Camp Medica Distribution S.R.L. - No. 29 Stanei Street, Bucharest, Romania
phone: +4021-450 58 90
e-mail: export@campmedica.ro
http : //www.campmedica.ro

"See Now" Oxycodone (OXY) Cassette Test Urine

CE

For in vitro Diagnosis Use
Product Code: SN 7.14

INTRODUCTION

The *"See Now"* Oxycodone (OXY) Test is a rapid and convenient immunochromatographic in vitro assay. It is intended for the qualitative detection of the presence of oxycodone and its metabolites in urine at or above the cutoff level of 100 ng/ml.
This assay provides only a preliminary result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed.

SUMMARY OF THE TEST

Oxycodone is known as Oxycontin, Roxicodone and is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiates derived from opium. Like other opiates, oxycodone is characterized by its analegestic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analegesics
such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and stripiac arrest. Oxycodone is metabolized by N- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% of a single dose of oxycodone is excreted in a 24 hour urine collection and consists of 13-19% free oxycodone, 7-29% glucuronide conjugated oxycodone, 13-14% glucuronide conjugated oxymorphone and an unknown amount of noroxycodone. The detection time window of oxycodone is 1-3 days following use.

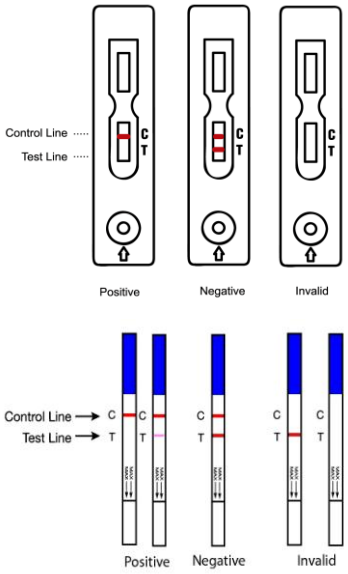
SPECIMEN COLLECTIONAND STORAGE

- Urine specimen may be collected at any time in a clean, dry container without preservatives.
- If specimen cannot be assayed immediately, they can be stored at 2-8°C for up to 72 hours prior to testing or frozen at –20ºC for longer period of time.
- Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.
- Urine specimens exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 2-3 drops (80-120 μl) of specimen without air bubbles into the sample well that is maked with an arrow on the testing device
- Read the results at 5 minutes. Ensure that the background of the test area is white before interpreting the result.

INTERPRETATION OF RESULTS



Positive
Only one color band appears at the control region. No apparent band at the test region. This indicates that drug presence is above the cutoff concentration.

Negative
Two distinct color bands appear at the control and test regions. This indicates that there is no drug in the sample or drug presence is below the cutoff concentration.

Invalid
No visible band at the control region. Repeat with a new test kit. If test still fails, please contact the distributor with the lot number.

Note: A faint line at the test region indicates the drug in sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a clinical determination is made.

STORAGE AND STABILITY

The test kit can be stored at temperature (2 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

- *FOR IN VITRO DIAGNOSTIC USE ONLY.*
- Don't use it after the expiration date.
- The test device should not be reused.

PERFORMANCE CHARACTERISTICS

- **Sensitivity**

The *"See Now"* Oxycodone Urinary Test detects the presence of oxycodone and its metabolites in urine at concentrations equal to or greater than 100 ng/ml.

- **Specificity**

A study was conducted with the *"See Now"* Oxycodone Urinary Rapid Test to determine the cross-reactivity of barbiturate-related compounds with the test device (Table I).

Table-I Concentration of oxycodone -related compounds showing a positive response approximately equivalent to the oxycodone cut off set for the test.

Structurally related compounds	ng/ml
OXY100 oxycodone	100
oxymorphone	100
Normorphine	100
Dihydrocodeine	20,000
Hydrocodone	50,000
Ethylmorphine	50,000

- **Reproducibility**

The precision was determined by replicate assays of both positive and negative urine samples with devices from three different production lots. The resultant data indicated no appreciable inter lot variation when testing both positive and negative samples across three different lots of devices.

