

# MEDTOX<sup>®</sup>

## PROFILE<sup>®</sup>-III / PROFILE<sup>®</sup>-IIIA / VERDICT<sup>®</sup>-III PACKAGE INSERT

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

The Lateral Flow (LatFlo<sup>®</sup>) Adulterant Strip (LFAS) is a one-step qualitative screening assay for the detection of Oxidants, 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.

### 1. INTENDED USE

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

AMP	Amphetamine (d-Amphetamine)	1000 ng/mL	OPI2	Opiates (Morphine)	2000 ng/mL
BAR	Barbiturates (Butalbital)	200 ng/mL	OPI	Opiates (Morphine)	300 ng/mL
BZO	Benzodiazepines (Nordiazepam)	300 ng/mL	OXY	Oxycodone	100 ng/mL
COC	Cocaine (Benzoylecgonine)	300 ng/mL	PCP	Phencyclidine (Phencyclidine)	25 ng/mL
MAMP	Methamphetamine (d-Methamphetamine)	1000 ng/mL	PPX	Propoxyphene (Norpropoxyphene)	300 ng/mL
MDMA	3,4 Methylendioxyamphetamine	1500 ng/mL	THC	Cannabinoids (11-nor-9-carboxy- $\Delta^8$ -THC)	50 ng/mL
MTD	Methadone (Methadone)	300 ng/mL			

THE PROFILE-III/VERDICT-III 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) OR HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) IS THE PREFERRED CONFIRMATORY METHOD. 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-III/VERDICT-III 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:

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 Methylendioxyamphetamine', (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 Ecstasy (MDMA) 'Methylendioxyamphetamine' and methamphetamine (d-methamphetamine) are detected on the device at the (MAMP) position. The (MAMP) antibody does not differentiate between methamphetamine and ecstasy.

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.

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

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

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

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

Oxycodone (OXY) (Oxycontin<sup>®</sup>, 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.

Phencyclidine (PCP) is a hallucinogenic drug.

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

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

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.<sup>1-5</sup>

<u>Drug</u>	<u>Detection Period</u>	<u>Drug</u>	<u>Detection Period</u>
Amphetamine Acid Conditions	1-3 days	Opiates	
Alkaline Condition	3-10 days	Heroin	1 day
		Morphine	1-3 days
		Codeine	1-3 days
Barbiturates		Oxycodone	1-3 days
Short-Acting	up to 6 days		
Long-Acting	up to 16 days		
Benzodiazepines	1-12 days	PCP	
		Single Use	7-8 days
		Chronic Use	2-4 weeks
Cocaine	1-3 days	Propoxyphene	Up to 1 week
Methadone	1-3 days	THC	
		Single Use	1-3 days
		Chronic, Light Use	3-29 days
		Chronic, Heavy Use	up to 12 weeks
Methamphetamine			
Acid Conditions	1-3 days		
Alkaline Conditions	3-10 days		

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-III/VERDICT-III 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 (C) 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 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 the appropriate "T" location on the device. Strips with two tests will be labeled with two colors and are on left-hand side of device. The top color will indicate the T1 test with T1= drug test name. The bottom color will indicate the T2 test with T2= drug test name. Strips with only one color will have test results appear at the T1 position. Negative results can be reported as soon as a line is visible.

#### Non-Negative 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. However, when the antibody-colloidal gold binds to the drug(s) in the urine, the antibody colloidal gold cannot bind to the drug conjugate immobilized on the membrane. When the drug concentration is at or above the cutoff concentration, the majority of the antibody-colloidal gold is bound to the drug from the urine. Therefore, as the drug bound antibody-colloidal gold migrates along the strip(s), it is unable to bind to the appropriate drug conjugate immobilized on the membrane. Therefore no line is generated at the drug-specific location in the result window for a positive sample. Read non-negative results at 5 minutes. The control line should be present for the test to be valid. The test result for Oxycodone after 5 minutes may not be consistent with the original reading. For all other tests, 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.

#### Control Line

Each test strip has an internal procedural control. A line must form at the Control (C) 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. 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-III/VERDICT-III Drugs of Abuse Test System contains all the reagents necessary to test one urine sample simultaneously for one or more drugs.

##### Kit Contents

The PROFILE-III/VERDICT-III Drugs of Abuse Test System kit contains twenty-five (25) test system bags and one instructional package insert or reference guide.

