PROFILE®-II / PROFILE®-IIA / PROFILE-II ER® / VERDICT®-II
PRODUCT INSERT

The **PROFILE®-II / PROFILE®-IIA / PROFILE-II ER® / VERDICT®-II** products are one-step qualitative screening assays for the detection of one or more of the following: Cannabinoids (THC), Opiates, Amphetamine, Cocaine, Phencyclidine, Tricyclic Antidepressants, Barbiturates, Methadone, Benzodiazepines, Propoxyphene, Methamphetamine/ 3,4 Methylenedioxymethamphetamine and Oxycodone or their metabolites in human urine. **All PROFILE-II / PROFILE-IIA / PROFILE-II ER / VERDICT-II product(s) are covered by this insert. Refer to product labeling for the actual drugs assayed by the kit or system configuration.**

The Lateral Flow (LatFlo®) Adulterant Strip (LFAS) is a one-step 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 adulteration prior to Drugs of Abuse urine (DAU) testing. The LFAS strip is only for Forensic/Toxicology use and not for in vitro diagnostic applications. **The LFAS test strip is only contained in products labeled PROFILE-IIA or VERDICT-II with "LFAS" on the label.**

1. 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: Cannabinoids (THC), Opiates, Amphetamine, Cocaine, Phencyclidine, Tricyclic Antidepressants, Barbiturates, Methadone, Benzodiazepines, Propoxyphene, Methamphetamine/ 3,4 Methylenedioxymethamphetamine and Oxycodone in human urine. The test is for *in vitro* diagnostics use and is intended **for laboratory use only**. It is not for over-the-counter sale. The test detects drug classes at the following cutoff concentrations:

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

2. SUMMARY AND EXPLANATION OF THE TEST

Qualitative PROFILE-II / VERDICT-II 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:

Marijuana (THC) is a hallucinogenic drug derived from the hemp plant. Marijuana contains a number of active ingredients collectively known as Cannabinoids.

Opiates (OPI) are a class of natural and semi-synthetic sedative narcotic drugs that include morphine, codeine and heroin.

The "Amphetamines" are a group of drugs that are central nervous system stimulants. This group includes 'amphetamine' and 'methamphetamine', and related designer drugs like '3,4 Methylenedioxymethamphetamine', (better known as Ecstasy or MDMA a psychoactive drug with hallucinogenic effects). The drug 'Amphetamine' (d-amphetamine) is detected on the device only at the (AMP) position. Both the designer drug Ectasy (MDMA) 'Methylenedioxymethamphetamine' and methamphetamine (d-methamphetamine) are detected on the device only at the (MAMP) position.

Cocaine (COC) is a central nervous system stimulant. Its primary metabolite is benzoylecgonine.

Phencyclidine (PCP) is a hallucinogenic drug.

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

Barbiturates (BAR) are a group of structurally related prescription drugs that are used to reduce restlessness and emotional tension, induce sleep and to treat certain convulsive disorders.

Methadone (MTD) is a synthetic opioid used clinically as a maintenance drug for opiate abusers and for pain management.

Benzodiazepines (BZO), a group of structurally related central nervous system depressants, are primarily used to reduce anxiety and induce sleep.

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

Oxycodone (Oxycontin®, Percodan®, Percocet®, etc) 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.

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]

Drug	Detection Period	Drug	Detection Period
THC		Tricyclic Antidepressants	1-7 days
Single Use	1-7 days		
Chronic, Use	Less than 30 days typical	Barbiturates	
		Short-Acting	up to 6 days
		Long-Acting	up to 16 days
Opiates			
Heroin	1 day	Methadone	1-3 days
Morphine	1-3 days		
Codeine	1-3 days	Benzodiazepines	1-12 days
Amphetamine		Methamphetamine/MDMA	
Acid Conditions	1-3 days	Acid Conditions	1-3 days
Alkaline Conditions	3-10 days	Alkaline Conditions	3-10 days
Cocaine Metabolite	Up to 5 days 1 to 3 days typical	Propoxyphene	up to 1 week
PCP		Oxycodone	1-3 days
Single Use	1-8 days		
Chronic Use	Up to 4 weeks		

The LFAS is a lateral flow strip with impregnated reagent test pads that detect specific analytes in human urine. The analytes detected are Oxidants and Nitrites. The strip also approximates the pH and specific gravity values. Urine samples with 'abnormal' values should be submitted to a reference laboratory for additional testing.

Oxidants The detection is based on the oxidative activity of compounds (e.g. chromate salts and/or Bleach) that catalyze the oxidation of an indicator by an organic hydroperoxide producing a blue/orange color. The color intensity is directly proportional to the concentration of Oxidants present in the sample and is observed visually and compared to the color comparator chart to obtain a result.

Nitrites The test is based on the principles of the Griess reaction for the detection of Nitrites. The test pad contains an amine and a coupling component. A red/orange colored azo compound is obtained by diazotization and subsequent coupling. The color intensity is directly proportional to the concentration of Nitrites present in the sample and is observed visually and compared to the color comparator chart to obtain a result.

pH The test paper contains indicators that change colors between pH 2 and pH 11. The color scale gives an approximate indication for pH values between those levels.

Specific Gravity The test pad reacts with ions in urine to indicate concentrations from 1.000 to 1.020. The color changes range from dark green with low ionic concentrations through green to yellow/orange in urines with high ionic concentrations. The color is observed visually and compared to the color comparator chart to obtain an approximate result.

3. PRINCIPLES OF THE PROCEDURE

The PROFILE-II/VERDICT-II 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 drug(s) 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 drug(s) 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 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 class(es) of drug(s) 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 then binds to the appropriate drug conjugate immobilized on the membrane. The binding of the antibody-colloidal gold to the drug conjugate generates an easily visible reddish-purple line at each of the labeled locations in the result window. Negative results can be reported as soon as the drug and control lines are visible.

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 5 minutes. The control line should be present for the test to be valid.

CTRL 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/VERDICT-II Drugs of Abuse Test contains all the reagents necessary to test one urine sample simultaneously for one or more drugs.

