



PROFILE[®] -III ER OXYCODONE

The MEDTOX[®] OXYCODONE product is a rapid qualitative screening assay for the detection of Oxycodone or its metabolites in human urine.

1. INTENDED USE

The MEDTOX[®] OXYCODONE Test System uses immunochromatographic test strips for the rapid, qualitative detection of Oxycodone in human urine. It is intended for prescription use.

The test detects Oxycodone at concentrations of 100 ng/mL and above.

THE MEDTOX[®] OXYCODONE 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) IS THE PREFERRED CONFIRMATORY METHOD. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT.

Special Condition for Use Statement

MEDTOX[®] OXYCODONE is intended for prescription point-of-care use including physician office laboratories and central laboratory settings. It is also intended for workplace settings, criminal justice or forensic settings, and drug rehabilitation centers. MEDTOX[®] OXYCODONE is not for over-the-counter sale.

Workplace operators that may use this device are defined as individuals with a minimum of a high school education who also satisfy the following training and certification guidelines:

(1) Training should be conducted by a qualified professional and include a demonstration of the MEDTOX[®] OXYCODONE test system and (2) the use of quality assurance samples for monitoring and confirming the performance of the test system. Trainers should observe and confirm that the operator (3) uses proper technique when running a test sample and quality assurance samples, (4) has a basic understanding of test results, including the potential for false positive and false negative results, (5) knows how to prepare a sample for shipment to the laboratory for confirmation testing, (6) has reviewed the information contained in the MEDTOX[®] Training and Certification Program (available at www.medtox.com) and (7) that the operator minimally achieves a score of 80% on the written exam provided by MEDTOX[®].

Operators achieving a score of 80% will be provided with a certificate of training participation. Quality assurance samples appropriate for training are available from MEDTOX[®] Diagnostics, Inc. Additionally, MEDTOX[®] Technical Support will provide access to assistance from individuals who are experienced in the interpretation of drug testing results.

2. SUMMARY AND EXPLANATION OF THE TEST

The qualitative MEDTOX[®] OXYCODONE Test screen utilizes a rapid, solid-phase immunoassay technology to provide a very rapid test requiring no instrumentation. This test may be used to screen urine samples for Oxycodone and its metabolites prior to confirmatory testing:

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

<u>Drug</u>	<u>Detection Period</u>
Oxycodone	1-3 days

3. PRINCIPLES OF THE PROCEDURE

The MEDTOX[®] OXYCODONE Test is a rapid, competitive, membrane-based immunochromatographic assay. A single urine sample can be evaluated for the presence of Oxycodone in a single device. The device consists of antibody-colloidal gold, drug-conjugate and a control line.

- 1. ANTIBODY-COLLOIDAL GOLD** Antibody-colloidal gold solutions were prepared by absorbing mouse monoclonal antibody developed to bind Oxycodone onto colloidal gold. The colloidal gold solution is applied to the sample well pad in the drug test.
- 2. DRUG-CONJUGATE** A drug derivative of Oxycodone was conjugated to bovine serum albumin (BSA). The drug conjugate is immobilized as a line at a labeled location on the membrane strip.
- 3. CONTROL LINE** Each test strip has rabbit polyclonal anti-mouse immunoglobulin antibody immobilized as a line on the membrane at a labeled location on the device. The anti-mouse immunoglobulin antibody binds to the mouse antibody coated on the colloidal gold.

Drugs in the urine and the drugs conjugated to the protein compete to bind to the antibody-colloidal gold. When the urine sample is placed flows in the sample well, the dried antibody-colloidal gold on the sample pad 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.

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. 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 "T" location for a positive sample. Read positive results at 5 minutes. The control line should be present for the test to be valid. The test must be read within 15 minutes of the sample application. The test result after 15 minutes may not be consistent with the original reading.

CTRL Line

Each test strip has an internal procedural control. A line must form at the Control "C" location on the device to indicate 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 "C" location(s) on the device.

4. MATERIALS PROVIDED/STORAGE CONDITIONS

Each MEDTOX[®] OXYCODONE Test contains all the reagents necessary to test one urine sample for Oxycodone.

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

Kit Contents-

1. Twenty-five individually bagged tests containing 1 foil wrapped test device with desiccant, twenty-five transfer pipettes, and 1 reference guide. The test strips each contain a membrane coated with drug conjugate and a pad coated with antibody dye complexes in a protein matrix.

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. For in-vitro diagnostic use only.

