control line forms when the antibody-colloidal gold binds to the anti-mouse immunoglobulin antibody immobilized on the membrane at the (CTRL) location(s) near the top of the device window.

4. MATERIALS PROVIDED/STORAGE CONDITIONS

Each PROFILE®-II VISUAL Drugs of Abuse Test System contains all the reagents necessary to test one urine sample simultaneously for one or more drugs.

The test device contains one or more test strips composed of a membrane strip coated with drug conjugate and a pad coated with antibody dye complexes in a protein matrix.

Kit Contents 1. Twenty-five (25) test devices in individual foil packages. 2. Twenty-five (25) disposable pipette tips. 3. One reference guide.	Storage Conditions The kit, in its original packaging, should be stored at 2-25°C (36-77°F) until the expiration date on the label.
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5. 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. 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. Do not store the test kit at temperatures above 25°C (77°F).
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 device is for *in vitro* diagnostic use only.

6. SAMPLE COLLECTION AND PREPARATION

The urine sample should be collected. No preservatives should be added. Urine may be tested immediately following collection. If it is necessary to store the urine, store under refrigeration for no more than one day. Urine may be frozen for longer storage. Stored urine must be brought to ambient temperature (18 to 25°C/64 to 77°F) and mixed well to assure a homogeneous sample prior to testing.

7. MATERIALS REQUIRED BUT NOT PROVIDED

1. Urine collection container.

NOTE: Specimen containers, disposable gloves and urine temperature strips are available from MEDTOX Diagnostics, Inc.

TEST PROCEDURE

1. Open one pouch for each sample to be tested and mark the device with the patient or sample identification (ID). (You may notice a reddish-purple color in the sample well. This is normal, do not discard the test).
2. Dispense 75µL of urine into sample well.
 - Place a disposable yellow sample tip securely onto the end of the green (75µL) MiniPet™.
 - Grasp the MiniPet under its collar using the index and middle fingers. With the thumb, depress the plunger *completely*.
 - Holding the MiniPet vertically (straight up-down), lower the yellow tip no more than ¼" into the urine specimen.
 - With tip in the urine specimen **slowly** and **smoothly** release the plunger allowing it to rise *completely*.
 - *Visually inspect* the urine sample in the tip. Ensure there are **no air bubbles** and that **no excess urine** is on the outer surface of the tip.
 - Hold the pipette tip directly over sample well. Depress plunger *completely* to dispense the entire contents of urine into **one** sample well of the testing device.
3. Repeat Step 2 for all sample wells.
4. Discard disposable yellow sample tip. Store the MiniPet in a dry, secure location at room temperature (18 – 25 °C or 64 – 77 °F). Replace the MiniPet if it becomes damaged or does not function properly.
5. Read the results at 10 minutes after sample application.

MiniPet™ is a trademark of TriContinent Scientific, Inc.

8. READING THE TEST RESULTS

Negative: The appearance of both a reddish-purple Control (CTRL) line and a specific drug test line indicates a negative test result. **The color intensities of the control lines and test lines may not be equal and may vary from test to test. The test line and control line positions may vary slightly from test strip to test strip. Any line of reddish-purple color, even those of faint intensity, indicates a negative test result.**

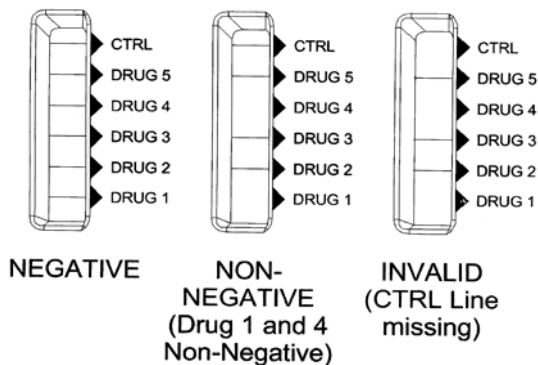
Non-Negative: The appearance of a control line and the absence of a test line indicate a preliminary positive test result for that drug.

Invalid: The control line must be present for the test to be valid. The absence of a control line indicates the test is invalid. The urine sample should be retested on a new device.

