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RapidOne™ OXY Package Insert

RapidOne™ OXY is a one-step, lateral flow immunoassay for the detection of the oxycodone drug analyte in urine. The **RapidOne™ OXY** is intended for use in the qualitative detection of oxycodone in human urine at the concentration level of 100ng/mL.

Compound	Abbreviation	Level
Oxycodone	OXY	100 ng/mL

RapidOne™ OXY provides only a preliminary analytical test result.

SUMMARY AND EXPLANATION

RapidOne™ OXY is a competitive immunoassay utilizing a highly specific reaction between antibodies and antigens for the detection of oxycodone in urine. The length of time following drug use for which a positive result may occur is dependent upon several factors including frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity, and diet.

PRINCIPLES OF THE TEST

Each **RapidOne™ OXY** assay is a one-step immunoassay. The specifically labeled drug (drug conjugate) competes for antibody binding sites with drugs or metabolites that may be present in the urine specimen. The test device consists of a membrane strip with an immobilized drug conjugate. A colloidal gold-labeled antibody complex is dried at one end of the membrane. A control line, comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of a drug analyte in the urine specimen, and therefore, it should be present in all reactions.

In the absence of any drug in the urine specimen, the colloidal gold-labeled antibody complex moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the 'test' area. **The formation of two visible lines occurs when the test is negative or below the cut-off for the drug.**

When a drug analyte is present in the urine specimen, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the antibody binding sites on the colloidal gold-labeled antibody complex. If a sufficient amount of drug analyte is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. **The formation of one visible line is indicative of a positive result.**

REAGENTS AND MATERIALS SUPPLIED

Each **RapidOne™ OXY** kit box contains:

1. **50 RapidOne™ OXY test sticks:** The test device consists of a dip stick and dessicant sealed in a foil pouch. The dip stick contains one channel for the complete immunoassay of oxycodone. The channel contains a membrane with two attached absorbent pads and a pad containing the immobilized colloidal gold-labeled antibody complex. The upper pad acts as a reservoir for the specimen after it migrates through the membrane. The test line contains a BSA-drug conjugate for the individual analyte, dried on the membrane. A second line (control), containing an appropriate IgG, is placed above the test line on all membranes.

2. Package Insert

3. Results Guide

WARNINGS AND PRECAUTIONS

For **forensic** use only

For professional use only

Follow proper handling and disposal procedures because urine specimens are potentially infectious.

Use only the test devices supplied. Avoid cross-contamination of urine specimens by using a new container for each urine specimen.

The foil pouch containing the test card must be completely sealed. **Do not use if foil pouch seal is not intact.**

Prior to use, ensure that the product has not expired by verifying that the date of use is prior to the expiration date embossed on the top of the foil pouch. The expiration date is the first four digits of the number embossed on the pouch. For example, 09/00 means the product expires in September 2000.

STORAGE

The **RapidOne™ OXY** dip stick should be stored at room temperature (15° to 30°C) or refrigerated (2° to 8°C). Allow test device to warm up to room temperature before conducting any testing.

SPECIMEN COLLECTION AND HANDLING

Use fresh urine specimens. Urine specimens do not require any special handling or pretreatment. It is best to test urine specimens immediately after collection. However, if necessary, urine specimens may be refrigerated at 2° to 8°C for two days or frozen at -20°C or colder for longer periods.

It is essential that **none** of the urine specimen (or other liquid) contact the test area window of the **RapidOne™ OXY** test device.

Handle and dispose of urine specimens as if they were infectious and capable of transmitting infection. Avoid contact with skin.