##### Test System Bag Contents

1. One (1) test device in a foil package.
  - a. The test strips each contain a membrane coated with drug conjugate and a pad coated with antibody dye complexes in a protein matrix.
  - b. 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-III/VERDICT-III product.**
2. One (1) cup with temperature strip attached.
3. One (1) lid.
4. Two (2) lid seals.
5. One (1) Color Comparator Chart (products with LFAS test strips only).

##### 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. 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 drug screen portion of the device is for in vitro diagnostic use only. The LFAS strip is for Forensic/Toxicology use only.

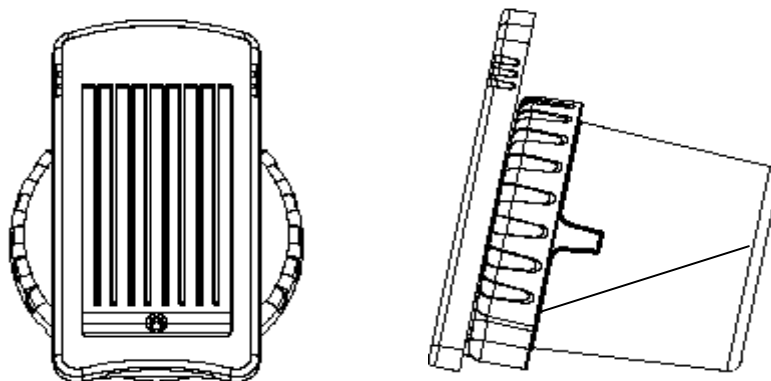
#### 6. SAMPLE COLLECTION AND PREPARATION

The urine sample should be collected in the provided cup. The urine volume should be above the minimum volume line. 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. TEST PROCEDURE

1. Fill the cup between the minimum and maximum volume lines.
2. Screw lid clock-wise onto the cup until tight.
3. Open pouch and label the device with the patient or sample identification.
4. Secure device snugly to lid as noted on the lid icon.
5. Tip the cup on its side as shown below to start flow (if less than 45 ml of urine, tilt the cup forward to begin flow).
6. If LFAS is present, read pH, Specific Gravity, and Nitrites in vertical position as soon as color changes. Read oxidant at 60 seconds.
7. Allow the test system to sit for 5 minutes.
8. Turn the test system upright and read the results. Negative results can be read as soon as a line is visible, non-negatives at 5 minutes.

**NOTE:** The test must be read within 15 minutes of the sample application for all tests except Oxycodone. Oxycodone should be read at 5 minutes. The test results may not be reliable after 15 minutes for all tests except Oxycodone. Oxycodone results may not be reliable after 5 minutes.



## 8. READING THE TEST RESULTS

**Negative:** The appearance of a reddish-purple line at both the control area (C) and appropriate test area (T) indicates a negative test result. **The color intensities of the control lines (C) and test lines (T) 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.**

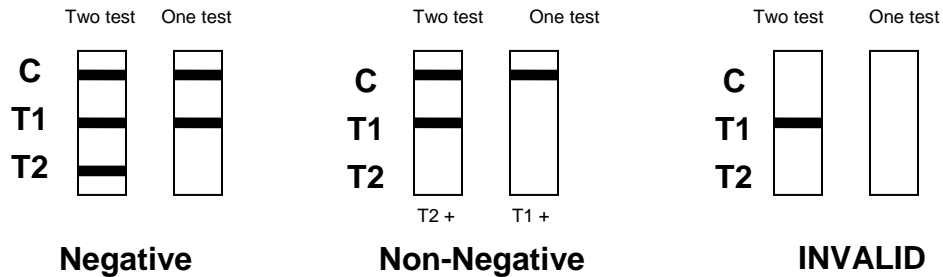
**Non-Negative:** The appearance of a control line and the absence of a test line indicate a preliminary positive test result for that drug.

**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 or those with abnormal LFAS tests should be sent to a reference laboratory for more definitive testing. 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.

## 10. QUALITY CONTROL

An internal procedural control is included on each device. A line must form at the Control (C) 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 (C) 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-III/VERDICT-III 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 may not be consistent with the original result obtained at 5 minutes.
4. The PROFILE-III/VERDICT-III 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.