6. SAMPLE COLLECTION AND PREPARATION

The urine sample should be collected in a clean glass or plastic container. 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. Urine collection container.

NOTE: Specimen containers, disposable gloves 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).
2. To run the test device
 - Hold device in hand at about a 60° angle.
 - Refer to the package labeling (# of tests) and the Urine Sample Volume table below to determine the volume needed to run your device.

Urine Sample Volume			
# of Tests	# of Strips	Pipette Mark	Volume
12	9	Base of Bulb	650µl
9	7	0.5ml	500µl
5 & 7	4 & 5	0.3ml	300µl

- Add the appropriate sample volume into the sample well with the transfer pipette supplied.
- Tilt the device from side to side to distribute urine evenly across test strips. Test reagents will start migrating up the strips and lines will begin to develop.
- Hold the device until the reddish-purple control lines have formed across the test strips at the "C" position (about 40 sec).
- Once the control lines have formed, lay the device flat and read after 5 minutes.

9. READING THE TEST RESULTS

Negative: The appearance of a reddish purple line at both the control area (C) and 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 faint color intensity indicates a negative test result.**

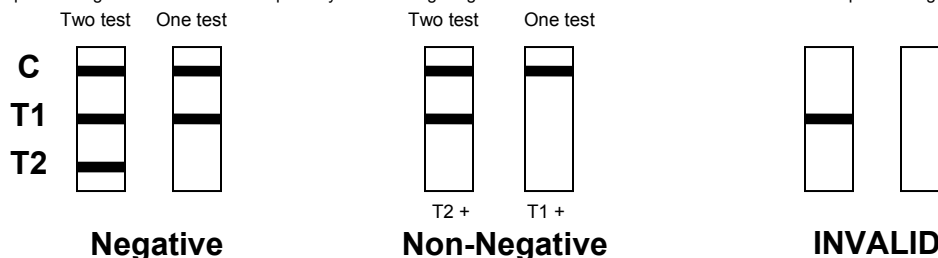
Positive: The appearance of a control line and the absence of a test line indicate a preliminary positive test result for that drug.

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.

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 POSITIVE test result for a specific drug indicates that the sample may contain drug/drug metabolite near or above the cutoff level. Examples of Negative and Non-Negative results are shown below.



11. QUALITY CONTROL

An internal procedural control is included on each test strip. A line must form at the control (C) position on the test strip to indicate that adequate sample volume has been added, the reagents migrated properly, and the test strip is intact. 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. A visible control line should always be present regardless of whether drug is absent or present in the sample. Minimally, a QC program includes external negative and positive control material used to monitor the performance of each new lot of product, each new shipment of product and may be used to assess the competency of new operators.

For additional information concerning QC, forensic or workplace testing requirements, contact the appropriate regulatory authority. Users should follow federal, state, and local QC requirements.

12. LIMITATIONS OF THE PROCEDURE

1. The MEDTOX[®] OXYCODONE Test is only for use with unadulterated human urine samples.
2. 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.

13. PERFORMANCE CHARACTERISTICS

13A. Sensitivity, Accuracy, and Precision

Accuracy in a Point of Care setting

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

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

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

13B. Non Crossreactive Endogenous Compounds

Listed compounds were initially dissolved in appropriate solvents and then added to drug-free urine for evaluation with the MEDTOX[®] OXYCODONE test. Most of the compounds were evaluated for reactivity with the test at 100 µg/mL (albumin was evaluated at 20 mg/mL and bilirubin was evaluated at 200 µg/mL). Samples were evaluated in triplicate by in-house operators. The listed compounds gave negative results with the MEDTOX[®] OXYCODONE test.

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

13C. Unrelated Compounds, Prescription and Over-the-Counter Medications

Listed compounds were initially dissolved in appropriate solvents and then added to drug-free urine for evaluation with the MEDTOX[®] OXYCODONE test. Most of the compounds listed in Section 13C were evaluated for reactivity with the test at 100 µg/mL. (Alprazolam, 1-hydroxy was evaluated at 25 µg/mL; Buprenorphine, Fentanyl, 1-11-Hydroxy- Δ^9 -THC, Lorazepam glucuronide, 11-Nor-9-carboxy- Δ^9 -THC, Olanzapine, Oxazepam glucuronide, and Triazolam, 1-hydroxy were evaluated at 10µg/mL). Samples were evaluated in triplicate by in-house operators, and the listed compounds gave negative results with the test.