PROCEDURES

RapidOne™ OXY SINGLE DIP STICK PROCEDURE

1. Allow test device to warm up to room temperature before conducting any testing.
2. Remove the test device from the foil pouch. Do not use if foil pouch is not intact. Label test device.
3. Insert the bottom end of the test device into the sample until the sample level is within the blue area on the test device.
4. Hold the test device in the sample until a reddish purple color begins to appear in the test results area. When this occurs, remove the test device from the sample and lay flat. Allow the test to proceed undisturbed until a reddish-purple control line appears and the test background has cleared. The control line [C] is the uppermost line in the test area. Once the control line is visible, the test is ready to be read; typically this occurs in 3-5 minutes.
5. Read results as explained under Interpretation of Results.

INTERPRETATION OF RESULTS

The control line is the uppermost line appearing in each test area. The test line may or may not appear directly below the control line [C].

Once a reddish-purple control line with a clear background forms in **all** channels the test may be read.

A **NEGATIVE** result is the presence of two reddish-purple lines, called the test line [T] and the control line [C], without regard to intensity; i.e., two lines, no matter how dark or light, indicate a negative result.

A **POSITIVE** result is the presence of **ONLY one line (the control line)**.

If no control line appears after approximately 10 minutes, consider the test invalid.

RapidOne™ OXY results are stable up to 60 minutes as long as the device is stored in a small plastic bag.

Do not read results after 60 minutes.

CONTROL LINE	TEST LINE	INTERPRETATION
No control line present	No test line present	Invalid test retest with new card
Control line present	Test line present	Negative
Control line present	No test line present	Positive

* Note If a test line appears but no control line appears, the test is also invalid.

QUALITY CONTROL

A procedural control (the control line [C]) is built into each test channel, indicating that the reagents on the device are present and functioning properly. It is also good laboratory practice to use positive and negative controls to ensure proper test performance. Control samples are commercially available. In order to conserve the use of control materials, it is recommended that the low volume procedure be used for testing. Positive and negative controls should be used prior to using a new lot/shipment of test devices, if the product has been stored outside the recommended storage conditions, or in accordance with your laboratory defined policies.

LIMITATIONS OF PROCEDURE

The assay is designed for use with human urine only.

RapidOne™ OXY provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method (1). HPLC may be used as the confirmatory method for tricyclic antidepressants. Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained. (2).

Other substances and/or factors not listed may interfere with the test and cause erroneous results, such as adulterants, procedural errors or cross reactivity with other drugs or agents. Refer to the Performance Characteristics section for more information. If adulteration is suspected, obtain a fresh urine specimen and repeat testing.

PERFORMANCE CHARACTERISTICS

SPECIFICITY

Interference and cross reactivity studies were performed by testing the drug analytes in the **RapidOne™ OXY** device with various other drugs. Below is the list of drugs that will give a positive result at or above the concentration stated. All of the following drugs were added to normal, drug-free urine.

Compound	CONCENTRATION (ng/mL)
Chemicals	
6-Acetylcodeine	25,000
6-acetylmorphine	75,000
Codeine	12,500
Dihydrocodeine	3,125
Hydromorphone	2,500
Hydrocodone	625
Morphine	6,250
Noroxycodone	50,000
Oxycodone	100
Oxymorphone	100
Thebaine	25,000

The following drugs are not detected by **RapidOne™ OXY** at concentrations less than 100,000 ng/mL unless otherwise specified by asterisk:

Acebutolol	Betamethasone
Acetaldehyde	Bilirubin
Acetaminophen (4-Acetamidophenol; N-Acetyl-p-aminophenol)	Bisacodyl
Acetazolamide	Bromazepam
Acetone	2-Bromo- α -ergocryptine (Bromocryptine mesylate)
3-(α -acetylbenzyl)-4-hydroxycoumarin (Warfarin)	(+) Brompheniramine (Dexbrompheniramine)
Acetophenetidin	(+/-) Brompheniramine
Acetopromazine	Bumetanide
N-Acetyl-L-cysteine	Bupivacaine
N-Acetylprocainamide (Acedainide)	Buprenorphine
Acetylsalicylic Acid (Aspirin; 2-Acetoxybenzoic Acid)	Buspirone
Albumin, standard	Butacaine
Allobarbital (5,5-Diallylbarbituric Acid)	Butabarbital
Allopurinol (4-Hydroxypyrazole(3,4-pyrimidine)	Butalbital
Alprazolam	Butethal
Alprenolol	2-Butynoic Acid Ethyl Ester (Ethyl-2-Butynoate)
Amantadine (Adamantan-1-amine)	Butyropheneone
Amcinonide	Caffeine (1,3,7-Trimethylxanthine)
(+) Amethopterin (4-Amino-10-methylfolic acid; Methotrexate; Methylaminopterin)	(+/-) Camphor
Amikacin	Cannabidiol
Amiloride	Cannabinol
p-Aminobenzoic Acid	Canrenoic Acid
DL-Aminoglutethimide	Captopril
Amiodarone	Carbamazepine
Amitriptyline	Carbamyl- β -methylcholine-chloride (Bethanechol Chloride)
Ammonium Chloride	Carboplatin
Amobarbital (amytal; 5-Ethyl-5-Isoamylbarbituric Acid)	(s)-(-)-Carbidopa
Amoxicillin	Carisoprodol
Amphotericin B	Cefaclor
D-Amphetamine	Cefadroxil
DL-Amphetamine	Cefotaxime
L-Amphetamine	Cefoxitin
Ampicillin	Ceftriaxone
D-Amygdalin	Cefuroxime
Aniline	Cephalexin
Antipyrine (Phenazone)	Cephaloridine
Apomorphine	Cephadrine (Cefradin)
Aprobarbital	α -Chloralose
(-) Arterenol [(-)Norepinephrine]	Chloramphenicol (Chloromycetin)
L-Ascorbic Acid	Chlorcyclizine
ASP-PHE-Methyl-Ester (Aspartame)	Chlordiazepoxide
D-Aspartic Acid	2-(p-Chlorophenoxy)-2-Methylpropionic Acid Ethyl Ester (Clofibrate)
DL-Aspartic Acid	Chloroquine
L-Aspartic Acid	Chlorothiazide
Astemizole	Chlorotrianisene
Atenolol	(+) Chlorpheniramine
Atropine (Tropine tropate)	(+/-) Chlorpheniramine
Azathioprine	Chlorpromazine
Baclofen	Chlorpropamide
Barbital (Barbitone; 5,5-Diethylbarbituric acid; Veronal)	Chlorprothixene
Barbituric Acid (2,4,6-Trihydroxypyrimidine; Malonylurea)	Chlorthalidone
Beclomethasone	Chlorzoxazone (5-Chloro-2-Hydroxybenzoxazole)
Beclomethasone Dipropionate	Cholesterol
Bendroflumethiazide	Cimetidine
Benzidine (4,4 Diaminobiphenyl)	Cinchonidine
Benzilic Acid β -diethylaminoethyl ester	Cinoxacin
Benzocaine (Ethyl-p-Aminobenzoate)	Clemastine
Benzoic Acid	Clenbuterol
Benzoylcegonine	Clindamycin
Benzphetamine	Clobazam
(α -dimethylphenethylamine)	Clobetasone Butyrate
Benzthiazide	Clomipramine
Benztropine Methanesulfonate (Benztropine Mesylate)	Clonazepam
Benzyl alcohol	Clonidine
Benzylamine	Cloxacillin
Berberine	Clozapine
	Cocaine (Ecgonine Methyl Ester Benzoate)
	Cocaethylene
	Colchicine

Cortisone	Ethambutol	Isonicotinic Acid (<i>Pyridine-4-Carboxylic Acid</i>)	6 α -Methylprednisolone (<i>Medrol</i>)
β -Cortol	Ethamivan (<i>N,N-Diethylvanillamide</i>)	Isonicotinic Acid Hydrazide	Methyl Salicylate
(-) Cotinine	Ethanol, Standard	Isopropamide	Methyl Viologen (<i>Gramoxone; Paraquat Dichloride</i>)
Creatinine	Ethopropazine	(+) Isoproterenol	Meticrane
Cromolyn (<i>Cromoglycic Acid</i>)	Ethosuximide (<i>2-Ethyl-2-Methylsuccinimide</i>)	(-) Isoproterenol	Metoclopramide
Cyclobenzaprine	2-Ethyl-2-Phenylmalonamide	(+/-) Isoproterenol	(+/-) Metoprolol
Cyclophosphamide	Ethylene Glycol	Isoxsuprine	Metronidazole
Cyclosporin A	Ethylenediaminetetraacetic Acid (<i>EDTA</i>)	Kanamycin	Mianserin
Cyproheptadine	Ethylmorphine* (10ug/mL)	Ketamine	Milrinone
Dantrolene	2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidone	Ketoprofen	Minaprine
Deferoxamine Mesylate (<i>Deferrioxamine Mesylate</i>)	17- α -Ethinylestradiol	Kynurenic Acid	Morphine-3- β -D-Glucuronide
Deoxyepinephrine	Etodolac	Labetalol	Nabumetone
R-(-)-Deprenyl (<i>Selegiline</i>)	Etoposide	Levorphanol	Nadolol
Desipramine	Famotidine	Lidocaine	Nafacillin
N-Desmethylclozapine (<i>Normethylclozapine</i>)	Fenfluramine	Lisinopril	Nalbuphine
Desmethyldiazepam	Fenopropfen [(+/-)-2-(3-Phenoxyphenyl) Propionic Acid]	Lithium Carbonate	Nalidixic Acid
Desoximetasone	Fentanyl (10 ug/ml)*	Loperamide	Nalmefene
Dexamethasone	Ferrous Sulfate	(+/-) Lorazepam	Naloxone
Dextromethorphan	Flufenamic Acid	Lormetazepam	Naltrexone
4,4'-Diaminophenyl Sulfone (<i>Dapsone</i>)	Flunisolide	Lysergic Acid Diethylamide (<i>LSD</i>)	Naphazoline
Diazepam	Flunitrazepam	Mebendazole	α -Naphthalene Acetic Acid
Diazoxide	Fluphenazine	Mecizine	β -Naphthalene Acetic Acid
Dichloromethane (<i>Methylene Chloride</i>)	Flurandrenolide	Meclofenamic Acid	α -Naphthol
Dichlorphenamide	Flurazepam	Medazepam	Neomycin Sulfate
Diclofenac	Flurbiprofen	Mefenamic Acid	Niacinamide
Dicyclomine	Formaldehyde	Melanin	Nialamide
Dieldrin	Furosemide	Melphalan	(+/-) Nicotine
Diethylthiocarbamic Acid	Gemfibrozil	(-) Menthol	Nicotinic Acid (<i>Niacin</i>)
N,N-Diethylnicotinamide (<i>Niacin Diethylamide; Nikethamide</i>)	Gentamicin Sulfate	Meperidine	Nifedipine
Diflorasone Diacetate	Gentisic Acid	Mephesisin	Nitrofurantoin
Diflucortolone pivalate	Glucose	Mephentermine	Nitrazepam
Diflunisal	(D)-(+)-Glucose (Dextrose)	Meprobamate	Nitrofurantoin
Digitoxin	Glybenclamide	6-Mercaptopurine	Nomifensine
Digoxin (12 β -Hydroxydigitoxin)	Griseofulvin	Mersalyl Acid	Norclomipramine
DL-3-4 Dihydroxymandelic Acid	Guaiaicol Glyceril Ether	Mescaline (3,4,5-Trimethoxyphenethylamine)	Norcocaine
DL-3-4 Dihydroxyphenyl Glycol	Guanethidine	DL-Metanephine	Norcocaine
3,4 Dihydroxyphenylacetic Acid	Halcinonide	Metaproterenol	11-Nor- Δ 8-Tetrahydrocannabinol-8 Carboxylic Acid* (10ug/mL)
7-(2,3-Dihydroxypropyl) Theophylline (<i>Dyphylline</i>)	Haloperidol	Metaraminol [(-)- <i>m-Hydroxyphenylpropanolamine</i>]	11-Nor- Δ 9-Tetrahydrocannabinol-9 Carboxylic Acid* (10ug/mL)
Dimenhydrinate	Hemoglobin	(+/-) Methadone	11-Nor- Δ 9-Tetrahydrocannabinol-9 Carboxylic Acid Glucuronide* (10ug/mL)
Dimercaprol (2,3,- <i>Dimercaptopropanol</i>)	Heroin (<i>Diacetylmorphine</i>)* (10ug/mL)	(+) Methamphetamine (<i>Methylamphetamine; d-Desoxyephedrine</i>)	Nordiazepam
4-Dimethylaminoantipyrine (<i>Aminopyrine</i>)	Hexachlorocyclohexane	(+/-) Methamphetamine	Nordoxepin
1,1-Dimethylbiguanide (<i>Metformin</i>)	Hexachlorophene	Methanol, Absolute	Norethindrone
Dimethyl Isosorbide	Hexobarbital	Methazolamide	Norflouxacin
Dimethyl Sulfoxide (<i>DMSO</i>)	Hippuric Acid	Methotrimetopazine	DL-Normetanephine
1,3-Dimethyluric Acid	Histamine [2 (<i>4-Imidazolyl Ethylamine</i>)]	Methoxamine	Normorphine
1,7-Dimethylxanthine	DL-Homatropine	Methoxyamine	d-Norpropoxyphene
Diphenhydramine	Hydralazine (<i>1-Hydrazinophthalazine</i>)	(S)-6-Methoxy- α -Methyl-2-Naphthalene Acetic Acid (+) Naproxen	Noroxymorphone
5,5 Diphenylhydantoin (<i>Phenytoin</i>)	(1S, 9R)- β -Hydrastine	(S)-6-Methoxy- α -Methyl-2-Naphthalene Acetic Acid (-) Naproxen	Nortriptyline
Dipyridamole	Hydrochlorothiazide	Methoxyphenamine	Noscapine
Dipyron	Hydrocortisone	5-Methoxytryptamine (<i>Methoxamine; O-Methylserotonin</i>)	Nylidrin
Disopyramide	Hydroflumethiazide	3-Methoxytyramine	Orotic Acid (<i>Uracil-6-Carboxylic Acid</i>)
Dobutamine	Hydroxocobalamin	2-Methyl-3-(3,4-Dihydroxyphenyl)-DL-Alanine	Orphenadrine
Doxepin	O-Hydroxyhippuric Acid	2-Methyl-3-(3,4-Dihydroxyphenyl)-L-Alanine	Oxalic Acid (<i>Ethanedioic Acid</i>)
Doxycycline	5-Hydroxyindole-3-Acetic Acid	6 α -Methyl-17 α -Hydroxyprogesterone (<i>Medroxyprogesterone</i>)	Oxazepam
Doxylamine	5-Hydroxy-2-indole-2-Carboxylic Acid	Methylene Blue	Oxolinic Acid
Droperidol	4-Hydroxy-3-Methoxyphenylacetic Acid (<i>Homovannilic Acid</i>)	3,3'-Methylene-bis-(4-Hydroxycoumarin) (<i>Dicumarol</i>)	Oxprenolol
Ecgonine	4-Hydroxy PCP	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	Oxybutynin Chloride
Ecgonine Methyl Ester	11-Hydroxy- Δ 9-Tetrahydrocannabinol* (10ug/mL)	(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Oxymetazoline
Emetine	5-Hydroxytryptamine (<i>Serotonin</i>)	(+/-) 3,4-Methylenedioxyamphetamine (MDMA)	Oxyphenbutazone
(-)- ψ -Ephedrine	3-Hydroxytyramine	1-Methylhistamine	Oxypurinol
(+)- ψ -Ephedrine	Hydroxyzine (<i>Atarax</i>)	6 α -Methyl-17- α -Hydroxyprogesterone (<i>Medroxyprogesterone</i>)	Paclitaxel
(+) Ephedrine	L-Hyoscyamine	Methylphenidate (<i>Ritalin</i>)	Pancuronium Bromide
(+/-) Ephedrine	Ibuprofen		Papaverine
(-) Epinephrine	Imidazole-4-Acetic acid		Pargyline
(+/-) Epinephrine	Imipramine		PCP Morphine
Erythromycin	Indapamide		Penicillin G (<i>Benzympenicillin</i>)
Eserine (Physootigmine)	Indole-3-Acetic acid		Pentachlorophenol
Estazolam	Indole-3-Butyric Acid		Pentobarbital (<i>Nembutal</i>)
β -Estradiol	DL-Indole-3-Lactic Acid		Pentoxifylline (<i>Trental</i>)
Estrilol	Indomethacin		Pentylentetrazole
Estrone	Ipratropium Bromide		Phencyclidine
Estrone- β -D-Glucuronide	Iproniazid		p-Phenylenediamine
Estrone-3-Sulfate			Phenelzine
Ethacrynic Acid			