### 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.

## 12. EXPECTED VALUES

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

AMP	Amphetamine	1000 ng/mL
COC	Benzoylcegonine	300 ng/mL
MAMP	Methamphetamine	1000 ng/mL
OPI	Morphine and Codeine	2000 ng/mL
PCP	Phencyclidine	25 ng/mL
THC	11-nor-9-carboxy- $\Delta^9$ -THC	50 ng/mL

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

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

### 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.

## 13. PERFORMANCE CHARACTERISTICS

### Sensitivity

The PROFILE-III/VERDICT-III Drugs of Abuse Test detects one or more of the following drugs at cutoff levels listed below. Cutoffs for amphetamines, cocaine metabolite, methamphetamines, opiates (OPI2), phencyclidine, and cannabinoids (THC) are based on SAMHSA recommendations for screening of these drugs in human urine<sup>3</sup>. The Opiate (OPI) test, if present, detects opiates below the SAMHSA recommendations for screening of opiates in human urines. There are no SAMHSA recommended screening cutoff levels for barbiturates, benzodiazepines, MDMA, methadone, Norpropoxyphene, or Propoxyphene.

AMP	Amphetamine	1000 ng/mL
BAR	Barbiturates (Butalbital)	200 ng/mL
BZO	Benzodiazepines (Nordiazepine)	300 ng/mL
COC	Benzoylcegonine	300 ng/mL
MAMP	Methamphetamine	1000 ng/mL
MDMA	3,4 Methylene-dioxy-methamphetamine	1500 ng/mL
MTD	Methadone	300 ng/mL
OPI2	Morphine	2000 ng/mL
OPI	Morphine	300 ng/mL
OXY	Oxycodone	100 ng/mL
PCP	Phencyclidine	25 ng/mL
PPX	Propoxyphene (Norpropoxyphene)	300 ng/mL
THC	11-nor-9-carboxy- $\Delta^9$ -THC	50 ng/mL

### Accuracy

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

#### ACCURACY COMPARED TO THE BOEHRINGER MANNHEIM QUALITATIVE CEDIA<sup>®</sup> or THE ROCHE ABUSCREEN ONLINE<sup>®</sup> II ASSAYS

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

PROFILE-III / VERDICT-III		<u>Positive</u>	<u>Negative</u>	<u>TOTAL</u>
AMP (1000 ng/mL cutoff)	Positive	64	0	64
	<u>Negative</u>	<u>2</u>	<u>618</u>	<u>620</u>
	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-III / VERDICT-III		<u>Positive</u>	<u>Negative</u>	<u>TOTAL</u>
COC (300 ng/mL)	Positive	96	8	104
	<u>Negative</u>	<u>2</u>	<u>578</u>	<u>580</u>
	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.

##### ROCHE ABUSCREEN ONLINE<sup>®</sup>-II OPIATE (2000 ng/mL cutoff)

PROFILE-III / VERDICT-III		<u>Positive</u>	<u>Negative</u>	<u>TOTAL</u>
OPI (2000 ng/mL cutoff)	Positive	68	0	68
	<u>Negative</u>	<u>0</u>	<u>89</u>	<u>89</u>
	TOTAL	68	89	157

Overall agreement: 100% (157/157).

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

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

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 PHENCYCLIDINE (25 ng/mL cutoff)**

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

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.

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

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

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.

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

	<u>Relative Sensitivity</u>	<u>Relative Specificity</u>
AMP	97% (64/66)	100% (618/618)
COC	98% (96/98)	99% (578/586)
OPI2	100% (68/68)	100% (89/89)
OPI3	100% (133/133)	>99% (550/551)
PCP	98% (56/57)	>99% (625/627)
THC	95% (94/204)	99% (477/480)

**ACCURACY COMPARED to GC/MS**

	<u>PROFILE-III/VERDICT-III</u>	<u>GC/MS</u>	<u>Values for discrepant Samples (ng/mL)</u>
AMP	Positive	48	50
	Negative	52	50
COC	Positive	49	50
	Negative	51	50
OPI2	Positive	47	47
	Negative	0	0
OPI3	Positive	50	50
	Negative	50	50
PCP	Positive	49	50
	Negative	51	50
THC	Positive	48	50
	Negative	52	50

**Precision (Amphetamines, Cocaine, Opiates, PCP, and THC)**

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: AMP=100%, COC=100%, OPI2= 96.7%, OPI= 100%, PCP=100% and THC= 95%.

