Atlas Medical

A rapid test for the qualitative detection of Methadone metabolite EDDP Rapid Test Device (Urine)

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

Store at (2-30º C)

INTENDED USE

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

Parameter	Calibrator	Cut-off (ng/mL)
EDDP (Methadone metabolite)	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	100

INTRODUCTION

EDDP is a methadone metabolite. Methadone is a prescribed opioid which is used to relieve chronic pain, as well as for the detoxification and treatment of narcotic or heroin addiction. EDDP testing is commonly carried out to assess whether individuals receiving methadone therapy are complying with their treatment. Methadone abuse can have side effects such as hallucinations and changes in the user's personality.

EDDP metabolites are secreted in urine or bile along with methadone drug. Current methadone immunoassays can detect only the parent drug and are subject to "false positives" from adulteration of samples for drug of abuse testing, or "false negatives" for methadone compliance testing urine samples from fast metabolisers.

PRINCIPLE

The EDDP Rapid Test Device (Urine) detects Methadone metabolite 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 wicking has occurred.

MATERIALS

Materials Provided

- Test Cassettes(contain mouse monoclonal anti-EDDP antibody coupled particles and Propoxyphenes-protein conjugate. A goat antibody is employed in the control line system).
- Disposable specimen droppers.
- Package insert

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 poteled 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

- Do not freeze.
- Do not use beyond the expiration date.
- 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.

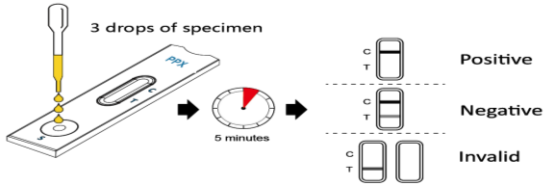
SPECIMEN COLLECTION AND STORAGE

- The EDDP Rapid Test Device (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 10 minutes.

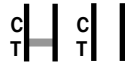


INTERPRETATION OF RESULTS

POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.



NOTE:

- 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 negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.

- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- 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.
- 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

- The EDDP Rapid Test Device (Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Methadone metabolite.
- 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.
- 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.
- 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.
- A positive result indicates the presence of a Methadone metabolite only, and does not indicate or measure intoxication.
- A negative result does not at any time rule out the presence of Methadone metabolite in urine, as they may be present below the minimum detection level of the test.
- This test does not distinguish between Methadone metabolite and certain medications.

PERFORMANCE CHARACTERISTICS

- **Accuracy**

The accuracy of the EDDP Rapid Test Device (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.

- **Reproducibility**

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

- **Precision**

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

- **Specificity**

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

EDDP related compounds	Concentration
EDDP	100
Meperidine	100,000
Methadone	100,000
Norfentanyl	100,000
Phencyclidine	100,000
Promazine	50,000
Promethazine	25,000
Prothipendyl	50,000
Prozine	12,500

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

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

REFERENCES

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
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.
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.

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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