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"See Now" Oxycodone (OXY) Cassette Test In human oral fluid specimens

CE

For in vitro Diagnosis Use

Product Code: SN 7.14.S

INTRODUCTION

The *"See Now"* Oxycodone (OXY) cassette test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of oxycodone (OXY) in human oral fluid specimens(saliva).This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result.

SUMMARY OF THE TEST

Oxycodone (OXY) 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 known to metabolize by demethylation into oxymorphone and noroxycodone The *"See Now"* Oxycodone (OXY) cassette test is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen.

MATERIALS PROVIDED

1. The *"See Now"* OXY cassette test. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-rabbit IgG antibody.
Test zone: contains drug bovine protein antigen conjugates
Control zone: contains Goat anti-rabbit IgG antibody
Conjugate pad: contains anti-drug antibody.
2. Instruction for use.

MATERIALS REQUIRED BUT NOT PROVIDED

1.Timer or clock.
2. Oral fluid collection swabs
3. Oral fluid collection tube.

SPECIMEN COLLECTION AND STORAGE

The test device should be stored at 4 to 30 °C and will be effective until the expiration date stated on the package. The product is humidity -sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

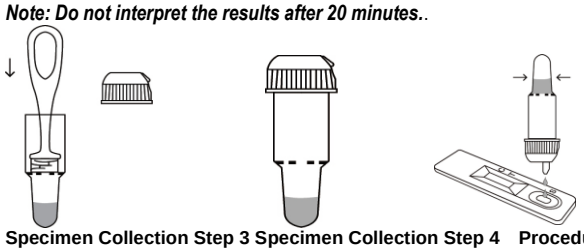
1. Remove the oral fluid collection swab from the sealed pouch and **insert the sponge end of the oral fluid collection swab into the mouth**. Actively swab the inside of the mouth and tongue to **collect oral fluid for a total of 3 minutes** until the sponge becomes fully saturated. Gentle pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.
2. Remove the oral fluid collection swab from the mouth.
3. Place the saturated swab into the collection chamber and press the sponge firmly down on the plastic strainer to release as much liquid as possible.
4. Tightly shut the outer cap of the collection tube.

TEST PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

1. Remove the test card from sealed pouch and use it within one hour.
2. Flip open the dropper tip of the collection tube.
3. Invert the collection tube and transfer 2 drops of oral fluid (approximately 80 uL) into the specimen well (S) of the test card. Avoid ping air bubbles in the specimen well.
4. Read results at 10 minutes.

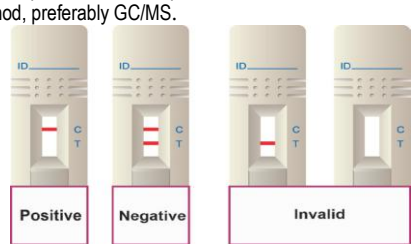
Note: Do not interpret the results after 20 minutes..



Specimen Collection Step 3 Specimen Collection Step 4 Procedure Step 3

INTERPRETATION OF RESULTS

The *"See Now"* OXY cassette test is a qualitative assay. It identifies the drug in human saliva at its cut-off concentration or higher. The concentration of the drug can not be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.



Negative:

Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug and their metabolites in the specimen, it only indicates the level of tested drug and their metabolites in the specimen is less than cut-off level.

Positive:

One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication the level of tested drug and their metabolites in the specimen is above the cut-off level.

Invalid:

If there is no colored band in control line zone of any strip, the test result is invalid. Retest the sample with a new device.

Note: A borderline(±) in test line zone should be considered negative result.

LIMITATION OF PROCEDURE

1. The *"See Now"* OXY cassette test 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) or gas chromatography/tandem mass spectrometry (GC/MS/MS) is preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

A. Sensitivity

The cut-off concentration (sensitivity level) of the *"See Now"* OXY cassette test is determined to be: OXY 50 ng/ml.

B. Precision

The results of 30 samples each of 50% above and 50% below cut-off specimens are 100% agreed by three observers. The test results were found to have no significant differences between these three observers.

C. Specificity

The relative specificity it is 95%.