**Reproducibility (Amphetamines, Cocaine, Opiates 300, PCP, and THC)**

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 AMP, COC, PCP and THC. 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 1056 and 4622 ng/mL for AMP; 487 and 1342 ng/mL for COC; 464 and 2000 ng/mL for OPI; 32 and 109 ng/mL for PCP and 66 and 198 ng/mL for THC. The panel was used to evaluate the lot-to-lot and lab-to-lab reproducibility.

**Lot-to-Lot Reproducibility (Amphetamines, Cocaine, Opiates 300, PCP, and THC)**

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 (Amphetamines, Cocaine, Opiates 300, PCP, and THC)**

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 OPI (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:

	<u>OnLine Positive</u>	<u>OnLine Negative</u>
PROFILE-III / VERDICT-III	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.

Conc. (ng/mL)	Number Tested	<b>Norpropoxyphene – Cut-off = 300 ng/mL</b>		% Agreement
		Positive	Negative	
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-III MAMP-MDMA and the GC/MS assay for methamphetamine and MDMA. The results obtained in the procedures are shown in the following tables.

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

PROFILE-III / VERDICT-III	<u>Positive</u>	<u>Negative</u>	<u>TOTAL</u>
MAMP (1000 ng/mL cut-off)	56	0	56
	<u>2</u>	<u>56</u>	<u>58</u>
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-III / VERDICT-III	<u>Positive</u>	<u>Negative</u>	<u>TOTAL</u>
MDMA (1500 ng/mL cut-off)	19	1	20
	<u>4</u>	<u>57</u>	<u>61</u>
TOTAL	23	58	81

Overall agreement: 94% (76/81). The false negative samples contained MDMA concentrations at 1641 ng/mL, 1775 ng/mL, 1800 ng/mL and 2388 ng/mL. The false positive was at 1300 ng/mL.

**Percent Agreement of MAMP-MDMA Compared to GC/MS**

	<u>POSITIVE</u>	<u>NEGATIVE</u>
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.

Conc. (ng/mL)	Methamphetamine Cut-off = 1000 ng/mL				MDMA Cut-off= 1500 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 (Barbiturates, Benzodiazepines and Methadone)**

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

**ACCURACY COMPARED TO GC/MS  
(Barbiturates, Benzodiazepines, and Methadone)**

DRUG CLASS	Concentration Range (ng/mL)	Number of Samples	PROFILE-III/VERDICT-III Results
<b>Barbiturates</b>	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
<b>Benzodiazepines</b>	303 – 30813	57	57/57 Positive
	234, 236, 238, 250, 283	5	5/5 Negative
<b>Methadone</b>	306 - 70560	57	57/57 Positive
	224, 226, 227, 230, 232	5	5/5 Negative

Additionally, the accuracy was evaluated in comparison to the Roche Diagnostics Systems, Inc, ABUSCREEN ONLINE® assays for barbiturates, benzodiazepines and methadone. 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  
(Barbiturates, Benzodiazepines, and Methadone)**

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

PROFILE-III / VERDICT-III		Positive	Negative	Total
BAR (200 ng/mL cutoff)	Positive	62	0	62
<b>Butalbital Test</b>	Negative	0	45	45
	Total	62	45	107

Overall agreement: 100% (107/107).

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

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

Overall agreement: 100% (102/102).

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

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

Overall agreement: 100% (100/100).

**PERCENT AGREEMENT COMPARED TO ROCHE ABUSCREEN ONLINE ASSAYS  
(Barbiturates, Benzodiazepines, and Methadone)**

	POSITIVE	NEGATIVE
Barbiturates	100% (62/62)	100% (45/45)
Benzodiazepines	100% (57/57)	100% (45/45)
Methadone	100% (55/55)	100% (45/45)

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

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.