9. INTERPRETATION OF TEST RESULTS

A **NEGATIVE** test result for a specific drug indicates that the sample does not contain the drug/drug metabolite above the cutoff level.

A **NON-NEGATIVE** 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 samples should be sent to a reference laboratory for more definitive testing. Examples of Negative and Non-Negative results are shown at right.



10. QUALITY CONTROL

An internal procedural control is included on each device. A line must form at the Control (CTRL) position in the result window to indicate that the proper sample volume was used and that the reagents are migrating properly. If a Control line does not form, the test is considered invalid. The Control line consists of immobilized anti-mouse antibody that reacts with the antibody-colloidal gold as it passes this region of the membrane. Formation of a visible line verifies the Control line antibody antigen reaction occurred. This line may be considered an internal negative procedural control. In addition, if the test has been performed correctly and the device is working properly, the background will clear such that result lines are distinct. The cleared background may be considered an internal positive procedural control. The visible Control line (CTRL) should always be present regardless of whether drug is absent or present in the sample.

The purpose of quality control in laboratory testing is to ensure accuracy, reliability of results and to detect errors. Because the devices are self-contained, single use tests, traditional quality control programs do not apply. The Quality Control program MEDTOX recommends for these non-instrumented test devices includes a combination of the internal device controls and external controls to ensure accuracy, reliability and to detect possible errors. The on-board reactive device controls may be one aspect of the quality program utilized by a laboratory to satisfy the daily quality control requirement established by the Laboratory Director. Another aspect of a quality control program includes an external negative control containing no drug and a positive drug control challenging to the assay cutoff concentration. These controls may be used to initially test each shipment of product received by the laboratory or to verify appropriate storage conditions and long-term stability of the test reagent. To follow good laboratory practices, we recommend that the user document the receipt of each new lot number of devices, the results of external controls performed initially and periodically thereafter, and the results of the internal controls within each device.

It is the responsibility of each Laboratory Director to demonstrate and document the validity of the alternate QC procedure they choose to use in their laboratory. For additional information or forensic and workplace testing requirements, users should contact and follow the appropriate federal, state, and local guidelines. Quality control materials are available from MEDTOX and commercial sources. Contact MEDTOX for further information.

11. LIMITATIONS OF THE PROCEDURE

1. The PROFILE®-II VISUAL Drugs of Abuse Test 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.
2. A positive result for any drug(s) does not indicate or measure intoxication. It only indicates the presence of specific drug(s) in the urine specimen.
3. Test results interpreted after 10 minutes may not be consistent with the original result obtained at 10 minutes.
4. The PROFILE®-II VISUAL Drugs of Abuse Test was not evaluated in point-of-care settings.
5. 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.

12. EXPECTED VALUES

The PROFILE®-II VISUAL Drugs of Abuse Test qualitatively detects oxycodone, propoxyphene, tricyclic antidepressants and/or their metabolites as listed (See Sensitivity).

13. PERFORMANCE CHARACTERISTICS

Sensitivity

The PROFILE®-II VISUAL Drugs of Abuse Test detects one or more of the following drugs at cutoff levels listed below. There are no SAMHSA recommended screening cutoff levels for oxycodone, tricyclic antidepressants, norpropoxyphene, or propoxyphene.

OXY	Oxycodone	100 ng/mL
PPX	Propoxyphene (Norpropoxyphene)	300 ng/mL
TCA	Tricyclic Antidepressants (Desipramine)	300 ng/mL

Accuracy

A panel of naturally metabolized urine samples for the following drug(s) was analyzed using the PROFILE® Drugs of Abuse Test and the Boehringer Mannheim qualitative CEDIA® assay or the ROCHE ABUSCREEN ONLINE® for each drug and the results were compared. Results are shown in the following tables.