1. 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.
2. The test device may contain a membrane strip laminated with Adulterant test pads for testing the presence of Oxidants and Nitrites, as well as determining approximate values of Specific Gravity and pH in human urine. **The LFAS test strip is not** contained in every PROFILE-II/VERDICT-II product.

25 Test Kit Contents-Device Only

1. Twenty-five (25) test devices in individual foil packages containing a disposable 100 µL sample pipette.
2. One reference guide.
3. For LFAS products only, five color comparator charts.

25 Test Kit Contents-Test System

The PROFILE Drugs of Abuse Test System kit contains twenty-five (25) individually bagged test systems and one reference guide.

Test System bag Contents

1. One (1) test device in a foil package containing a disposable 100 µL sample pipette.
2. For LFAS products only, one color comparator chart.
3. Split Specimen Kit containing the following:
   One (1) calibrated collection container with temperature strip.
   Two (2) specimen bottles.
   One (1) specimen transport (Bio-Hazard) bag.

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.

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. Never pipette by mouth and avoid contact with broken skin.
2. Avoid cross-contamination of urine samples by using a new urine specimen container and pipette 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 drug screen portion of the device is for in vitro diagnostic use only. The LFAS strip is for Forensic/Toxicology use only.
8. If any of the lines formed are outside the arrow indicated by the drug name, the test is invalid.

6. SAMPLE COLLECTION AND PREPARATION

The urine sample should be collected in a clean glass or plastic container. Approximately 100 µL is required for each sample well. Collection of 45 mL of urine is more than sufficient for initial and subsequent testing. No preservatives should be added. Urine may be tested immediately following collection. The specimen may be refrigerated if testing is going to be delayed for more than a 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. External controls
2. Timer
3. A Urine collection container is not provided with the 'Device Only' 25 Test Kit.
4. Specimen containers, external controls and urine temperature strips are available from MEDTOX Diagnostics, Inc.

8. TEST PROCEDURE

1. Open one pouch for each sample to be tested and label 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. Apply 100 µl of urine to sample well as follows:
   - Hold the 100 µl sample pipette by the upper bulb.
   - Lower the pipette stem into the urine sample.
   - Squeeze the upper bulb then release it. This motion will draw 100 µl of urine into the stem. The urine sample should reach the top of the stem, and a drop or two should overflow into the middle bulb, if not, repeat this process.
   - Dispense the urine into the sample well by squeezing the upper bulb. This will empty the stem delivering 100 µL of sample. Excess urine in the middle bulb should remain in the bulb.
3. Repeat Step 2 for each additional sample well (for multi-strip devices).
4. Read the results at 5 minutes after application.

   NOTE: For all tests except OXY, read results at 5 minutes or within 15 minutes of the sample application. The test result after 15 minutes may not be consistent with the original reading.
   For OXY only, read results at 5 minutes. The test result after 5 minutes may not be consistent with the original reading.

9. READING THE TEST RESULTS

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 reddish-purple line visible at 5 minutes indicates a negative test result. Line intensity will vary from test to test.

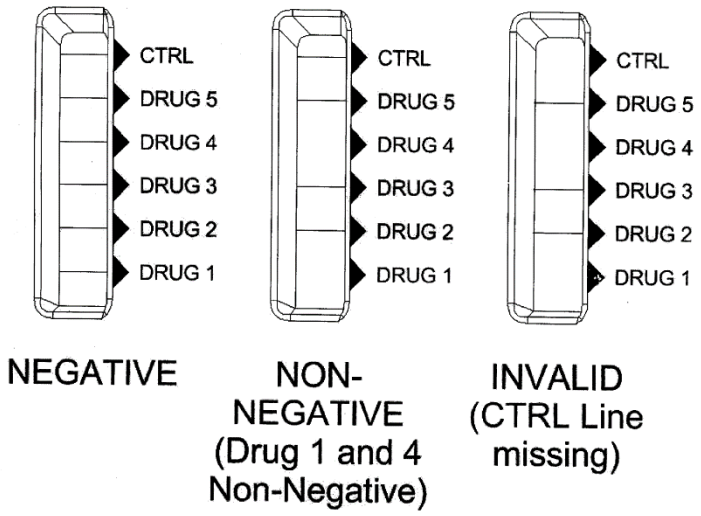
Non-Negative: The appearance of both a reddish-purple Control (CTRL) line and the absence of a line next to a specific drug name at 5 minutes indicates a preliminary positive test result for that drug. Occasionally a white line (line lighter than the background of the strip) may appear next to a specific drug name. This indicates a preliminary positive test result for that 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 device. If the second test is also invalid, send the urine sample to a reference laboratory for additional testing.

10. 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. Examples of Negative and Non-Negative results are shown below.



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

11. <u>QUALITY CONTROL</u>

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.

12. LIMITATIONS OF THE PROCEDURE

1. The PROFILE-II/VERDICT-II 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 15 minutes (after 5 minutes for OXY) may not be consistent with the original result obtained at 5 minutes.
4. The PROFILE-II/VERDICT-II Drugs of Abuse Test was not evaluated in point-of-care settings (except OXY clone was 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.

LFAS Strip
The purpose of the adulteration strip is to screen for abnormal conditions in human urine samples, such as dilution or the addition of drug-test interfering substances. Occasionally medications may discolor the urine, and make it difficult to read the result. When in doubt send the urine sample to a reference laboratory for additional testing.

Oxidant
Nitrites, acting as oxidizing agents in solution, will produce a blue/green color change on the Oxidant pad.

Nitrite
Abnormal results can be caused by the presence of diagnostic or therapeutic dyes in the urine. Very high concentrations of oxidant such as 80% bleach will produce a brown color change on the Nitrite pad.

13. EXPECTED VALUES

The Substance Abuse and Mental Health Services Administration (SAMHSA) recommends the following screening test cutoffs:

THC	11-nor-9-carboxy-Δ^9-THC	50 ng/mL
OPI	Morphine	2000 ng/mL
AMP	Amphetamine	1000 ng/mL
COC	Benzoylecgonine	300 ng/mL
PCP	Phencyclidine	25 ng/mL
MAMP	Methamphetamine	1000 ng/mL

There are no SAMHSA recommended screening levels for tricyclic antidepressants, benzodiazepines, methadone, barbiturates, MDMA, propoxyphene and oxycodone and/or their metabolites.

