Atlas Medical

CE

Rapid Test Device (Urine)

For the qualitative, presumptive detection of Morphine/Heroin in human urine specimens

IVD *For in vitro diagnostic and professional use only.*

2 – 30°C Store at 2-30 °C

INTENDED USE

The OPI Rapid Test cassette (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Morphine/Heroin in human urine specimens at the cut-off concentrations listed below:

Test	Calibrator	Cut-off
Opiates (OPI 300)	Morphine	300 ng/mL

INTRODUCTION

Opiate refers to any drug that is derived from the opium poppy, including the natural products, Morphine and Codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances, which control pain by depressing the central nervous system. Large doses of Morphine can produce higher tolerance levels and physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.

PRINCIPLE

The OPI Rapid Test cassette (Urine) detects OPI through visual interpretation of color development on the cassette. 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

- Test cassettes.
- Disposable pipettes.
- Package insert.

Materials Required But Not Provided

- Positive and negative controls.
- Timer.
- Centrifuge.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch or canister 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 completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., 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 testing.
- Do not eat, drink or smoke in the area where 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 standard procedures for the 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.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch or canister.
- The test must remain in the sealed pouch or closed canister until use.
- **Do not freeze.**
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination.
- Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

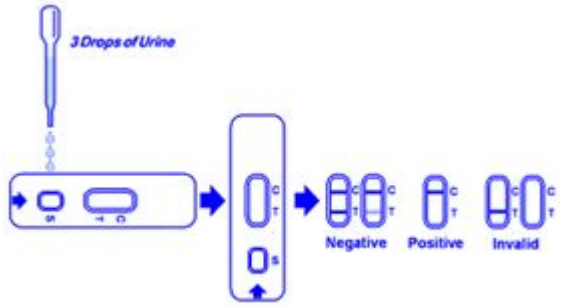
SPECIMEN COLLECTION AND PREPARATION

- The OPI Rapid Test Cassette (Urine) 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

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

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
2. Using the provided disposable pipette, transfer 3 drops of specimen (approximately 120 µL) to the specimen well (S) of the device and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area. As the test begins to work, color will migrate across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.



INTERPRETATION OF RESULTS

(Please refer to the 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 Morphine concentration is below the detectable level (300ng/mL).

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Morphine concentration exceeds the detectable level (300ng/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 Cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

NOTES:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

1. Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal

positive procedural control, confirming sufficient specimen volume and correct procedural technique.

2. External controls are not supplied with this kit. 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.

LIMITATIONS

1. The OPI Rapid Test Cassette (Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Morphine/Heroin.
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 Morphine/Heroin only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of Morphine/Heroin in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between Morphine/Heroin and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the OPI Rapid Test Cassette (Urine) 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.

B. Reproducibility

The reproducibility of the OPI Rapid Test Cassette (Urine) was verified by blind tests performed at four different locations. Samples with Morphine/Heroin concentrations at 50% of the cut-off were all determined to be negative, while samples with Morphine/Heroin concentrations at 200% of the cut-off were all determined to be positive.

C. Precision

Test precision was determined by blind tests with control solutions. Controls with Morphine/Heroin concentrations at 50% of the cut-off yielded negative results, and controls with Morphine/Heroin concentrations at 150% of the cut-off yielded positive results.

D. Specificity

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

OPIATES 300	**(ng/ml)**
Morphine	300
Acetylcodeine	150
Buprenorphine	3,125
Codeine	250
Diacetyl Morphin	250
Dihydrocodeine	586
Ethylmorphine	200
Hydrocodone	12,500
Hydromorphone	12,500
6-Monoacetylmorphine	250
Morphine-3-glucuronid	2,500
Nalorphine	25,000
Thebaine	25,000

Cross-Reactivity

The following compounds yielded negative results up to a concentration of 100 µg/mL:

(-)Cotinine	Creatinine	Methamphetamine
(-)Isoproterenol	Cyclobenzaprine	Metoclopramide
(+)-cis-Diltiazem	Delorazepam	Metoprolol
(+)-Naproxen	Desipramine HCl	Nifedipine
(+/-) Phenylpropanolamine	Dexamethasone	Nimesulide
(+/-)Epinephrine	Dextromethorphan	Nitrazepam
3,4-Methylenedioxyamphetamine	Diazepam	N-Methylephedrine
3,4-Methylenedioxy-methamphetamine	Diclofenac	Olanzapine
4-Dimethylaminoantipyrine	Dicumarol	Opipramol
Acetaminophen	Diflunisal	Oxalic acid
Acetophenetidine	Digoxin	Oxazepam
Acetylsalicylic acid	Dimenhydrinate	Oxymetazoline
Alprazolam	Diphenhydramine	Pennicilline G
Amikacin	DL-Propanolol	Perphenazine
Aminopyrine	DL-Tryptophan	Phencyclidine
Amitriptyline	DL-Tyrosine	Pheniramine
Amoxicilline	Dopamine	Phenothiazine
Amphetamine	Doxepin	Phentermine
Ampicilline	Doxylamine	Prednisolone
Apomorphine	d-Propoxyphene	Prednisone
Ascorbic acid	Ecgonine HCl	Procaine
Aspartame	Ephedrine	Promazine
Atropine	Erythromycine	Promethazine
Baclofen	Estron 3 sulfate	Prothipendyl
Benzocaine	Etodolac	Protriptyline
beta-phenylethylamine	Fenfluramine	Quetiapine
Bilirubin	Fentanyl	Quinidine
Bromazepam	Fluoxetine	Ranitidine
Caffeine	Flupentixol	Risperidone
Cannabidiol	Furosemide	Salbutamol
Cannabinol	Gastrozepin	Salicylic acid
Carbamazepine	Gentamicin	Secobarbital
Chloramphenicol	Gentisic acid	Sertraline
Chlordiazepoxide	Guaiacol Glyceryl Ether	Spironolactone
Chloroquine	Hemoglobin	Sulfamethoxazole
Chlorpheniramine	Hydralazine	Sulindac
Chlorprothixene	Hydrochlorothiazide	Temazepam
Cholesterol	Hydrocortisone	Theophylline
Chorptothixene	Ibuprofen	Thiamine
Cimetidine	Imipramine	Thioridazine
Ciprofloxacin	Ketamine	Tobramycin
Citalopram	Ketoprofen	Triamterene
Clindamycin	L - Thyroxine	Trimethoprim
Clobazam	Lidocaine	Trimipramine
Clomipramine	Lincomycin	Tyramine
Clonazepam	Loperamide	Vancomycin
Clonidine	L-Phenylephrine	Venlafaxine
Clorazepate	Maprotiline	Verapamil
Clozapine	Mephentermine hemisulfate salt	Zolpidem
Cocain	Methadone	

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ATLAS MEDICAL
William KJames House, Cowley Rd,
Cambridge, CB4 0WX
Tel: ++44 (0) 1223 858 910
Fax: ++44 (0) 1223 858 524

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REF	Product Reference No.	IVD	For in-vitro diagnostic use.
	Caution.		Store at
	Read product insert before use.		Number of tests in the pack.
LOT	Lot (batch) number.		Manufacturer.
	Expiry date.		Manufacturer telephone number.
	Manufacturer fax number.		