Accuracy (Propoxyphene)

One-hundred forty one (141) clinical samples were evaluated by the Roche Abuscreen OnLine Propoxyphene assay, using a 300 ng/mL cut off. Sixty (60) samples were found to be negative and eighty-one (81) samples were found to be positive by the Roche method. Three aliquots of each sample were prepared, and assayed by three operators in a masked manner. There was no significant difference in the results obtained by the three operators, therefore the results of all three operators are included in the table. Results of this comparison are as follows:

	ACCURACY COMPARED TO GC/MS (Propoxyphene)	
	OnLine Positive	OnLine Negative
Positive	238	0
Negative	5*	180

PPX (300 ng/mL cutoff)

* GC/MS results are 390, 441, 499, 536 and 679 ng/mL

In addition to the 141 clinical samples, eight additional clinical samples containing only norpropoxyphene were diluted with drug-free urine in order to obtain an adequate number of samples that had concentrations of drug that were challenging to the cutoff. These eight diluted samples, and the 141 clinical samples described above were analyzed by GC/MS for propoxyphene and norpropoxyphene. The level of quantitation of the GC/MS was 30 ng/mL. Only ten of the samples contained propoxyphene, and each of these samples had norpropoxyphene levels greater than 1,647 ng/mL. As in the study above, three aliquots of the 149 samples were prepared, coded, and assayed by three operators in a masked manner. There was no significant difference in the results obtained by the three operators, therefore the results of all three operators are included in the comparison table.

GC/MS Range (ng/mL)	None detected	150-265	339-450	>472
Number of samples	60	8 (Diluted samples)	7	74
Positive	0	12	19	219
Negative	180	12	2	3

Sensitivity/Precision/Distribution of Random Error (Propoxyphene)

Performance around the specific cut-off of 300 ng/ml for norpropoxyphene was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 5 different days by 3 operators. Drug-free urine was also tested on each day. There was no significant difference in the results of the three operators so the results were combined and are shown in the following table.

Conc. (ng/mL)	Number Tested	Norpropoxyphene – Cut-off = 300 ng/mL		
		Positive	Negative	% Agreement
0	45	0	45	100
30	45	0	45	100
75	45	1	44	98
150	45	9	36	80
225	45	16	29	64
300	45	37	8	82
375	45	42	3	93
450	45	44	1	98
600	45	45	0	100

Accuracy (Tricyclic Antidepressants)

The accuracy was evaluated by assaying a coded panel of clinical urine samples containing varying concentrations of drugs and comparing the results to validated methods. A validated HPLC assay measured tricyclic antidepressant levels. Results are shown in the following tables.

DRUG CLASS	ACCURACY COMPARED TO HPLC (Tricyclic Antidepressants)		PROFILE Results
	Concentration Range (ng/mL)	Number of Samples	
Tricyclic Antidepressants	305 – 19224	50	49/50 Positive
	228, 235, 238, 246	5	5/5 Negative

Only one tricyclic antidepressant positive sample containing a combination of nortriptyline and amitriptyline for a combined tricyclic antidepressant concentration of 519 ng/mL tested negative.

Additionally, the accuracy was evaluated in comparison to the Roche Diagnostics Systems, Inc, ABUSCREEN ONLINE® assays. A panel of clinical urine samples was analyzed and the results obtained in the procedures were compared. Results are shown in the following tables.

ACCURACY COMPARED TO THE ROCHE ABUSCREEN ONLINE® II OR HPLC ASSAYS (Tricyclic Antidepressants)

	HPLC Tricyclic Antidepressants (25 ng/mL limit of quantitation)			
	Positive	Negative	Total	
	TCA (300 ng/mL cutoff)	49	0	49
Desipramine Test	1	45	46	
	Total	50	45	95

Overall agreement: 99% (94/95). Only one tricyclic antidepressant positive sample containing a combination of nortriptyline (499 ng/mL) and amitriptyline (20 ng/mL) for a combined tricyclic antidepressant concentration of 519 ng/mL tested negative.

PERCENT AGREEMENT COMPARED TO ROCHE ABUSCREEN ONLINE ASSAYS OR HPLC (Tricyclic Antidepressants)

	POSITIVE	NEGATIVE
Tricyclic Antidepressants	98% (49/50)	100% (45/45)

Sensitivity / Precision / Distribution of Random Error (Tricyclic Antidepressants)

Performance around the specific cutoff for each drug was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 5 different days by 3 operators. Drug-free urine was also tested on each day. Operator-to-operator agreement was excellent, therefore, the data were combined and summarized in the following tables.