The PROFILE-II/VERDICT-II Drugs of Abuse Test qualitatively detects THC, opiates, amphetamines, cocaine, phencyclidine, tricyclic antidepressants, barbiturates, methadone, benzodiazepines, propoxyphene, methamphetamine/MDMA and oxycodone and/or their metabolites as listed (See Sensitivity).

LFAS Test:
Urines that produce an abnormal result on the LFAS adulteration strip should be sent to a reference laboratory for more definitive testing to determine if the urine may be dilute, substituted, invalid and/or adulterated.

14. PERFORMANCE CHARACTERISTICS

Sensitivity
The PROFILE-II/VERDICT-II Drugs of Abuse Test detects one or more of the following drugs at cutoff levels listed below. Cutoffs for cannabinoids (THC), opiates (OPI2), amphetamines, cocaine metabolite, phencyclidine, and methamphetamines are based on SAMHSA recommendations for screening of these drugs in human urine. The opiate (OPI3) test, if present, detects opiates below the

SAMHSA recommendations for screening of opiates in human urine. There are no SAMHSA recommended screening cutoff levels for propoxyphene, MDMA, barbiturates, benzodiazepines, methadone, tricyclic antidepressants and oxycodone.

THC	11-nor-9-carboxy-Δ^9-THC	50 ng/mL
OPI2	Morphine	2000 ng/mL
OPI3	Morphine	300 ng/mL
AMP	Amphetamine	1000 ng/mL
COC	Benzoylecgonine	300 ng/mL
PCP	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 (Nordiazepine)	300 ng/mL
PPX	Propoxyphene (Norpropoxyphene)	300 ng/mL
MAMP	Methamphetamine	1000 ng/mL
MDMA	Methylenedioxymethamphetamine	1500 ng/mL
OXY	Oxycodone	100 ng/mL

Accuracy

A panel of naturally metabolized urine samples for the following drug(s) was analyzed using the PROFILE-II/VERDICT-II 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 COMPARED TO THE BOEHRINGER MANNHEIM QUALITATIVE CEDIA® or THE ROCHE ABUSCREEN ONLINE® II ASSAYS

CEDIA MULTI-LEVEL THC **(50 ng/mL cutoff)**

PROFILE-II/VERDICT-II		Positive	Negative	TOTAL
THC (50 ng/mL cutoff)	Positive	194	3	197
	Negative	10	477	487
	TOTAL	204	480	684

Overall agreement: 98% (671/684). Samples having discrepant results were analyzed by GC/MS. The three false positive samples were found to contain 16, 28, and 32 ng/mL while the ten false negative samples contained 32, 35, 41, 42, 46, 46, 49, 50, 50, and 90 ng/mL.

ROCHE ABUSCREEN ONLINE®-II OPIATE **(2000 ng/mL cutoff)**

PROFILE-II/VERDICT-II		Positive	Negative	TOTAL
OPI (2000 ng/mL cutoff)	Positive	68	0	68
	Negative	0	89	89
	TOTAL	68	89	157

Overall agreement: 100% (157/157)

CEDIA OPIATE **(300 ng/mL cutoff)**

PROFILE-II/VERDICT-II		Positive	Negative	TOTAL
OPI (300 ng/mL cutoff)	Positive	133	1	134
	Negative	0	550	550
	TOTAL	133	551	684

Overall agreement: >99% (683/684). The discrepant sample was analyzed by GC/MS. The one false positive sample did not contain morphine or codeine detectable at the GC/MS cutoff of 300 ng/mL.

CEDIA AMPHETAMINE **(1000 ng/mL cutoff)**

PROFILE-II/VERDICT-II		Positive	Negative	TOTAL
AMP(1000 ng/mL cutoff)	Positive	64	0	64
	Negative	2	618	620
	TOTAL	66	618	684

Overall agreement: >99% (682/684). Samples having discrepant results were analyzed by GC/MS. The two false negative samples contained amphetamine at 2353 and 3569 ng/mL.

CEDIA COCAINE **(300 ng/mL cutoff)**

PROFILE-II/VERDICT-II		Positive	Negative	TOTAL
COC (300 ng/mL)	Positive	96	8	104
	Negative	2	578	580
	TOTAL	98	586	684

Overall agreement: 99% (674/684). Samples having discrepant results were analyzed by GC/MS. Of the eight false positive samples one contained 151 ng/mL while seven did not contain cocaine metabolite detectable at the GC/MS cutoff of 150 ng/mL. The two false negative samples contained cocaine metabolite at 688 and 666 ng/mL.

CEDIA PHENCYCLIDINE **(25 ng/mL cutoff)**

PROFILE-II/VERDICT-II		Positive	Negative	TOTAL
PCP (25 ng/mL)	Positive	56	2	58
	Negative	1	625	626
	TOTAL	57	627	684

Overall agreement: >99% (681/684). Samples having discrepant results were analyzed by GC/MS. The two false positive samples did not contain phencyclidine detectable at the GC/MS cutoff of 25ng/mL. The one false negative sample contained phencyclidine at 28 ng/mL.

RELATIVE SENSITIVITY AND SPECIFICITY COMPARED TO THE BOEHRINGER MANNHEIM QUALITATIVE CEDIA® or THE ROCHE ABUSCREEN ONLINE® II ASSAYS (THC, Opiates, Amphetamine, Cocaine, and PCP)

	Relative Sensitivity	Relative Specificity
THC	95% (194/204)	99% (477/480)
OPI2	100% (68/68)	100% (89/89)
OPI3	100% (133/133)	>99% (550/551)
AMP	97% (64/66)	100% (618/618)
COC	98% (96/98)	99% (578/586)
PCP	98% (56/57)	>99% (625/627)

ACCURACY COMPARED to GC/MS

		PROFILE-II/VERDICT-II	GC/MS	Values for Discrepant Samples (ng/mL)
THC	Positive	48	50	
	Negative	52	50	35 and 46
OPI2	Positive	47	47	
	Negative	0	0	No Discrepants
OPI3	Positive	50	50	
	Negative	50	50	No Discrepants
AMP	Positive	48	50	
	Negative	52	50	2353 and 3569
COC	Positive	49	50	
	Negative	51	50	666
PCP	Positive	49	50	
	Negative	51	50	28

Precision (THC, Opiates, Amphetamine, Cocaine, and PCP)
Performance around the specific cutoff for each drug was measured by testing standard drug solutions diluted in drug-free urine in replicates of 20 each on 3 different days by 3 operators. Twenty replicates of drug-free urine were also tested on each day. At 25% above the cutoff, the precision of each assay was as follows: THC=95%, OPI2= 96.7%, OPI3=100%, AMP=100%, COC=100%, and PCP=100%.

