OXYCODONE

One Step
Oxycodone Test Device
Package Insert

A rapid, one step test for the qualitative detection of oxycodone in human urine.

For healthcare professionals including professionals at point of care sites

For in vitro diagnostic use only.

INTENDED USE

The OXYCODONE One Step Oxycodone Test Device is a rapid chromatographic immunoassay for the qualitative detection of oxycodone in human urine at a cut-off concentration of 100 ng/mL.

This assay 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, particularly when preliminary positive results are used.

SUMMARY

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form**.**

Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%)[1]. The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

The OXYCODONE One Step Oxycodone Test Device yields a positive result when the oxycodone level in urine exceeds 100 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cutoff for oxycodone positive specimens.

PRINCIPLE

The OXYCODONE One Step Oxycodone Test Device is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Oxycodone, if present in the urine specimen below 100 ng/mL, will not saturate the binding sites of antibody in the test device. The antibody coated particles will then be captured by immobilized Oxycodone conjugate and a visible colored line will appear in the test line region. The colored line will not form in the test line region if the Oxycodone level exceeds 100 ng/mL because it will saturate all the binding sites of anti-Oxycodone antibody.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains monoclonal anti-Oxycodone antibody-coupled particles and Oxycodone-protein conjugate. A goat antibody is employed in the control line.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until ready for use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Used test device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

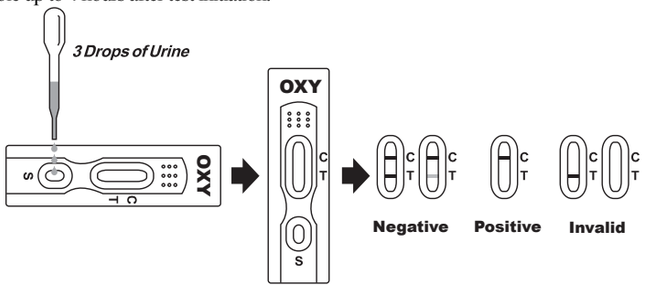
Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

DIRECTIONS FOR USE

Allow test device, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). Refer to illustration.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. Results may be stable up to 4 hours after test initiation.



INTERPRETATION OF RESULTS

(Please refer to illustration above)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Oxycodone concentration is below the detectable level (100 ng/mL).

*** NOTE:** The shade of red in the test region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region. This positive result indicates that the Oxycodone concentration is above the detectable level (100 ng/mL).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow local, state, and federal guidelines for testing QC materials.

LIMITATIONS

1. The OXYCODONE One Step Oxycodone Test Device provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods.[1,2]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive Result does not indicate level or intoxication, administration route or concentration in urine.
5. A Negative Result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted by laboratory personnel using the OXYCODONE One Step Oxycodone Test Device and a commercially available rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other OXY Rapid Test		Total Results
The OXYCODONE One Step Oxycodone Test Device	Results	Positive	Negative	
	Positive	142	0	142
	Negative	4	154	158
Total Results		147	154	300
% Agreement with commercial kit		97%	97%	97%

When compared to GC/MS at the cut-off of 100 ng/mL, the following results were tabulated:

Method		GC/MS				% Agreement with GC/MS
The OXYCODONE One Step Oxycodone Test Device	Results	NEG	Near-cutoff NEG	Near-cutoff POS	POS	
	Positive	0	5	2	135	98%
	Negative	147	8	2	1	97%

Eight (80) of these clinical samples were also run using the OXYCODONE One Step Oxycodone Test Device by an untrained operator at a different site. Based on GC/MS data, the operator obtained a statistically similar Positive Agreement, Negative Agreement and Overall Agreement rate as the laboratory personnel.

Analytical Sensitivity

A drug-free urine pool was spiked with Oxycodone at the following concentrations: 0 ng/mL, 50 ng/mL, 75 ng/mL, 100 ng/mL, 125 ng/mL, 150 ng/mL and 200 ng/mL. The result demonstrates 100% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Oxycodone Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0	30	30	0
50	-50%	30	30	0
75	-25%	30	23	7
100	Cutoff	30	13	17
125	+25%	30	7	23
150	+50%	30	0	30
200	+100%	30	0	30

Specificity

The following table lists compounds that are positively detected in urine by the OXYCODONE One Step Oxycodone Test Device at 5 minutes.

Compound	Concentration (ng/mL)
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethylmorphine	25,000
Hydrocodone	1562
Hydromorphone	12,500
Oxymorphone	1562
Thebaine	50,000

Precision

A study was conducted at three independent physician's office sites (A. internal medicine, B. pediatrics, C. general practice) by three independent, untrained, licensed medical assistants using three different lots of product and run in three consecutive days to demonstrate the within-run, between-run and between-operator precision. An identical panel of coded specimens containing no oxycodone, oxycodone spiked at levels +/- 25% of the assay cut-off and oxycodone spiked at levels +/-50% of the 100 ng/mL assay cut-off were provided to each site. The results are given below:

Oxycodone concentration (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	**15**	**15**	**0**	**15**	**0**	**15**	**0**
50	**15**	**15**	**0**	**15**	**0**	**15**	**0**
75	**15**	**15**	**0**	**15**	**0**	**15**	**0**
125	**15**	**13**	**2**	**10**	**5**	**6**	**9**
150	**15**	**0**	**15**	**0**	**15**	**0**	**15**

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 50 ng/mL and 150 ng/mL of Oxycodone respectively. The OXYCODONE One Step Oxycodone Test Device was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Benzoylecgonine to 50 ng/mL and 150 ng/mL. The spiked, pH-adjusted urine was tested with the OXYCODONE One Step Oxycodone Test Device in duplicate and interpreted according to the package insert. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-negative urine or Oxycodone positive urine. The following compounds show no interference when tested with the OXYCODONE One Step Oxycodone Test Device at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen
6-Acetylcodeine
Acetylsalicylic acid
Amitriptyline
Amoxicillin
L-Ascorbic acid
D/L-Amphetamine
Apomorphine
Atropine
Benzoic acid
Benzphetamine
D/L-Brompheniramine
Caffeine
Cannabinol
Chloramphenicol
Chlorothiazide
Chlorpromazine
Cholesterol
Clonidine
Cortisone
Creatinine
Dextromethorphan
Diclofenac
Acetophenetidin
N-Acetylprocainamide
Aminopyrine
Amobarbital
Ampicillin
D-Amphetamine
L-Amphetamine
Aspartame
Benzilic acid
Benzoylecgonine
Bilirubin
Buspirone
Cannabidol
Chloralhydrate
Chlordiazepoxide
D/L-Chloropheniramine
Chloroquine
Clomipramine
Cocaine
L-Cotinine
Deoxycorticosterone
Diazepam
Dicyclomine
Diflunisal
Diphenhydramine
Doxylamine
L(–)-Epinephrine
β-Estradiol
Ethyl-p-aminobenzoate
Fenoprofen
Gentisic acid
Heroin (Diacetylmorphine)
Hydrochlorothiazide
O-Hydroxyhippuric acid
p-Hydroxymethamphetamine
Ibuprofen
D/L-Isoproterenol
Ketamine
Labetalol
Loperamide
Meperidine
Meprobamate
Methadone
(+/-)3,4-Methylenedioxyamphetamine
Methylphenidate
Morphine
Morphine sulfate
Naloxone
Naproxen
Nifedipine
Norcodeine
Normorphone
Noscapine
Oxalic acid
Oxolinic acid
Papaverine
Pentazocine hydrochloride
Perphenazine
Phenelzine
L-Phenylephrine
Phenylpropanolamine
Prednisone
Promazine
D/L-Propranolol
D-Pseudoephedrine
Quinidine
Ranitidine
Secobarbital
Sulfamethazine
Sustiva (Efavirenz)
Tetracycline
Tetrahydrocortisone 3 (β-D-glucuronide)
Theophylline
Thioridazine
Trazodone
Triamterene
Trimethoprim
D/L-Tryptophan
Uric acid
Zomepirac
Digoxin
5,5-Diphenylhydantoin
[1R,2S] (-) Ephedrine
L -Ψ-Ephedrine
Estrone-3-sulfate
Erythromycin
Furosemide
Hemoglobin
Hydralazine
Hydrocortisone
p-Hydroxyamphetamine
p-Hydroxytyramine
Iproniazid
Isoxsuprine
Ketoprofen
Levorphanol
Maprotiline
Mephentermine
D-Methamphetamine
Methoxyphenamine
(+/-)3,4-Methylenedioxymethamphetamine
6-Monoacetylmorphine
Morphine-3-β-D-glucuronide
Nalidixic acid
Naltrexone
Niacinamide
Nimesulidate
Norethindrone
D-Norpropoxyphene
D/L-Octopamine
Oxazepam
Oxymetazoline
Penicillin-G
Pentobarbital
Phencyclidine (PCP)
Trans-2-phenylcyclopropylamine hydrochloride
β-Phenylethylamine
Prednisolone
Procaine
Promethazine
D-Propoxyphene
Quinacrine
Quinine
Salicylic acid
Serotonin (5-Hydroxytyramine)
Sulindac
Temazepam
Tetrahydrocortisone 3-acetate
Tetrahydrozoline
Thiamine
Tolbutamide
Tolbutamide
Trifluoperazine
Tryptamine
Tyramine
Verapamil

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