


EDDP (100) Test Strip (Urine)

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

IVD *pr in vitro diagnostic and professional use only*

 Store at 2-30 °C

INTENDED USE

The EDDP Rapid Test Strip (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 strip(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.

MATERIALS

Materials Provided

- Test strips.
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

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 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 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.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- 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 STORAGE

- The EDDP Rapid Test Strip (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, or remove one strip from the canister, and use it as soon as possible. For best results, the assay should be performed within one hour. Canisters should be closed tightly after removing strips.
2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
3. Holding the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip. (See the illustration below)
4. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and 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

NEGATIVE: Two lines adjacent to each drug name appear.

One red line should be in the control region (C) of the specific drug test, and another apparent red or pink line adjacent to each drug test should be in the test region (T) of the specific drug test.



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 colored line appears in the control region (C) of the specific drug test. No line appears in the test region (T) of the specific drug test. The absence of a test line indicates a positive result for that drug.



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

- 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 Strip (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 Strip (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 Strip (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 drug/metabolite concentrations at 50% of the cut-off yielded negative results, and controls with drug/metabolite concentrations at 150% of the cut-off yielded positive results.

Specificity

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

EDDP related compounds	Concentration ng/ml
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 yielded negative results up to a concentration of 100 µg/mL:

















(-)-Ephedrine	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine	Dextromethorphan	Pheniramine
4-Dimethylaminoan tyrine	Dextrophan tartrate	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiaicol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Ibuprofen	VitaminC (Ascorbic Acid)

Bilirubin	Imipramine	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	Chloroquine
Methadone		

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PP11799A01
Rev A (02.09.2019)

 REF	Catalogue Number		Temperature limit
 IVD	In Vitro diagnostic medical device		Caution
 V	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