Tricyclic Antidepressants (Desipramine) Cutoff = 300 ng/mL

Conc. (ng/mL)	Number Tested	Positive	Negative	% Agreement
Negative	45	0	45	100
30	45	2	43	96
75	45	17	28	62
150	45	33	12	73
225	45	34	11	76
300	45	40	5	89
375	45	41	4	91
450	45	44	1	98
600	45	45	0	100

Accuracy in a Point of Care setting (Oxycodone)

The accuracy was evaluated by assaying a panel of blind coded clinical urine samples containing varying concentrations of drugs and comparing to GC/MS results. The samples were obtained from MEDTOX Laboratories. Samples that screened negative by the predicate device were not confirmed by GC/MS. Positive samples were confirmed by GC/MS. The GC/MS determination included Oxycodone and oxymorphone and a weighted concentration using 100% cross-reactivity for Oxycodone and a 50% cross-reactivity for oxymorphone was calculated. Clinical urine samples containing Oxycodone and oxymorphone at higher concentrations were diluted with negative urine to obtain the desired number of samples with concentrations below and above the cutoff. The testing was performed by nine point of care personnel at three sites.

OXYCODONE Results vs stratified GC/MS Values

MEDTOX® OXYCODONE Results	Negative by Immunoassay (Predicate Device)	Concentration up to 50% below the cutoff	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)
Positive	0	2	2	6	37
Negative	103	5	4	1	1

GC/MS values used to categorize samples in this table are determined by adding together the concentration of Oxycodone plus 50% of the concentration of oxymorphone, based on the OXYCODONE cross-reactivity studies.

% Agreement among positives is 96%. % Agreement among negatives is 97%.

A second, in-house accuracy study was done using many of the same samples as in the POC study above. Results between the two studies were similar.

Sensitivity/Precision at One Location (Oxycodone)

Performance around the specific cutoff for Oxycodone was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 6 different intervals by 3 in-house operators. Drug free urine was also tested on each interval. The results were interpreted at five minutes and are summarized below:

OXYCODONE Precision Study Results

Concentration of sample (ng/mL)	Number of determinations	Results #Neg / #Pos
0	54	54 / 0
25	54	54 / 0
50	54	50 / 4
75	54	14 / 40
100	54	4 / 50
125	54	1 / 53
150	54	0 / 54

Sensitivity/Precision at Point of Care Sites (Oxycodone)

Performance around the cutoff was evaluated by testing standard drug solutions diluted in drug-free urine at the various concentrations listed in the following table. 9 POC users at 3 different sites each tested 5 replicates of the 6 levels. The results obtained from the 3 sites, (Site1, Site2, Site3) are listed below:

OXYCODONE Precision Study Results at Point of Care Sites

Concentration of sample (ng/mL)	Number of determinations			Results #Neg / #Pos		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
0	15	15	15	15 / 0	15 / 0	15 / 0
25	15	15	15	15 / 0	15 / 0	15 / 0
50	15	15	15	13 / 2	15 / 0	14 / 1
100	15	15	15	0 / 15	3 / 12	3 / 12
125	15	15	15	0 / 15	2 / 13	1 / 14
150	15	15	15	0 / 15	0 / 15	0 / 15

Non Crossreactive Endogenous Compounds

Fifteen compounds were dissolved in appropriate solvents at a concentration of at least 1.0 mg/mL. Each compound was further diluted to 100 µg/mL except for albumin (20mg/mL) and bilirubin (200 µg/mL). None of these compounds showed cross-reactivity at the listed concentrations.

Acetaldehyde	Creatinine	Hemoglobin, Human
Acetone	Epinephrine	Sodium Chloride
Albumin, Human	β-Estradiol	Tetrahydrocortisone
Bilirubin	Estril	d,1-Thyroxine
Cholesterol	Glucose Std. Solution	Uric Acid

Unrelated Compounds, Prescription and Over-the-Counter Medications

The following compounds were tested for reactivity to the PROFILE®-II VISUAL Drugs of Abuse Test System. Listed compounds were dissolved in appropriate solvents and then added to drug-free urine for testing. Unless otherwise noted by a drug name abbreviation such as "AMP" or "BAR" etc., all of the listed compounds were negative in each of the tests at 100 µg/mL or the highest level tested. If a drug name is followed by an abbreviation such as "AMP" or "BAR" etc., check the "Related Compounds and Cross Reactants" listing for the drug in question under the appropriate heading (AMP, BAR, etc.) to find its level of cross-reactivity to that test.