Reproducibility (THC, Opiates 300, Amphetamine, Cocaine, and PCP)
A panel of 55 naturally metabolized human urine samples was prepared. All samples in the panel had been screened for the presence or absence of THC, OPI, AMP, COC, and PCP. In addition, each of the 55 samples had also been quantitated by GC/MS conducted at SAMHSA cutoffs for positive samples or at limit of quantitation for negative samples to determine the concentration of a specific drug. Five of the 55 samples were drug-free negatives and 50 of the samples were positive for one or more of the five drugs. The concentration of primary metabolite in the positive samples was between 66 and 198 ng/mL for THC; 464 and 2000 ng/mL for OPI3; 1056 and 4622 ng/mL for AMP; 487 and 1342 ng/mL for COC; and 32 and 109 ng/mL for PCP. The panel was used to evaluate the lot-to-lot and lab-to-lab reproducibility.

Lot-to-Lot Reproducibility (THC, Opiates 300, Amphetamine, Cocaine, and PCP)
Three aliquots of each of the 55 samples were prepared and each of the three sets of aliquots was coded and used to evaluate the performance of one of three lots of drug tests for the five drugs above. There was one incorrect result (a false negative on an amphetamine low positive sample) on the 825 tests for a reproducibility of >99%.

Lab-to-Lab Reproducibility (THC, Opiates 300, Amphetamine, Cocaine, and PCP)
Three aliquots of each of the 55 samples were prepared and each of the three sets of aliquots was tested by one of three study participants using one lot of the five drug test panel above. There was >99% agreement between the three participants. Overall, there were three incorrect results, two incorrect results for OPI3 (one false negative on an opiate low positive sample and one false negative on an opiate high positive sample) and one incorrect result for PCP (one false negative a low positive sample), on the 825 tests.

Reproducibility (Opiates 2000)
A panel of 25 naturally metabolized human urine samples was prepared. All samples in the panel had been screened for the presence or absence of opiates. In addition, each of the positive samples had also been quantitated by GC/MS conducted at SAMHSA cutoff for positive samples to determine the concentration of morphine and codeine. The concentration of morphine and/or codeine in the positive samples was between 2000 and 6000 ng/mL. The panel was used to evaluate Opiates 2000 for lot-to-lot and lab-to-lab reproducibility. There were no incorrect results on the 75 tests (25 samples x 3 lots) for a lot-to-lot reproducibility of 100%. There were no incorrect results on the 75 tests (25 samples x 3 study participants) for a lab-to-lab reproducibility of 100%.

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:

	OnLine Positive	OnLine Negative
PROFILE-II/VERDICT-II	238	0
PPX (300 ng/mL cutoff)	5	180

* 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.

Norpropoxyphene – Cut-off = 300 ng/mL

Conc. (ng/mL)	Number Tested	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 (Methamphetamine and MDMA)

A panel of naturally metabolized urine samples was analyzed using the PROFILE-II/VERDICT-II PPX/MAMP-MDMA and the GC/MS assay for methamphetamine and MDMA. The results obtained in the two procedures are shown in the following tables.

GC/MS Methamphetamine (limit of quantitation 50 ng/mL)

PROFILE-II/VERDICT-II		Positive	Negative	TOTAL
MAMP (1000 ng/mL cut-off)	Positive	56	0	56
	Negative	2	56	58
	TOTAL	58	56	114

Overall agreement: >98% (112/114). Samples having discrepant results were analyzed by GC/MS. The false negative samples contained methamphetamine at 1056 ng/mL and at 1136 ng/mL.

GC/MS MDMA (limit of quantitation 50 ng/mL)

PROFILE-II/VERDICT-II		Positive	Negative	TOTAL
MDMA (1500 ng/mL cut-off)	Positive	19	1	20
	Negative	4	57	61
	TOTAL	23	58	81

Percent Agreement of MAMP-MDMA Compared to GC/MS

	POSITIVE	NEGATIVE
MAMP	97% (56/58)	100% (56/56)
MDMA	83% (19/23)	98% (57/58)

Sensitivity/Precision MAMP-MDMA

Performance for methamphetamine and MDMA was evaluated by testing standard drug solutions diluted in drug-free urine in duplicates of 8 drug concentrations on 5 different days by 3 operators. Drug-free urine was also tested on each day. The complete results for both drugs are shown in the tables below.

	Methamphetamine Cut-off = 1000 ng/mL				MDMA Cut-off= 1500 ng/mL				
Conc. (ng/mL)	No. Tested	(+)	(-)	% Agreement	Conc(ng/mL)	No. Tested	(+)	(-)	% Agreement
0	30	0	30	100	0	30	0	30	100
100	30	0	30	100	500	30	0	30	100
250	30	0	30	100	750	30	0	30	100
500	30	26	4	87	1000	30	12	18	60
750	30	27	3	90	1250	30	23	7	77
1000	30	28	2	93	1500	30	25	5	83
1250	30	29	1	97	2000	30	30	0	100
1500	30	30	0	100	2500	30	30	0	100
2000	30	30	0	100	3000	30	30	0	100

Reproducibility (MAMP-MDMA)

A panel of 18 spiked human urine samples, comprised of drug-free and drug standard samples, was prepared. The panel was examined by 3 operators, once a day for 5 days. The concentration of methamphetamine and MDMA had been quantitated by GC/MS in each of the 18 samples. There was 100% agreement between the three operators over the 5 day period at 0 ng/mL, 1500 ng/mL (cut-off + 50%) and 2000 ng/mL (cut-off + 100%) for methamphetamine. There was also 100% agreement between the three operators over the 5 day period for 0 ng/ml, 2000 ng/mL (cut-off +33%), 2500 ng/mL (cut-off + 67%) and 3000 ng/mL (cut-off + 100%) for MDMA.

