INTENDED USE

The MTD One Step Methadone Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Methadone in human urine at a cut-off concentration of 300 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

PRINCIPLE

The MTD One Step Methadone Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Methadone, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody-coated particles in the test. The antibody coated particles will then be captured by immobilized Methadone-protein conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Methadone level exceeds 300 ng/mL because it will saturate all the binding sites of anti-Methadone antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

- Test Device
- Packaging Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Specimen collection container

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

SPECIMEN COLLECTION AND STORAGE

- The MTD Test Device is intended only for use with human urine specimens.
- Collected urine specimens must be put in clear and dry containers. Ensure that a sufficient quantity of the specimen is collected to allow submerging the dipping area of the Device.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. 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.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

DIRECTIONS FOR USE

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 Device by the end, where the product name is printed. To avoid contamination, do not touch the Device membrane.
3. Holding the Device vertically, **dip the test Device in the urine specimen for at least 10-15 seconds**. Do not immerse past the maximum line (MAX) on the test Device.
4. After the test has finished running, remove the Device 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 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:

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.

LIMITATIONS

1. The MTD One Step Methadone Test Device (Urine) provides only a qualitative, preliminary, analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[2,3]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the MTD One Step Methadone 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.

B. Reproducibility

The reproducibility of the MTD One Step Methadone Test Device (Urine) was verified by blind tests performed at four different locations. Samples with Methadone concentrations at 50% of the cut-off were all determined to be negative, while samples with Methadone 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 concentrations at 50% of the cut-off yielded negative results, and controls with Methadone 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 MTD One Step Methadone Test Device (Urine) identified positive results at 5 minutes.

Methadone related Compounds	Concentration (ng/ml)
Methadone	300
Doxylamine	50,000

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

Acetaminophen	Diazepam	Maprotiline	-Phenylethylamine
Acetophenetidin	Diclofenac	Meperidine	Phenylpropanolamine
N-Acetylprocainamide	Diflunisal	Meprobamate	Prednisolone
Acetylsalicylic acid	Digoxin	Methamphetamine	Prednisone
Aminopyrine	Diphenhydramine	Methoxyphenamine	Procaine
Amitryptyline	EDDP	( ) - 3,4-Methylenedioxy-amphetamine	Promazine
Amobarbital	EMDP	( ) - 3,4-Methylenedioxymeth-	Promethazine
Amoxicillin	Ecgonine hydrochloride	Amphetamine	D,L-Propranolol
Ampicillin	Ecgonine methylester	(-) -ψ- Ephedrine	D-Propoxyphene
L-Ascorbic acid	(-) -ψ- Ephedrine	Morphine-3-	D-Pseudoephedrine
D,L-Amphetamine sulfate	[1R,2S] (-) Ephedrine	β-D glucuronide	Quinacrine
Apomorphine	L - Epinephrine	Morphine Sulfate	Quinidine
Aspartame	Erythromycin	Nalidixic acid	Quinine
Atropine	-Estradiol	Naloxone	Ranitidine
Benzilic acid	Estrone-3-sulfate	Naltrexone	Salicylic acid
Benzoic acid	Ethyl-p-aminobenzoate	Naproxen	Secobarbital
Benzoylecgonine	Fenoprofen	Niacinamide	Serotonin
Benzphetamine	Furosemide	Nifedipine	Sulfamethazine
Bilirubin	Gentisic acid	Norcodein	Sulindac
( ) - Brompheniramine	Hemoglobin	Norethindrone	Temazepam
Caffeine	Hydralazine	D-Norpropoxyphene	Tetracycline
Cannabidiol	Hydrochlorothiazide	Noscapine	Tetrahydrocortisone,

Index or Symbols

	Attention, see instructions for use		Tests per Kit		Manufacturer
IVD	For *in vitro*		Use by	2	Do not reuse
	Store between 2 - 30°C	LOT	Lot Number	REF	Catalogue Number

CE

Deniz Biyokimya Ürünleri Dış Tic. A.Ş.
Fatih Mh. 1191. Sk. No:5/2 Gaziemir
35410 İZMİR / TÜRKİYE