**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

**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

**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

**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<sup>®</sup> 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
<b>100</b>	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 (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

**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.

Acecaïnide (N-Acetylprocainamide)	Acetaminophen	Acetylsalicylic Acid
Allobarbitol- <b>BAR</b>	Alphenal- <b>BAR</b>	Alprazolam- <b>BZO</b>
Alprazolam, 1-Hydroxy- <b>BZO</b>	p-Aminobenzoic Acid	7-Aminoclonazepam
7-Aminoflunitrazepam	Amino glutethimide	l-Aminopyrine (4-(dimethylamino) antipyrine)
Amitriptyline	Amobarbital- <b>BAR</b>	Amoxapine
Amoxicillin	d-Amphetamine- <b>AMP</b>	l- Amphetamine- <b>AMP</b>
Ampicillin	Apomorphine	l-Ascorbic Acid
Aspartame	Atenolol	Atomoxetine
Atropine Sulfate	Barbital- <b>BAR</b>	Barbituric Acid
Benzilic Acid	Benzoic Acid	Benzocaine (ethyl-4-aminobenzoate)
Benzoyllecgonine- <b>COC</b>	Benzphetamine	Benztropine
Brompheniramine	Buprenorphine	Bupropion
Butabarbital- <b>BAR</b>	Butalbital- <b>BAR</b>	Caffeine
Cannabidiol	Cannabinol	Captopril
Carbamazepine	Carbamazepine- 10,11 epoxide	Carisoprodol (Meprobamate)
Cephalexin	Chloral Hydrate	Chloramphenicol
Chlordiazepoxide	Chloroquine	Chlorothiazide
Chlorpheniramine	Chlorpromazine	Chlorprothixene
Clobazam- <b>BZO</b>	Clomipramine	Clonazepam- <b>BZO</b>
Clonidine	Clorazepate- <b>BZO</b>	Clozapine
Cocaine- <b>COC</b>	Codeine- <b>OPI, OXY</b>	Cortisone
Cotinine	Cyclobenzaprine	Cyclopentobarbital- <b>BAR</b>
Deoxycorticosterone	Desalkylflurazepam- <b>BZO</b>	Desipramine
Desmethylchlordiazepoxide- <b>BZO</b>	Desmethylflunitrazepam- <b>BZO</b>	Desmethylvenlafaxine
Dexamethasone	Dextromethorphan	Diacetylmorphine- <b>OPI</b>
Diazepam- <b>BZO</b>	Diclofenac	Diethylpropion
Diflunisal	Digoxin	Dihydrocodeine- <b>OPI, OXY</b>
Dimenhydrinate (Dramamine)	1,3-Dimethylbarbituric acid	Diphenhydramine
Diphenylhydantoin (Phenytoin)- <b>BAR</b>	Domperidone	Dopamine
Doxepin	Doxylamine	Ecgonine
EDDP-(Primary metabolite of methadone)	Efavirenz (Sustiva)	EMDP-(Secondary metabolite of methadone)
Ephedrine- <b>MAMP</b>	Equilin	Erythromycin
Estrone	Ethanol	Ethylmorphine- <b>OPI, OXY</b>
Fenfluramine- <b>MAMP</b>	Fenoprofen	Fentanyl (Synthetic opiate)
Flunitrazepam- <b>BZO</b>	Fluoxetine (Prozac)	Flurazepam
Furosemide	Fluvoxamine	Gentisic Acid (2,5-Dihydroxybenzoic acid)
Glutethimide	Guaiaicol Glyceril Ether	Haloperidol
Hexobarbital	Hippuric acid	Hydralazine
Hydrochlorothiazide	Hydrocodone- <b>OPI, OXY</b>	Hydrocortisone
Hydromorphone- <b>OPI, OXY</b>	Hydroxybupropion	Hydroxyhippuric Acid
l-11-Hydroxy-Δ <sup>9</sup> -THC	p-Hydroxyphenobarbital- <b>BAR</b>	4-Hydroxyphenacyclidine- <b>PCP</b>
3-Hydroxytyramine	Hydroxyzine	Ibuprofen
Imipramine	Iproniazid	(R)-Isoproterenol
Isoxsuprine- <b>COC</b>	Ketamine	Ketoprofen
Labetalol	Levorphanol- <b>OPI</b>	Lidocaine
Lithium carbonate	Loperamide	Lorazepam- <b>BZO</b>
Lorazepam glucuronide- <b>BZO</b>	Loxapine	Lysergic Acid
Lysergic Acid Diethylamide (LSD)	Maprotiline	MDA- <b>AMP</b>
MDE (MDEA)- <b>MAMP</b>	MDMA	Melanin