Acecaïnide (N-Acetylprocainamide)	Desmethyl chlordiäzepoxide (Norchlordiäzepoxide)	Lysergic Acid	Phenmetrazine
Acetaminophen	Desmethylflunitrazepam	Lysergic Acid Diethylamide (LSD)	Phenobarbital
Acetylsalicylic Acid	Desmethylvenlafaxine	Maprotiline	Phenothiazine
Allobarbital	Dexamethasone	MDA	Phentermine
Alprazolam	Dextromethorphan	MDE (MDEA)	Phentoin (Diphenylhydantoin)
Alprazolam, 1-Hydroxy	Diazepam	MDMA	Phenylbutazone
p-Aminobenzoic Acid	Diclofenac	Melanin	Phenylephrine
7-Amino-clonazepam	Diethylpropion	Meperidine	Phenylpropanolamine
7-Amino-flunitrazepam	Diffunisal	Mephobarbital	Piroxicam
Aminoglutethimide	Digoxin	Mepivacaine	Prazosin
1-Aminopyrine (4-(dimethylamino) antipyrine)	Dimenhydrinate (Dramamine)	Mesoridazine	Prednisolone
Amitriptyline	1,3-Dimethylbarbituric acid	Methadone	Prednisone
Amobarbital	Diphenhydramine	d-Methamphetamine	Procaine
Amoxapine	Domperidone	l-Methamphetamine	Procainamide
Amoxicillin	Dopamine	Methaqualone	Prochlorperazine
d-Amphetamine	Doxepin	Methcathinone	Promazine
l-Amphetamine	Doxylamine	Methocarbamol	Promethazine
Ampicillin	Ecgonine	Methoxyphenamine	Propoxyphene
Aprobarrital	Ecgonine Methyl Ester	Methylphenidate	Propranolol
l-Ascorbic Acid	EDDP	Methylprylon	Protriptyline
Aspartame	Efavirenz (Sustiva)	Metoprolol	d-Pseudoephedrine
Atenolol	EMDP	Midazolam	Pyrilamine
Atropine Sulfate	Ephedrine	Mirtazapine	Quetiapine (Seroquel)
Barbital	Equilin	Nalidixic Acid	Quinidine
Barbituric Acid	Erythromycin	Naproxen	Ranitidine
Benzilic Acid	Estrone	Niacinamide	Riboflavin
Benzoic Acid	Ethanol	Nicotine	Rifampin
Benzocaine (ethyl -4-aminobenzoate)	Fenfluramine	Nifedipine	Salicylic Acid
Benzoylcegonine	Fenopropfen	Nitrazepam	Secobarbital
Benzphetamine	Fentanyl (Synthetic opiate)	Nitrofurantoin	Selegiline (Deprenyl)
Benztropine	Flunitrazepam	Norclomipramine	Serotonin (5-Hydroxytryptamine)
Brompheniramine	Fluoxetine (Prozac)	Nordiazepam	Sertraline (Zoloft)
Buprenorphine	lurazepam	Nordoxepin	Sildenafil (Viagra)
Bupropion	Furosemide	Norethindrone	Sulfamethazine
Butabarrital	Fuvoxamine	Norlysergic Acid	Sulindac
Butalbital	Gentisic Acid (2,5-Dihydroxybenzoic acid)	Normeperidine	Talbutal
Caffeine	Glutethimide	Norpropoxyphene	Temazepam
Cannabidiol	Guaiacol Glyceryl Ether	l-Norpseudoephedrine	Tetracycline
Cannabinal	Haloperidol	11-Nor-9-carboxy- Δ^9 -THC	Δ^9 -Tetrahydrocannabinol
Captopril	Hexobarbital	11-Nor-9-carboxy- Δ^8 -THC	Δ^8 -Tetrahydrocannabinol (also called Δ^6 -Tetrahydrocannabinol)
Carbamazepine	Hippuric acid	Nortriptyline	Tetrahydrozoline
Carbamazepine-10,11 epoxide	Hydralazine	Noscapine	Theophylline
Carisoprodol (Meprobamate)	Hydrochlorothiazide	Nylidrin	Thiamine
Cephalexin	Hydrocortisone	Octopamine	Thiopental
Chloral Hydrate	Hydroxybupropion	Ofloxacin	Thioridazine
Chloramphenicol	Hydroxyhippuric acid	Olanzapine (Zyprexa)	Thiohixine
Chlordiazepoxide	l-11-Hydroxy- Δ^9 -THC	Omeprazole	Tolbutamide
Chloroquine	p-Hydroxyphenobarbital	Orphenadrine	Tolmetin (Tolectin)
Chlorothiazide	4-Hydroxyphenacyclidine	Oxalic Acid	Trazodone
Chlorpheniramine	3-Hydroxytyramine	Oxaprosin	Triamterene
Chlorpromazine	Hydroxyzine	Oxazepam	Triazolam
Chlorprothixene	Ibuprofen	Oxazepam glucuronide	Triazolam, 1-hydroxy
Clobazam	Imipramine	Oxolinic Acid	Trifluoperazine
Clomipramine	lproniazid	Oxymetazoline	Trimethoprim
Clonazepam	(R)-Isoproterenol	Papaverine hydrochloride	Trimipramine
Clonidine	Isoxsuprine	Penicillin G	Tripelennamine
Clorzepate	Ketamine	Pentazocine	Tryptamine
Clozapine	Ketoprofen	Pentobarbital	Tryptophan
Cocaine	Labetalol	Perphenazine	Tyramine
Cortisone	Lidocaine	Phenallymal (Alphenal)	Tyrosine
Cotinine	Lithium carbonate	Phenacetin (Acetophenetidin)	Valproic Acid
Cyclobenzaprine	Loperamide	Phencyclidine	Venlafaxine
Cyclopentobarbital	Lorazepam	Phendimetrazine	Verapamil
Deoxycorticosterone	Lorazepam glucuronide	Phenelzine	Zomepirac
Desalkylflurazepam	Loxapine	Phenethylamine	
Desipramine		Pheniramine	