Accuracy (Tricyclic Antidepressants, Barbiturates, Methadone and Benzodiazepines)

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. Validated GC/MS assays measured barbiturates, methadone and benzodiazepines levels. Results are shown in the following tables.

ACCURACY COMPARED TO GC/MS OR HPLC

(Tricyclic Antidepressants, Barbiturates, Methadone and Benzodiazepines)

DRUG CLASS	Concentration Range (ng/mL)	Number of Samples	PROFILE-II/VERDICT-II Results
Tricyclic Antidepressants	305 – 19224	50	49/50 Positive
	228, 235, 238, 238, 246	5	5/5 Negative
Barbiturates			
Phenobarbital	201 – 27776	36	36/36 Positive
	155, 155, 156, 158, 161	5	5/5 Negative
Butalbital	240 - 3814	27	27/27 Positive
	109, 151, 194	3	3/3 Positive
Pentobarbital	264	1	1/1 Positive
Methadone	306 – 70560	57	57/57 Positive
	224, 226, 227, 230, 232	5	5/5 Negative
Benzodiazepines	303 – 30813	57	57/57 Positive
	234, 236, 238, 250, 283	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 a validated HPLC assay for tricyclic antidepressants and to the Roche Diagnostics Sytems, Inc, ABUSCREEN ONLINE® assays for barbiturates, methadone and benzodiazepines. 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, Barbiturates, Methadone and Benzodiazepines)

HPLC Tricyclic Antidepressants (25 ng/mL limit of quantitation)

PROFILE-II/VERDICT-II		Positive	Negative	Total
TCA (300 ng/mL cutoff)	Positive	49	0	49
Desipramine Test	Negative	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.

ABUSCREEN ONLINE® II Barbiturates Result (Secobarbital)
(300 ng/mL cutoff)

PROFILE-II/VERDICT-II		Positive	Negative	Total
BAR (200 ng/mL cutoff)	Positive	62	0	62
Butalbital Test	Negative	0	45	46
	Total	62	45	107

Overall agreement: 100% (107/107).

ABUSCREEN ONLINE® II Methadone Result
(300 ng/mL cutoff)

PROFILE-II/VERDICT-II		Positive	Negative	Total
MTD (300 ng/mL cutoff)	Positive	55	0	55
Methadone Test	Negative	0	45	45
	Total	55	45	100

Overall agreement: 100% (100/100).

ABUSCREEN ONLINE® II Benzodiazepines Result
(300 ng/mL cutoff)

PROFILE-II/VERDICT-II		Positive	Negative	Total
BZO (300 ng/mL cutoff)	Positive	57	0	57
Nordiazepam Test	Negative	0	45	45
	Total	57	45	102

Overall agreement: 100% (102/102).

PERCENT AGREEMENT COMPARED TO ROCHE ABUSCREEN ONLINE ASSAYS OR HPLC
(Tricyclic Antidepressants, Barbiturates, Methadone and Benzodiazepines)

	POSITIVE	NEGATIVE
Tricyclic Antidepressants	98% (49/50)	100% (45/45)
Barbiturates	100% (62/62)	100% (45/45)
Methadone	100% (55/55)	100% (45/45)
Benzodiazepines	100% (57/57)	100% (45/45)

Sensitivity/ Precision/ Distribution of Random Error (Tricyclic Antidepressants, Barbiturates, Methadone and Benzodiazepines) 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

Barbiturates (Butalbital) Cutoff = 200 ng/mL

Conc. (ng/mL)	Number Tested	Positive	Negative	% Agreement
Negative	45	0	45	100
50	45	0	45	100
100	45	0	45	100
150	45	12	33	73
200	45	43	2	96
250	45	45	0	100
300	45	45	0	100

Methadone (Methadone) Cutoff = 300 ng/mL

Conc. (ng/mL)	Number Tested	Positive	Negative	% Agreement
Negative	45	0	45	100
30	45	3	42	93
75	45	28	17	62
150	45	35	10	78
225	45	43	2	96
300	45	45	0	100
375	45	45	0	100
450	45	43	2	96
600	45	44	1	98

Benzodiazepines (Nordiazepam) Cutoff = 300 ng/mL

Conc. (ng/mL)	Number Tested	Positive	Negative	% Agreement
Negative	45	0	45	100
30	45	0	45	100
75	45	6	39	87
150	45	27	18	60
225	45	41	4	91
300	45	42	3	93
375	45	43	2	96
450	45	45	0	100
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.

MEDTOX® 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 MEDTOX® 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:

MEDTOX® 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:

MEDTOX® 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

Unrelated Compounds, Prescription and Over-the-Counter Medications

The following compounds were tested for reactivity. 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.

Acecainide (N-Acetylprocainamide)
Allobarbital-**BAR**
Alprazolam, 1-Hydroxy-**BZO**
7-Aminoflunitrazepam
Amitriptyline-**TCA**
Amoxicillin
Ampicillin
Aspartame
Atropine Sulfate
Benzilic Acid
Benzoylecgonine-**COC**
Brompheniramine
Butabarbital-**BAR**
Cannabidiol
Carbamazepine
Cephalexin
Chlordiazepoxide
Chlorpheniramine
Clobazam-**BZO**
Clonidine
Cocaine-**COC**
Cotinine
Deoxycorticosterone
Desmethylchlordiazepoxide-BZO
Dexamethasone
Diazepam-**BZO**
Diflunisal
Dimenhydrinate (Dramamine)
Diphenylhydantoin (Phenytoin)-**BAR**
Doxepin-**TCA**
EDDP-(Primary metabolite of methadone)
Ephedrine-**MAMP**
Estrone
Fenfluramine-**MAMP**
Flunitrazepam-**BZO**
Furosemide
Glutethimide
Hexobarbital
Hydrochlorothiazide
Hydromorphone-**OPI, OXY**
l-11-Hydroxy-Δ^9-THC
3-Hydroxytyramine
Imipramine-**TCA**
Isoxsuprine-**COC**
Labetalol
Lithium carbonate
Lorazepam glucuronide-**BZO**
Lysergic Acid Diethylamide (LSD)
MDE (MDEA)-**MAMP**
Meperidine
Mesoridazine
l-Methamphetamine-**MAMP**