Phenformin
Pheniramine
Phenobarbital
Phenol
Phenolphthalein
Phenothiazine (*Thiodiphenylamine*)
Phenoxymethylpenicillin acid
(*Penicillin V*)
Phentermine
(α,α -*Dimethylphenethylamine*)
Phentolamine
DL-Phenylalanine
L-Phenylalanine
Phenylbutazone
L-Phenylephrine
(+/-)- α -Phenylethylamine
(α -*Methylbenzylamine*)
 β -Phenylethylamine
(R)-(+)- α -Phenylethylamine
(+/-) Phenylpropanolamine (PPA)
Phenyltoloxamine
Phthalic acid
(*1,2-Benzenedicarboxylic Acid*)
Picrotoxin
Pilocarpine
Pimozide
Pinacidil
Pindolol
L-Pipecolic Acid
Pipemidic Acid
Piroxicam
Potassium Chloride
Potassium Iodide
Prazepam
Prazosin
Prednisolone (*1-Dehydrocortisol*)
Prednisone (*Dehydrocortisone*)
5-Pregnen-3 β -OL-20-one
(*Epipregnanolone; Pregnenolone*)
Prilocaine
Primaquine
Primidone (*2-Desoxyphenobarbital*)
Proadifen
Probenecid [*p*-(*Dipropylsulfamoyl*)
Benzoic Acid]
Procainamide
Procaine (*Novocaine*)
Prochlorperazine
Procyclidine
Promazine
Promethazine
Propionylpromazine
d-Propoxyphene
DL-Propranolol
2-Propylpentanoic Acid (*Valproic Acid*)
Protein
Protriptyline
d -Pseudoephedrine
Pyridine-2-Aldoxime Methochloride
(*Pralidoxime Chloride*)
Pyridoxine
Pyrilamine (*Mepyramine*)
Quinidine
Quinine
Quinolinic Acid
(*2,3-Pyridinedicarboxylic Acid*)
Ranitidine (Zantac)
Rescinnamine
Reserpine
Riboflavin
Ritodrine
Salbutamol (*Albuterol*)
Salicylamide (*2-Hydroxybenzamide*)
Salicylic Acid (*2-Hydroxybenzoic Acid*)
(-) Scopolamine (*Hyoscine*)
Secobarbital (*Quinalbarbitone*)
Sodium Chloride
Sodium Formate
(+/-) Sotalol
Strychnine
Succinylcholine Chloride
Sulfamethazine
Sulfamethoxazole
Sulfanilamide
(*p-Aminobenzenesulfonamide*)
Sulfathiazole
Sulfisoxazole
Sulindac
(+/-) Sulpiride
Suxibuzone
Talbutal
Tamoxifen
Tannic Acid
Temazepam
Tenoxicam
Terbutaline
Terfenadine
Tetracycline
Tetraethyl Thiuram Disulfide
(*Disulfiram*)
 Δ 8-Tetrahydrocannabinol
 Δ 9-Tetrahydrocannabinol
Tetrahydrozoline
Theobromine (*3,7-Dimethylxanthine*)
Theophylline (*1,3-Dimethylxanthine*)
Thiamine (*Aneurine*)
Thimerosal (*Sodium*
Ethylmercurithiosalicylate)
Thioridazine
Cis-Thiothixene
Thymol (*5-Methyl-2-Isopropylphenol*)
Timolol
Tobramycin
Tolazamide
Tolbutamide
Tolmetin
Toluene
cis-Tramadol
Trans-2-Phenylcyclopropylamine
(*Tranlycypromine*)
Trazodone
Triamcinolone (*Fluoxyprednisolone*)
Triamterene
Triazolam* (10ug/mL)
Trichlormethiazide
Trichloroacetic acid
2,2,2 Trichloroethanol
Trifluoperazine
Triflupromazine
DL-Trihexyphenidyl
Trimethobenzamide
Trimethoprim
3,5,5-Trimethyloxazolidine-2,4-dione
(*Trimethadione*)
Trimipramine
Triprolidine
DL-Tropic Acid
Tropine
Tryptamine [*3-(2-Aminoethyl) Indole*]
DL-Tryptophan (*3 β -Indolylalanine;*
(+/-)- α -Amino-3-Indolepropionic Acid)
d-Tubocurarine Chloride
Tyramine (*4-Hydroxyphenethylamine*)
DL-Tyrosine
Urea (Carbamide)
Uric Acid
Vancomycin
(+/-) Verapamil
Vincamine
Xylometazoline
Yohimbine
Zearalenone
Zomepirac
Zopiclone