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

Mephobarbital  
 Methadone-**MTD**  
 Methaqualone  
 Methoxyphenamine  
 Metoprolol  
 6-Monoacetylmorphine-**OPI**  
 Morphine 6-β-D-Glucuronide-**OPI**  
 Nalorphine-**OPI**  
 Niacinamide  
 Nitrazepam-**BZO**  
 Norcodeine-**OPI, OXY**  
 Norethindrone  
 Norpropoxyphene-**PPX**  
 Noscapine  
 Ofloxacin  
 Orphenadrine  
 Oxazepam-**BZO**  
 Oxycodone-**OXY**  
 Papaverine hydrochloride  
 Pentobarbital-**BAR**  
 Phencyclidine-**PCP**  
 Phenethylamine-**MAMP**  
 Phenobarbital-**BAR**  
 Phenytoin (Diphenylhydantoin)-**BAR**  
 Phenylpropranolamine  
 Prednisolone  
 Procainamide  
 Promethazine  
 Protriptyline  
 Quetiapine (Seroquel)  
 Riboflavin  
 Secobarbital-**BAR**  
 Sertraline (Zoloft)  
 Sulindac  
 Temazepam glucuronide-**BZO**  
 Δ<sup>9</sup>-Tetrahydrocannabinol  
 Theophylline  
 Thioridazine  
 Tolmetin (Tolectin)  
 Triazolam-**BZO**  
 Trimethoprim  
 Tryptamine  
 Tyrosine  
 Verapamil

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

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

l-Amphetamine  
 MDA  
 Phentermine

Ephedrine  
 MDMA  
 MDE (MDEA)  
 l-Methamphetamine  
 d-Methamphetamine  
 Phenethylamine  
 Tyramine

**Result**

Positive at 100 µg/mL  
 Positive at 400 ng/mL  
 Positive at 10 µg/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  
 Negative at 100 µg/mL  
 Negative at 100 µg/mL

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

Allobarbital  
 Alphenal  
 Amobarbital  
 Barbitol  
 Butabarbitol  
 Cyclopentobarbital  
 p-Hydroxyphenobarbital  
 Pentobarbital  
 Phenobarbital  
 Phenytoin (Diphenylhydantoin)  
 Secobarbital  
 Talbutal

Amino glutethimide  
 Barbituric Acid  
 1,3 Dimethylbarbituric Acid  
 Glutethimide  
 Hexobarbital  
 Mephobarbital

**Result**

Positive at 500 ng/mL  
 Positive at 100 ng/mL  
 Positive at 2500 ng/mL  
 Positive at 2500 ng/mL  
 Positive at 750 ng/mL  
 Positive at 250 ng/mL  
 Positive at 500 ng/mL  
 Positive at 500 ng/mL  
 Positive at 800 ng/mL  
 Positive at 2500 ng/mL  
 Positive at 75 ng/mL  
 Positive at 50 ng/mL

Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL

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

Alprazolam  
 Alprazolam, 1-OH  
 Clobazam  
 Clonazepam  
 Clorazepate  
 Desalkylflurazepam  
 Desmethylchloridiazepoxide  
 Desmethylflunitrazepam  
 Diazepam  
 Flunitrazepam  
 Lorazepam  
 Lorazepam glucuronide

**Result**

Positive at 250 ng/mL  
 Positive at 25 µg/mL  
 Positive at 50 ng/mL  
 Positive at 250 ng/mL  
 Positive at 250 ng/mL  
 Positive at 250 ng/mL  
 Positive at 500 ng/mL  
 Positive at 75 ng/mL  
 Positive at 50 ng/mL  
 Positive at 75 ng/mL  
 Positive at 2.5 µg/mL  
 Positive at 1 µg/mL

Midazolam	Positive at 5 µg/mL
Nitrazepam	Positive at 50 ng/mL
Oxazepam	Positive at 500 ng/mL
Oxazepam glucuronide	Positive at 2.5 µg/mL
Temazepam	Positive at 50 ng/mL
Temazepam glucuronide	Positive at 750 ng/mL
Triazolam	Positive at 750 ng/mL

7-Aminoclonazepam	Negative at 100 µg/mL
7-Aminoflunitrazepam	Negative at 100 µg/mL
Chlordiazepoxide	Negative at 100 µg/mL
Flurazepam	Negative at 100 µg/mL
Triazolam, 1-OH	Negative at 10 µg/mL