Acetaminophen
Alphenal-**BAR**
p-Aminobenzoic Acid
Amino glutethimide
Amobarbital-**BAR**
d-Amphetamine-**AMP**
Apomorphine
Atenolol
Barbital-**BAR**
Benzoic Acid
Benzphetamine
Buprenorphine
Butalbital-**BAR**
Cannabinol
Carbamazepine- 10,11 epoxide
Chloral Hydrate
Chloroquine
Chlorpromazine
Clomipramine
Clorazepate-**BZO**
Codeine-**OPI, OXY**
Cyclobenzaprine-**TCA**
Desalkylflurazepam-**BZO**
Desmethylflunitrazepam-**BZO**
Dextromethorphan
Diclofenac
Digoxin
1,3-Dimethylbarbituric acid
Domperidone
Doxylamine
Efavirenz (Sustiva)
Equilin
Ethanol
Fenoprofen
Fluoxetine (Prozac)
Fluvoxamine
Guaiacol Glyceryl Ether
Hippuric acid
Hydrocodone-**OPI, OXY**
Hydroxybupropion
p-Hydroxyphenobarbital-**BAR**
Hydroxyzine
Iproniazid
Ketamine
Levorphanol-**OPI**
Loperamide
Loxapine
Maprotiline-**TCA**
MDMA
Mephobarbital
Methadone-**MTD**
Methaqualone

Acetylsalicyclic Acid
Alprazolam-**BZO**
7-Aminoclonazepam
l-Aminopyrine (4-(dimethylamino) antipyrine)
Amoxapine
l- Amphetamine-**AMP**
l-Ascorbic Acid
Atomoxetine
Barbituric Acid
Benzocaine (ethyl-4-aminobenzoate)
Benztropine
Bupropion
Caffeine
Captopril
Carisoprodol (Meprobamate)
Chloramphenicol
Chlorothiazide
Chlorprothixene
Clonazepam-**BZO**
Clozapine-**TCA**
Cortisone
Cyclopentobarbital-**BAR**
Desipramine
Desmethylvenlafaxine
Diacetylmorphine-**OPI**
Diethylpropion
Dihydrocodeine-**OPI, OXY**
Diphenhydramine
Dopamine
Ecgonine
EMDP-(Secondary metabolite of methadone)
Erythromycin
Ethylmorphine-**OPI, OXY**
Fentanyl (Synthetic opiate)
Flurazepam
Gentisic Acid (2,5-Dihydroxybenzoic acid)
Haloperidol
Hydralazine
Hydrocortisone
Hydroxyhippuric Acid
4-Hydroxyphencyclidine-**PCP**
Ibuprofen
(R)-Isoproterenol
Ketoprofen
Lidocaine
Lorazepam-**BZO**
Lysergic Acid
MDA-**AMP**
Melanin
Mepivacaine
d-Methamphetamine-**MAMP**
Methcathinone

Methocarbamol
Methylprylon
Mirtazapine
Morphine 3-β-D-Glucuronide-**OPI**
Naltrexone-**OXY**
Naproxen
Nifedipine
Norclomipramine
Nordoxepin-**TCA**
Normeperidine
Nortriptyline-**TCA**
Octopamine
Omeprazole
Oxaprosin
Oxolinic Acid
Oxymorphone-**OXY**
Pentazocine
Phenacetin (Acetophenetidin)
Phenelzine
Phenmetrazine
Phentermine-**AMP**
Phenylephrine-**MAMP**
Prazosin
Procaine-**MAMP**
Promazine-**TCA**
Propranolol
Pyrilamine
Ranitidine
Salicylic Acid
Serotonin (5-Hydroxytryptamine)
Sulfamethazine
Temazepam-**BZO**
Δ^9-Tetrahydrocannabinol
Thebaine-**OPI**
Thiopental
Tolbutamide
Triamterene
Trifluoperazine
Tripelennamine
Tyramine
Venlafaxine

Methoxyphenamine
Metoprolol
6-Monoacetylmorphine-**OPI**
Morphine 6-β-D-Glucuronide-**OPI**
Nalorphine-**OPI**
Niacinamide
Nitrazepam-**BZO**
Norcodeine-**OPI, OXY**
Norethindrone
Norpropoxyphene-**PPX**
Noscapine
Ofloxacin-**OPI**
Orphenadrine
Oxazepam-**BZO**
Oxycodone-**OXY**
Papaverine hydrochloride
Pentobarbital-**BAR**
Phencyclidine-**PCP**
Phenethylamine-**MAMP**
Phenobarbital-**BAR**
Phenytoin (Diphenylhydantoin)-**BAR**
Phenylpropanolamine
Prednisolone
Procainamide
Promethazine
Protriptyline
Quetiapine (Seroquel)-**TCA**
Riboflavin
Secobarbital-**BAR**
Sertraline (Zoloft)
Sulindac
Temazepam glucuronide-**BZO**
Δ^8-Tetrahydrocannabinol
Theophyline
Thioridazine
Tolmetin (Tolectin)
Triazolam-**BZO**
Trimethoprim
Tryptamine
Tyrosine
Verapamil

Methylphenidate
Midazolam-**BZO**
Morphine-**OPI, OXY**
Nalidixic Acid
Naloxone-**OXY**
Nicotine
Nitrofurantoin
Nordiazepam-**BZO**
Norlysergic Acid
l-Norpseudoephedrine
Nylidrin
Olanzapine-**TCA**
Oxalic Acid
Oxazepam glucuronide-**BZO**
Oxymetazoline
Penicillin G
Perphenazine
Phendimetrazine
Pheniramine
Phenothiazine
Phenylbutazone
Piroxicam
Prednisone
Prochlorperazine-**TCA**
Propoxyphene-**PPX**
d-Pseudoephedrine
Quinidine
Rifampin
Selegiline (Deprenyl)
Sildenafil (Viagra)
Talbutal-**BAR**
Tetracycline
Tetrahydrozoline
Thiamine
Thiothixene
Trazodone
Triazolam, 1-hydroxy
Trimipramine-**TCA**
Tryptophan
Valproic Acid
Zomepirac

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 (20 mg/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	Estriol	d,1-Thyroxine
Cholesterol	Glucose Std. Solution	Uric Acid

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. Compounds that reacted with the test are listed first, and related compounds that did not react with the highest concentration tested are listed second as Negative at 100,000 ng/mL (or highest level tested).