SENSITIVITY

1) Known concentrations of drug were added to normal, drug-free urine. Ten (10) determinations were made at each serial dilution of the single analyte. Sensitivity is defined as that concentration which produced positive responses in all 10 replicates.

DRUG	AVERAGE CONCENTRATION (ng/mL)
Oxycodone	100

SUMMARY

	Conc. (ng/ml)	Results (+/-10)
Oxycodone	50	1/10
	75	10/10
	100	10/10
	125	10/10

No immunoassay that produces a single response in relation to the presence of multiple components in a mixture can reliably quantify the concentration of these components. The **Rapid One™ OXY** test detects several opiates. Attempts to establish semi- quantitative concentrations with **Rapid One™ OXY** are not recommended. The sensitivity of this test to detect oxycodone is at an average concentration of 100ng/mL.

ACCURACY

The **RapidOne™ OXY** was compared to GC/MS at the claimed cut-off level. **RapidOne™ OXY** was proven to correlate greater than 99% with GC/MS at a 95% confidence level.

	RDS Pos/Neg	GC/MS Pos/Neg
Oxycodone		
>43 ng/mL	38/0	38/0
<43 ng/mL	0/2	0/2

REPRODUCIBILITY

Reproducibility studies were carried out using commercially available standards. Each standard was diluted in normal, drug-free urine to give the appropriate concentration. Each specimen, at the concentration of analyte, was tested four times daily, in duplicate, for five consecutive days using two different lots of **RapidOne™ OXY**.

Drug	Concentration	#	Results	Precision
Oxycodone	0	40	40 neg	>99%
	50	40	37 neg	>92%
	100	40	40 pos	>99%
	125	40	40 pos	>99%

BIBLIOGRAPHY

1. Urine Testing for Drugs of Abuse, National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
2. R. C. Baselt, Disposition of Toxic Drugs and Chemicals in Man, 2nd Ed., Biomedical Publications, Davis Ca., 1982.

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