**Cocaine-(COC)** (Benzoyllecgonine) 300 ng/mL

Cocaine	Positive at 800 ng/mL
Isosuprine	Positive at 6 µg/mL

Ecgonine	Negative at 100 µg/mL
Ecgonine Methyl Ester	Negative at 100 µg/mL

**Methamphetamine-(MAMP)** (d-Methamphetamine) 1000 ng/mL,

(MDMA) 1500 ng/mL

Ephedrine	Positive at 2.5 µg/mL
Fenfluramine	Positive at 25 µg/mL
MDE (MDEA)	Positive at 5 µg/mL
l-Methamphetamine	Positive at 7.5 µg/mL
Phenethylamine	Positive at 2.5 µg/mL

d-Amphetamine	Negative at 100 µg/mL
l-Amphetamine	Negative at 100 µg/mL
MDA	Negative at 100 µg/mL
Phentermine	Negative at 100 µg/mL
Pseudoephedrine	Negative at 100 µg/mL
Tyramine	Negative at 100 µg/mL

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

Primary metabolite (EDDP)	Negative at 100 µg/mL
Secondary metabolite (EMDP)	Negative at 100 µg/mL

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

Diacetylmorphine	Positive at 2.0 µg/mL
Dihydrocodeine	Positive at 3 µg/mL
Ethylmorphine	Positive at 400 ng/mL
Hydrocodone	Positive at 2.0 µg/mL
Hydromorphone	Positive at 3 µg/mL
Levorphanol	Positive at 12.5 µg/mL
6-Monoacetyl Morphine	Positive at 3 µg/mL
Morphine 3-β-D-Glucuronide	Positive at 3 µg/mL
Morphine 6-β-D-Glucuronide	Positive at 25 µg/mL
Norcodeine	Positive at 25 µg/mL
Thebaine	Positive at 50 µg/mL

Apomorphine	Negative at 100 µg/mL
Nalorphine	Negative at 100 µg/mL
Naloxone	Negative at 100 µg/mL
Naltrexone	Negative at 100 ug/mL
Oxycodone	Negative at 100 µg/mL
Oxymorphone	Negative at 100 µg/mL

**Opiates(300)-(OPI)** (Morphine) 300ng/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 12.5 µg/mL
Nalorphine	Positive at 75 µg/mL
Norcodeine	Positive at 12.5 µg/mL
Thebaine	Positive at 12.5 µg/mL

Apomorphine	Negative at 100 µg/mL
Levorphanol	Negative at 100 µg/mL
Naloxone	Negative at 100 µg/mL
Naltrexone	Negative at 100 µg/mL
Oxycodone	Negative at 100 µg/mL
Oxymorphone	Negative at 100 µg/mL

**Oxycodone (OXY)** (Oxycodone) 100 ng/mL

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

<b>Propoxyphene-(PPX)</b> (Norpropoxyphene) 300 ng/mL	<b>Result</b>
Propoxyphene	Positive at 50 ng/mL

<b>Phencyclidine-(PCP)</b> (Phencyclidine) 25 ng/mL	<b>Result</b>
4-Hydroxyphencyclidine	Positive at 5 µg/mL

<b>Cannabinoids-(THC)</b> (11-nor-9-carboxy-Δ <sup>9</sup> -THC) 50 ng/mL	<b>Result</b>
Cannabidiol	Negative at 100 µg/mL
Cannabinol	Negative at 100 µg/mL
1-11 Hydroxy-Δ <sup>9</sup> -THC	Negative at 50 µg/mL
Δ <sup>8</sup> –Tetrahydrocannabinol	Negative at 100 µg/mL
Δ <sup>9</sup> –Tetrahydrocannabinol	Negative at 100 µg/mL

**Interference-Oxycodone**  
pH and Specific Gravity:

The MEDTOX<sup>®</sup> 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<sup>®</sup> 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.<sup>7</sup> 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<sup>®</sup> 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<sup>®</sup> OXYCODONE TESTS**

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

**Interference Methamphetamine Only**

Following the study of M.L. Smith, et. al.<sup>7</sup> 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 600 ng/mL of methamphetamine. Each spiked sample was tested in triplicate on the test. None of these drugs affected the expected negative or positive results with the 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	Salicylic Acid

**14. BIBLIOGRAPHY**

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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-III/VERDICT-III 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. 5,202,268, 6,566,051, 6,376,251, 7,458,942

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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