Cannabinoids-(THC) (11-nor-9-carboxy-Δ^9-THC) 50 ng/mL

	Result
Cannabidiol	Negative at 100,000 ng/mL
Cannabinol	Negative at 100,000 ng/mL
l-11 Hydroxy-Δ^9-THC	Negative at 50,000 ng/mL
Δ^8 –Tetrahydrocannabinol	Negative at 100,000 ng/mL
Δ^9 –Tetrahydrocannabinol	Negative at 100,000 ng/mL

Opiates(2000)-(OPI) (Morphine) 2000 ng/mL

	Result
Codeine	Positive at 800 ng/mL
Diacetylmorphine	Positive at 2,000 ng/mL
Dihydrocodeine	Positive at 3,000 ng/mL
Ethylmorphine	Positive at 400 ng/mL
Hydrocodone	Positive at 2,000 ng/mL
Hydromorphone	Positive at 3,000 ng/mL
Levorphanol	Positive at 12,500 ng/mL
6-Monoacetyl Morphine	Positive at 3,000 ng/mL
Morphine 3-β-D-Glucuronide	Positive at 3,000 ng/mL
Morphine 6-β-D-Glucuronide	Positive at 25,000 ng/mL
Norcodeine	Positive at 25,000 ng/mL
Ofloxacin	Positive at 50,000 ng/mL
Thebaine	Positive at 50,000 ng/mL
Apomorphine	Negative at 100,000 ng/mL
Nalorphine	Negative at 100,000 ng/mL
Naloxone	Negative at 100,000 ng/mL
Naltrexone	Negative at 100,000 ng/mL
Oxycodone	Negative at 100,000 ng/mL
Oxymorphone	Negative at 100,000 ng/mL
Procaine	Negative at 100,000 ng/mL

Opiates(300)-(OPI) (Morphine) 300 ng/mL

	Result
Codeine	Positive at 100 ng/mL
Diacetylmorphine	Positive at 200 ng/mL
Dihydrocodeine	Positive at 400 ng/mL
Ethylmorphine	Positive at 200 ng/mL
Hydrocodone	Positive at 800 ng/mL
Hydromorphone	Positive at 800 ng/mL
6-Monoacetylmorphine	Positive at 200 ng/mL
Morphine 3-β-D-Glucuronide	Positive at 200 ng/mL
Morphine 6-β-D-Glucuronide	Positive at 12,500 ng/mL
Nalorphine	Positive at 75,000 ng/mL
Norcodeine	Positive at 12,500 ng/mL
Thebaine	Positive at 12,500 ng/mL
Apomorphine	Negative at 100,000 ng/mL
Levorphanol	Negative at 100,000 ng/mL
Naloxone	Negative at 100,000 ng/mL
Naltrexone	Negative at 100,000 ng/mL
Oxycodone	Negative at 100,000 ng/mL
Oxymorphone	Negative at 100,000 ng/mL
Procaine	Negative at 100,000 ng/mL

Amphetamines- (AMP) (d-Amphetamine) 1000 ng/mL

	Result
l-Amphetamine	Positive at 100,000 ng/mL
MDA	Positive at 400 ng/mL
Phentermine	Positive at 10,000 ng/mL

Ephedrine	Negative at 100,000 ng/mL
MDMA	Negative at 100,000 ng/mL
MDE (MDEA)	Negative at 100,000 ng/mL
l-Methamphetamine	Negative at 100,000 ng/mL
d-Methamphetamine	Negative at 100,000 ng/mL
Phenethylamine	Negative at 100,000 ng/mL
Tyramine	Negative at 100,000 ng/mL

Cocaine-(COC) (Benzoylecgonine) 300 ng/mL

	Result
Cocaine	Positive at 800 ng/mL
Isoxsuprine	Positive at 6,000 ng/mL
Ecgonine	Negative at 100,000 ng/mL
Ecgonine Methyl Ester	Negative at 100,000 ng/mL

Phencyclidine-(PCP) (Phencyclidine) 25 ng/mL

	Result
4-Hydroxyphencyclidine	Positive at 5,000 ng/mL

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

	Result
Amitriptyline	Positive at 500 ng/mL
Clozapine	Positive at 2,000 ng/mL
Cyclobenzaprine	Positive at 5,000 ng/mL
Doxepin	Positive at 1,000 ng/mL
Imipramine	Positive at 200 ng/mL
Maprotiline	Positive at 500 ng/mL
Nordoxepin	Positive at 750 ng/mL
Nortriptyline	Positive at 500 ng/mL
Olanzapine	Positive at 10,000 ng/mL
Prochlorperazine	Positive at 25,000 ng/mL
Promazine	Positive at 250 ng/mL
Quetiapine (Seroquel)	Positive at 2,500 ng/mL
Trimipramine	Positive at 2,500 ng/mL
Chlorpromazine	Negative at 100,000 ng/mL
Chlorprothixine	Negative at 100,000 ng/mL
Clomipramine	Negative at 100,000 ng/mL
Loxapine	Negative at 100,000 ng/mL
Mirtazepine	Negative at 100,000 ng/mL
Norclomipramine	Negative at 100,000 ng/mL
Perphenazine	Negative at 100,000 ng/mL
Phenothiazine	Negative at 100,000 ng/mL
Protriptyline	Negative at 100,000 ng/mL
Thiothixene	Negative at 100,000 ng/mL

