Atlas Medical

One Step Oxycodone Test Device (Urine)
(100 ng/ml)

IVD *For In-Vitro diagnostic and professional use only*

Store at (2-30º C)

INTENDED USE

The OXY Rapid Test Device (Urine) is a rapid visual immunoassay for the qualitative detection of Oxycodone in human urine specimens at the cut-off concentrations listed below:

Parameter	Calibrator	Cut-off (ng/mL)
OXY (Oxycodone)	Oxycodone	100

INTRODUCTION

Oxycodone is a semi-synthetic opiate manufactured by modifying the chemical thebaine, an organic chemical found in opium.

Oxycodone use. can be injected intramuscularly,intravenously, subcutaneously or orally in form of tablets When using oxycodone products under the care of a physician most users will experience mild side effects such as headaches, increased pressure of cerebral and spinal fluid,nausea, breathing irregularity,heart failure,and overdose death due to cardiac arrest Oxycodone is metabolized in the liver and excreted through the kidney. The half-life of oxycodone in the body is around twelve hours.

PRINCIPLE

The OXY Rapid Test Device detects Oxycodone through visual interpretation of color development on the device. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Oxycodone test device.
- Disposable Dropper.
- Instructions for use.

Materials Required But Not Provided

- Specimen collection container
- Timer
- Positive control
- Negative control

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Device is stable through the expiration date printed on the label 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.

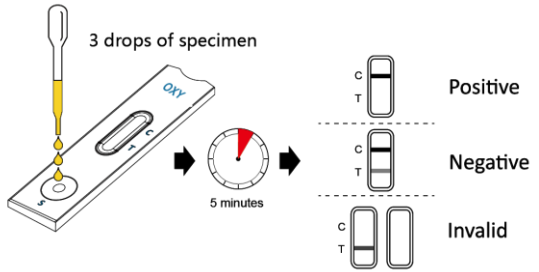
SPECIMEN COLLECTION AND STORAGE

- The OXY Rapid Test Device is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Allow the 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** to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should be **read at 5 minutes.** It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

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 results. The negative result does not indicate the absence of drug in the specimen, it only indicates that the oxycodone level 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 that the oxycodone level in the specimen is above the cut-off level.

Invalid:

If there are no colored bands in control line zone, the test result is invalid. Retest the sample with a new device.

Note: A very faint colored band in test line zone indicates that the amount of oxycodone in the sample is near the cut-off level. These specimens and any

positive samples should be confirmed by and alternate method such as GC/MS.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Control standards can be used to validate reagent performance and establish test reliability. Controls which are not provided with this test are commercially available.

LIMITATION

1. The OXY Rapid Test Device is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Oxycodone.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a Oxycodone only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of Oxycodone in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between Oxycodone and certain medications.

PERFORMANCE CHARACTERISTICS

- **Accuracy**

The accuracy of the OXY Rapid Test Device was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

- **Reproducibility**

The accuracy of the OXY Rapid Test Device was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

- **Precision**

The accuracy of the OXY Rapid Test Device was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

- **Specificity**

The following tables list the concentrations of compounds (ng/mL) above which the OXY Rapid Test Device identified positive results **at 5 minutes.**

OXY related compounds	**Concentration (ng/ml)**
Oxycodone	100
Hydrocodone Result 1	25,000
Hydromorphone	50,000
Naloxone	50,000
Oxymorphone	250

The following compounds were found not to cross-react when tested at concentrations at 100 g/ml.

(-)-Ephedrine	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine	Dextromethorphan	Pheniramine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	Vitamin C (Ascorbic Acid)
Bilirubin	Imipramine	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	
Chloroquine	Methadone	
(-)-Ephedrine	Chlorpheniramine	

REFERENCES

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2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
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4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.

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PPI1707A01
Rev A (02.09.2019)

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry