EDDP One Step Test Strip (Urine)
Package Insert

Cat: EDDP-101 **Specimens:** Urine

Version: Z **Effective Date:** 2020-9

For professional in vitro diagnostic use only.

INTENDED USE

The EDDP One Step 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

Methadone (MTD) is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia,sedation and respiratory depression.Overdose of methadone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver. The kidneys are a major route of methadone excretion. Methadone has a biological half-life of 16-50 hours. EDDP (2-Ethyliden-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine) is the most important metabolite of methadone. It is excreted into the bile and urine together with the other metabolite EMDP (2-Ethyl-5-Methyl-3, 3-Diphenylpyrrolidine). EDDP is formed by N-demethylation and cyclization of methadone in the liver. The part of the unchanged excreted methadone is variable and depends on the urine's pH value,dose,and the patient's metabolism.Therefore, the detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.

PRINCIPLE

The EDDP One Step Test 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.

REAGENTS

The test contains drug-bovine protein antigen conjugate on the membrane and the conjugate pad of each test contains monoclonal anti-drug antibody.

REAGENTS

Each test consists of a reagent strip. The amount of each antigen and/or antibody coated on the strip is less than 0.001 mg for antigen conjugates and goat anti-rabbit IgG antibodies, and less than 0.0015 mg for antibody components.

The control zone of each test contains goat anti-rabbit IgG antibody. The test zone of each test contains drug-bovine protein antigen conjugate, and the conjugate pad of each test contains monoclonal anti-drug antibody and rabbit antibody-colored particle complex.

MATERIALS

Materials Provided

- Individually pouched test strips
- 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 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.
- Read the entire procedure carefully prior to testing.
- 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 standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.

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 One Step 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, and use it as soon as possible. For best results, the assay should be performed within one hour.
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 8-10 seconds**. Do not immerse past the maximum line (MAX) on the test strip.
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

POSITIVE RESULT:

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

NEGATIVE RESULT:

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 RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be disgarded. 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:

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 negative. 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

- 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 OF THE TEST

1. The EDDP One Step Test Strip (Urine) is for professional *in vitro* diagnostic use, and should be only used for the qualitative detection of Methadone metabolite.
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 Methadone metabolite only, and does not indicate or measure intoxication.
6. 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.
7. This test does not distinguish between Methadone metabolite and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the EDDP One Step 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.

B. Reproducibility

The reproducibility of the EDDP One Step 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.

C. 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 results.

D. Specificity

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

EDDP related compounds	Concentration (ng/ml)	EDDP related compounds	Concentration (ng/ml)
EDDP	100	Promazine	50,000
Meperidine	100,000	Promethazine	25,000
Methadone	100,000	Prothipendyl	50,000
Norfentanyl	100,000	Prozine	12,500
Phencyclidine	100,000		

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

Acetophenetidine	Clozapine	Furosemide	Oxycodone
Acetylcodeine	Cocain	Gastrozepin	Oxymetazoline
Acetylsalicylic acid	Codein	Gentamicin	Pennicilline G
Alprazolam	(-)Cotinine	Gentisic acid	Perphenazine

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

LITERATURE 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.

Index of Symbols

Consult Instruction for use		Tests per kit		Do not use if package is damaged	
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
2℃ 30℃	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number
	Keep away from sunlight		Keep dry		Manufacturer
	Caution		Date of manufacture	EC REP	Authorized Representative

Hangzhou Sejoy Electronics& Instruments Co.,Ltd.
Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,Hangzhou City 311100 Zhejiang China

EC REP **Shanghai International Holding Corporation GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

CE