Acecaidine (N-Acetylprocainamide)	Acetaminophen	Acetylsalicylic Acid
Allobarbitol	Alphenal	Alprazolam
Alprazolam, 1-Hydroxy	p-Aminobenzoic Acid	7-Aminoclonazepam
7-Aminoflunitrazepam	Amino glutethimide	l-Aminopyrine (4-(dimethylamino) antipyrine)
Amitriptyline-TCA	Amobarbitol	Amoxapine
Amoxicillin	d-Amphetamine	l- Amphetamine
Ampicillin	Apomorphine	l-Ascorbic Acid
Aspartame	Atenolol	Atomoxetine

Atropine Sulfate
Benzilic Acid
Benzoylcegonine
Brompheniramine
Butabarbital
Cannabidiol
Carbamazepine
Cephalexin
Chlordiazepoxide
Chlorpheniramine
Clobazam
Clonidine
Cocaine
Cotinine
Deoxycorticosterone
Desmethylchlordiazepoxide
Dexamethasone
Diazepam
Diflunisal
Dimenhydrinate (Dramamine)
Domperidone
Doxepin-**TCA**
EDDP-(Primary metabolite of methadone)
Ephedrine
Estrone
Fenfluramine
Flunitrazepam
Furosemide
Glutethimide
Hexobarbital
Hydrochlorothiazide
Hydromorphone-**OXY**
l-11-Hydroxy- Δ^9 -THC
3-Hydroxytyramine
Imipramine-**TCA**
Isoxsuprine
Labetalol
Lithium carbonate
Lorazepam glucuronide
Lysergic Acid Diethylamide (LSD)
MDE (MDEA)
Meperidine
Mesoridazine
l-Methamphetamine
Methocarbamol
Methylprylon
Mirtazapine
Morphine 3- β -D-Glucuronide
Naltrexone-**OXY**
Naproxen
Nifedipine
Norclomipramine
Nordoxepin-**TCA**
Normeperidine
Nortriptyline-**TCA**
Octopamine
Omeprazole
Oxaprosin
Oxolinic Acid
Oxymorphone-**OXY**
Pentazocine
Phenacetin (Acetophenetidin)
Phenelzine
Phenmetrazine
Phentermine
Phenylephrine
Prazosin
Procaine
Promazine-**TCA**
Propranolol
Pyrilamine
Ranitidine
Salicylic Acid
Serotonin (5-Hydroxytryptamine)
Sulfamethazine
Temazepam
 Δ^9 -Tetrahydrocannabinol
Thebaine-**OXY**
Thiopental
Tolbutamide
Triamterene
Trifluoperazine
Tripeleminamine
Tyramine-
Venlafaxine

Barbital
Benzoic Acid
Benzphetamine
Buprenorphine
Butalbital
Cannabinol
Carbamazepine- 10,11 epoxide
Chloral Hydrate
Chloroquine
Chlorpromazine
Clomipramine
Clorazepate
Codeine-**OXY**
Cyclobenzaprine-**TCA**
Desalkylflurazepam
Desmethyflunitrazepam
Dextromethorphan
Diclofenac
Digoxin
1,3-Dimethylbarbituric acid
Dopamine
Doxylamine
Efavirenz (Sustiva)
Equilin
Ethanol
Fenoprofen
Fluoxetine (Prozac)
Fluvoxamine
Guaiacol Glyceryl Ether
Hippuric acid
Hydrocodone-**OXY**
Hydroxybupropion
p-Hydroxyphenobarbital
Hydroxyzine
Iproniazid
Ketamine
Levorphanol
Loperamide
Loxapine
Maprotiline-**TCA**
MDMA
Mephobarbital
Methadone
Methaqualone
Methoxyphenamine
Metoprolol
6-Monoacetylmorphine
Morphine 6- β -D-Glucuronide-**OXY**
Nalorphine
Niacinamide
Nitrazepam
Norcodeine-**OXY**
Norethindrone
Norpropoxyphene-**PPX**
Noscapine
Ofloxacin
Orphenadrine
Oxazepam
Oxycodone
Papaverine hydrochloride
Pentobarbital
Phencyclidine
Phenethylamine
Phenobarbital
Phenytoin (Diphenylhydantoin)
Phenylpropanolamine
Prednisolone
Procainamide
Promethazine-**PPX**
Protriptyline
Quetiapine (Seroquel)-**TCA**
Riboflavin
Secobarbital
Sertraline (Zoloft)
Sulindac
Temazepam glucuronide
 Δ^8 -Tetrahydrocannabinol
Theophylline
Thioridazine
Tolmetin (Tolactin)
Triazolam
Trimethoprim
Tryptamine
Tyrosine
Verapamil