13D. Related and Reactive Compounds

The following Oxycodone metabolites and related compounds were initially dissolved in appropriate solvents and then added at varying concentrations to drug-free urine for evaluation with the MEDTOX[®] OXYCODONE test. Samples were evaluated in triplicate by in-house operators. Results are expressed as the minimum concentration of metabolite or compound required to produce a positive test result with the test. Percent cross reactivity of a compound is calculated by dividing the cutoff concentration by the minimum concentration required to obtain a positive result and then multiplying by 100%.

Oxycodone, cutoff = 100 ng/mL	Result	% Cross-Reactivity
Apomorphine	Negative at 100,000 ng/mL	< 1%
Codeine	Positive at 2,500 ng/mL	4%
Diacetylmorphine	Negative at 100,000 ng/mL	< 1%
Dihydrocodeine	Positive at 5,000 ng/mL	4%
Ethylmorphine	Positive at 5,000 ng/mL	4%
Hydrocodone	Positive at 25,000 ng/mL	1%
Hydromorphone	Positive at 50,000 ng/mL	1%
Levorphanol	Negative at 50,000 ng/mL	< 1%
Morphine	Positive at 25,000 ng/mL	2%
6-Monoacetylmorphine	Negative at 100,000 ng/mL	< 1%
Morphine 3- β -D-Glucuronide	Negative at 100,000 ng/mL	< 1%

Oxycodone, cutoff = 100 ng/mL	Result	% Cross-Reactivity
	Positive at 100 ng/mL	100%
Morphine 6-β-D-Glucuronide	Negative at 10,000 ng/mL	1%
Nalorphine	Negative at 100,000 ng/mL	< 1%
Naloxone	Positive at 10,000 ng/mL	1%
Naltrexone	Positive at 50,000 ng/mL	< 1%
Norcodeine	Positive at 50,000 ng/mL	< 1%
Oxymorphone	Positive at 200 ng/mL	50%
Procaine	Negative at 100,000 ng/mL	< 1%
Thebaine	Negative at 100,000 ng/mL	< 1%

13E. Interference

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.² 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	Phenobarbital
Brompheniramine maleate	Dextromethorphan	d-Pseudoephedrine
Caffeine	Diphenhydantoin	Salicylic Acid
Carbamazepine	Doxylamine	

14. BIBLIOGRAPHY

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- Smith, M.L., Shimomura, E.T., Summers, J., Paul, B.D., Nichols, D., Shippee, R., Jenkins, A.J., Darwin, W.D., and Cone, E.J. Detection Times and Analytical Performance of Commercial Urine Opiate Immunoassays Following Heroin Administration, Journal of Analytical Toxicology, Volume 24:7. October 2000, pages 522-529.

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 of the level of drug/drug metabolites detected by the MEDTOX[®] OXYCODONE 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, 6,653,139

Patents pending.

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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)].

To place an order or for technical services call 1-800-832-3244.