Barbiturate-(BAR) (Butalbital) 200 ng/mL

	Result
Allobarbital	Positive at 250 ng/mL
Alphenal	Positive at 100 ng/mL
Amobarbital	Positive at 2,500 ng/mL
Barbital	Positive at 2,500 ng/mL
Butabarbital	Positive at 1,000 ng/mL
Cyclopentobarbital	Positive at 250 ng/mL
Diphenylhydantoin (Phenytoin)	Positive at 2,500 ng/mL

p-Hydroxyphenobarbital	Positive at 500 ng/mL
Pentobarbital	Positive at 500 ng/mL
Phenobarbital	Positive at 800 ng/mL
Secobarbital	Positive at 50 ng/mL
Talbutal	Positive at 75 ng/mL
Aminoglutethimide	Negative at 100,000 ng/mL
Barbituric Acid	Negative at 100,000 ng/mL
1,3 Dimethylbarbituric Acid	Negative at 100,000 ng/mL
Glutethimide	Negative at 100,000 ng/mL
Hexobarbital	Negative at 100,000 ng/mL
Mephobarbital	Negative at 100,000 ng/mL

Methadone-(MTD) (Methadone) 300 ng/mL

	Result
Primary metabolite (EDDP)	Negative at 100,000 ng/mL
Secondary metabolite (EMDP)	Negative at 100,000 ng/mL

Benzodiazepine-(BZO) (Nordiazepam) 300 ng/mL

	Result
Alprazolam	Positive at 100 ng/mL
Alprazolam, 1-OH	Positive at 2,500 ng/mL
Clobazam	Positive at 50 ng/mL
Clonazepam	Positive at 250 ng/mL
Clorazepate	Positive at 250 ng/mL
Desalkylflurazepam	Positive at 250 ng/mL
Desmethylchlordiazepoxide	Positive at 500 ng/mL
Desmethylflunitrazepam	Positive at 75 ng/mL
Diazepam	Positive at 100 ng/mL
Flunitrazepam	Positive at 75 ng/mL
Lorazepam	Positive at 750 ng/mL
Lorazepam glucuronide	Positive at 250 ng/mL
Midazolam	Positive at 5,000 ng/mL
Nitrazepam	Positive at 50 ng/mL
Oxazepam	Positive at 250 ng/mL
Oxazepam glucuronide	Positive at 500 ng/mL
Temazepam	Positive at 50 ng/mL
Temazepam glucuronide	Positive at 250 ng/mL
Triazolam	Positive at 750 ng/mL
7-Aminoclonazepam	Negative at 100,000 ng/mL
7-Aminoflunitrazepam	Negative at 100,000 ng/mL
Chlordiazepoxide	Negative at 100,000 ng/mL
Flurazepam	Negative at 100,000 ng/mL
Triazolam, 1-OH	Negative at 100,000 ng/mL

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

	Result
Propoxyphene	Positive at 50 ng/mL
Promethazine	Negative at 100,000 ng/mL

Methamphetamine-(MAMP) (d-Methamphetamine) 1000 ng/mL, (MDMA) 1500 ng/mL

	Result
Ephedrine	Positive at 2,500 ng/mL
Fenfluramine	Positive at 25,000 ng/mL
MDE (MDEA)	Positive at 5,000 ng/mL
l-Methamphetamine	Positive at 7,500 ng/mL
Phenethylamine	Positive at 2,500 ng/mL
Phenylephrine	Positive at 50,000 ng/mL
Procaine	Positive at 10,000 ng/mL
d-Amphetamine	Negative at 100,000 ng/mL
l-Amphetamine	Negative at 100,000 ng/mL
MDA	Negative at 100,000 ng/mL
Phentermine	Negative at 100,000 ng/mL
Pseudoephedrine	Negative at 100,000 ng/mL
Tyramine	Negative at 100,000 ng/mL

Oxycodone (OXY) 100 ng/mL	**Result**
Codeine	Positive at 2,500 ng/mL
Dihydrocodeine	Positive at 2,500 ng/mL
Ethylmorphine	Positive at 2,500 ng/mL
Hydrocodone	Positive at 10,000 ng/mL
Hydromorphone	Positive at 10,000 ng/mL
Morphine	Positive at 5,000 ng/mL
Naloxone	Positive at 10,000 ng/mL
Naltrexone	Positive at 25,000 ng/mL
Norcodeine	Positive at 50,000 ng/mL
Oxymorphone	Positive at 200 ng/mL
Apomorphine	Negative at 100,000 ng/mL
Diacetylmorphine	Negative at 100,000 ng/mL
Levorphanol	Negative at 50,000 ng/mL
6-Monoacetylmorphine	Negative at 100,000 ng/mL
Morphine 3-β-D-Glucuronide	Negative at 100,000 ng/mL
Morphine 6-β-D-Glucuronide	Negative at 10,000 ng/mL
Nalorphine	Negative at 100,000 ng/mL
Thebaine	Negative at 100,000 ng/mL

Interference-Oxycodone

pH and Specific Gravity:

The MEDTOX® 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 MEDTOX® 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 MEDTOX® 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 MEDTOX® OXYCODONE TESTS

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

Interference Propoxyphene/Methamphetamine Only

Following the study of M.L Smith, et. al.[5] the following drugs were tested to determine the degree of interference they may have on the test. Commercial negative urine was spiked with 100 µg/mL of each of these drugs and with either 75 ng/mL or 600 ng/mL of norpropoxyphene or methamphetamine. Each spiked sample was tested in triplicate on the test. None of these drugs affected the expected negative or positive results with either the 75 ng/mL or 600 ng/mL fortified samples. The drugs are listed below.

Acetylsalicylic Acid	Chlorpheniramine	Ibuprofen
Acetaminophen	Cocaine	Morphine
Brompheniramine maleate	Dextromethorphan	Phenobarbital
Caffeine	5,5 Diphenylhydantoin	d-Pseudoephedrine
Carbamazepine	Doxylamine	Salicyclic Acid

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16. 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/VERDICT-II 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.
U.S. Patent Nos. 6,566,051, 6,376,251, 6,653,139

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