Barbituric Acid
Benzocaine (ethyl-4-aminobenzoate)
Benztropine
Bupropion
Caffeine
Captopril
Carisoprodol (Meprobamate)
Chloramphenicol
Chlorothiazide
Chlorprothixene
Clonazepam
Clozapine-**TCA**
Cortisone
Cyclopentobarbital
Desipramine
Desmethylvenlafaxine
Diacetylmorphine
Diethylpropion
Dihydrocodeine-**OXY**
Diphenhydramine

Ecgonine
EMDP-(Secondary metabolite of methadone)
Erythromycin
Ethylmorphine-**OXY**
Fentanyl (Synthetic opiate)
Flurazepam
Gentisic Acid (2,5-Dihydroxybenzoic acid)
Haloperidol
Hydralazine
Hydrocortisone
Hydroxyhippuric Acid
4-Hydroxyphenacylidine
Ibuprofen
(R)-Isoproterenol
Ketoprofen
Lidocaine
Lorazepam
Lysergic Acid
MDA
Melanin
Mepivacaine
d-Methamphetamine
Methcathinone
Methylphenidate
Midazolam
Morphine-**OXY**
Nalidixic Acid
Naloxone-**OXY**
Nicotine
Nitrofurantoin
Nordiazepam
Nortlysergic Acid
l-Norpseudoephedrine
Nylidrin
Olanzapine-**TCA**
Oxalic Acid
Oxazepam glucuronide
Oxymetazoline
Penicillin G
Perphenazine
Phendimetrazine
Pheniramine
Phenothiazine-**TCA**
Phenylbutazone
Piroxicam
Prednisone
Prochlorperazine-**TCA**
Propoxyphene-**PPX**
d-Pseudoephedrine
Quinidine
Rifampin
Selegiline (Deprenyl)
Sildenafil (Viagra)
Talbutal
Tetracycline
Tetrahydrozoline
Thiamine
Thiothixene
Trazodone
Triazolam, 1-hydroxy
Trimipramine-**TCA**
Tryptophan
Valproic Acid
Zomepirac

Related Compounds and Cross Reactants

The following metabolites and compounds were tested. Reference standards for the various metabolites and compounds were prepared in negative urine samples. None of the compounds reacted with the remaining tests in the panel. Results are expressed as the minimum concentration required to produce a positive result in the indicated assay.

Oxycodone (OXY) cutoff= 100 ng/mL

Apomorphine
Codeine
Diacetylmorphine
Dihydrocodeine
Ethylmorphine
Hydrocodone
Hydromorphone
Levorphanol
Morphine
6-Monoacetylmorphine
Morphine 3-β-D-Glucuronide
Morphine 6-β-D-Glucuronide
Nalorphine
Naloxone
Naltrexone
Norcodeine
Oxymorphone
Thebaine

Result

Negative at 100,000 ng/mL
Positive at 2,500 ng/mL
Negative at 100,000 ng/mL
Positive at 2,500 ng/mL
Positive at 2,500 ng/mL
Positive at 10,000 ng/mL
Positive at 10,000 ng/mL
Negative at 50,000 ng/mL
Positive at 5,000 ng/mL
Negative at 100,000 ng/mL
Negative at 100,000 ng/mL
Negative at 10,000 ng/mL
Negative at 100,000 ng/mL
Positive at 10,000 ng/mL
Positive at 25,000 ng/mL
Positive at 50,000 ng/mL
Positive at 200 ng/mL
Negative at 100,000 ng/mL

Tricyclic Antidepressant-(TCA) (Desipramine) 300 ng/mL

Amitriptyline
Carbamazepine
Carbamazepine-10, 11 epoxide
Chlorpromazine
Chlorprothixine
Clomipramine
Clozapine
Cyclobenzaprine
Doxepin
Imipramine
Loxapine
Maprotiline
Mirtazapine
Norclomipramine
Nordoxepin
Nortriptyline
Olanzapine
Perphenazine
Phenothiazine
Prochlorperazine
Promazine
Protriptyline
Quetiapine (Seroquel)
Thiothixene
Trimipramine

Result

Positive at 500 ng/mL
Negative at 100 µg/mL
Negative at 100 µg/mL
Negative at 100 µg/mL
Negative at 100 µg/mL
Negative at 100 µg/mL
Positive at 2.5 µg/mL
Positive at 750 ng/mL
Positive at 750 ng/mL
Negative at 100 µg/mL
Positive at 750 ng/mL
Negative at 100 µg/mL
Negative at 100 µg/mL
Positive at 500 ng/mL
Positive at 500 ng/mL
Positive at 500 ng/mL
Positive at 75 µg/mL
Negative at 100 µg/mL
Negative at 100 µg/mL
Positive at 5,000 ng/mL
Positive at 250 ng/mL
Negative at 100 µg/mL
Positive at 5 µg/mL
Negative at 100 µg/mL
Positive at 5 µg/mL

Propoxyphene-(PPX)(Norpropoxyphene) 300 ng/mL

Promethazine
Propoxyphene

Result

Positive at 100,000 ng/mL
Positive at 50 ng/mL

Interference-Oxycodone

pH and Specific Gravity:

The OXYCODONE test was assayed with six negative clinical samples with pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 ± 0.1. Each sample was assayed in triplicate. The pH samples were fortified with Oxycodone to the concentrations of 25 ng/mL and 150 ng/mL. All the pH levels gave negative results when fortified to 25 ng/mL, and all pH levels gave positive results when fortified to 150 ng/mL.

The OXYCODONE test was assayed with eight samples with specific gravity values of 1.003, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035 ± 0.001. Each sample was assayed in triplicate. The specific gravity samples were fortified with Oxycodone to the concentrations of 25 ng/mL and 150 ng/mL. All the specific gravity levels gave negative results when fortified to 25 ng/mL, and all specific gravity levels gave positive results when fortified to 150 ng/mL.

Common Drugs:

Following the study of M.L. Smith, et. al.⁵ drug free urine samples were spiked with Oxycodone to the concentrations of 25 ng/mL and 150 ng/mL. 100 µg/mL of the common drugs were then added to the preparation and assayed by the OXYCODONE test. Samples were evaluated in triplicate by in-house operators. None of the common drugs listed in the following table affected the expected results.

COMMON DRUGS EVALUATED WITH OXYCODONE TESTS

Acetylsalicylic Acid	Chlorpheniramine	Ibuprofen
Acetaminophen	Cocaine	Morphine- OXY
Brompheniramine maleate	Dextromethorphan	Phenobarbital-
Caffeine	Diphenhydantoin	d-Pseudoephedrine
Carbamazepine	Doxylamine	Salicylic Acid

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15. LIMITED EXPRESS WARRANTIES

The manufacturer makes no express warranty other than the diagnostic test kit will measure certain drugs and/or drug metabolites when used in accordance with the manufacturer's printed instructions. The use of the kit for any other purpose is outside the intended use of this product. The manufacturer gives no express warranty as to what the legal or clinical significance is of the levels of drug(s)/drug metabolites detected by the PROFILE®-II VISUAL Drugs of Abuse Test. The manufacturer disclaims any and all implied warranties of merchantability, fitness for use or implied utility for any other purposes. Any and all damages for failure of the kit to perform to its instructions are limited to the replacement value of the kit.

Covered by one or more patents. Patents Pending.

U.S. Patent Nos. 5,202,268, 6,566,051, 6,376,251, 6,653,139

This product does not contain controlled substances.

This product does not contain hazardous or toxic chemicals as defined by the OSHA Hazard Communication Rule [29 CFR 1910.1200(g)].

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