

HEALTH-CHEM DIAGNOSTICS, LLC

3341 S.W. 15th Street – Pompano Beach, FL 33069 - USA – Phone: (954) 979-3845 – Fax: (954) 979-7997 Website:
www.healthchemdiagnostics.com

ONE STEP METHADONE TEST STRIP™

NAME AND INTENDED USE

The Health-Chem **One Step Methadone Test Strip™** is a rapid, qualitative, competitive binding immunoassay for the determination of Methadone in urine in a convenient One Step strip test format. This test is not intended to monitor drug levels, but only to screen urine samples for the presence of Methadone. Both the testing and the results of the testing are intended to be used by medical and legal professionals only. The test should not be used without appropriate supervision. The **One Step Methadone Test Strip™** assay is not intended for Over The Counter (OTC) sale to lay persons.

EXPLANATION OF THE TEST

The **One Step Methadone Test Strip™** assay is a rapid, qualitative, competitive binding immunoassay for the determination of Methadone in urine. The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectroscopy (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The **One Step Methadone Test Strip™** is not intended to monitor drug levels, but only to screen urines for the presence of methadone and its metabolites.

The method employs unique polyclonal antibodies to selectively identify Methadone in test samples with a high degree of sensitivity. Methadone is a prescription drug which can also be abused. Acute higher doses induce analgesia, sedation, respiratory depression and coma. Methadone is excreted in the urine in unchanged forms, diphenylpyrrodine derivatives methadol, normethadol and conjugates.

The **One Step Methadone Test Strip™** test is based on the principle of the highly specific immunochemical reactions of antigens and antibodies which are used for the analysis of specific compounds in biological fluids. The assay relies on the competition for binding antibody between drug conjugates and drugs which may be present in the urine being tested. When methadone is present in the urine, they compete with the drug conjugates which are coated on a membrane for the limited antibodies present in the dye antibody conjugates. When a sufficient amount of drug is present, it will prevent the binding of dye-antibody conjugate to the drug conjugate on the membrane. Therefore a positive urine sample will not generate a color band on test region, indicating a positive result, while the presence of the color band on test region indicates a negative result. The legally allowable level for Methadone is set at 200 ng/ml of urine by the National Institute on Drug Abuse.

The **One Step Methadone Test Strip™** test is an easy, fast, visually read competitive binding immunoassay method for the screening of urine for the presence of Methadone without the need for instrumentation.

PRINCIPLE OF THE PROCEDURE

One Step Methadone Test Strip™ test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody-antigen complex. This complex competes with the immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 200 ng/ml which is suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

A **NEGATIVE** specimen produces two distinct color bands in both the test line and control area.

A **POSITIVE** specimen produces only one color band in the control area.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers.
2. Clock or timer.

WARNINGS AND PRECAUTIONS

1. For **in vitro** diagnostic use only.
2. For professional medical and legal use only.
3. Avoid cross contamination of urine samples by using a new urine specimen cup for each sample.
4. Do not use the test strip beyond the expiration date imprinted on the outside of the foil pouch.
5. Urine specimens may be infectious. Upon completion of all testing dispose of residual urine in a medically approved manner.
6. Properly handle and dispose of all used reaction devices in an approved biohazard container.

STORAGE AND STABILITY

The reagents supplied can be stored under refrigeration (2°-8°C)(35° - 46°F) **[DO NOT FREEZE]** or at room temperature (18° - 30°C)(64° - 86°F) and will be stable for 12 months.

SAMPLE COLLECTION AND PREPARATION

Urine (1.0 ml) - The sample must be collected in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2°-8°C) and stored up to 48 hours, or frozen (-20°C or colder) prior to assaying. If samples are refrigerated or frozen, they should be allowed to come to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for

testing.

ASSAY PROCEDURE

1. Remove the **One Step Methadone Test Strip™** from its protective foil wrapper by tearing along the notch.
2. Add 1 ml of urine to be tested to a 13 x 100mm test tube. Holding the strip in a vertical position, place into the urine and simultaneously start timing. Make sure only the end with the arrow pointing down is placed into the urine specimen. The urine level should not be higher than the maximum fill line indicated on the strip. (See figure 1)

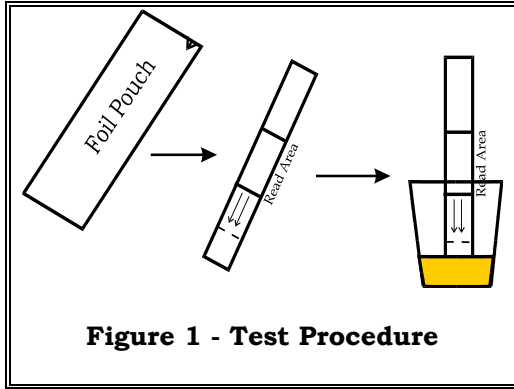


Figure 1 - Test Procedure

3. Read the results after 3 minutes. Test results should not be interpreted after 5 minutes.

NOTES:

1. In order to prevent any incorrect results, the test results should not be interpreted after 5 minutes.
2. Refrigerated strips should be allowed to come to room temperature before opening the pouch.

READING THE TEST RESULTS

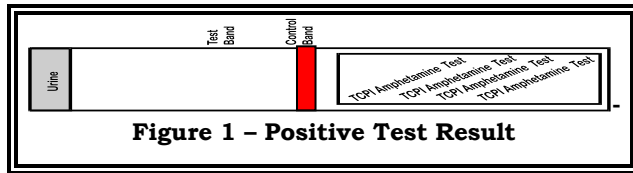


Figure 1 - Positive Test Result

1. **POSITIVE:** One magenta band appears on the control region. No visible band on the test region (lower portion of the read area). This is an indication that the Methadone level is above the detection sensitivity level of 200 ng/ml of urine.

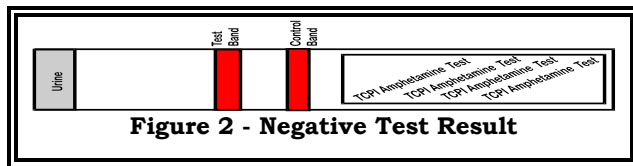


Figure 2 - Negative Test Result

2. **NEGATIVE:** In addition to the control band, a magenta band also appears on the test region (lower portion of the read area). If this is the case, the Methadone level is below the detection sensitivity level of 200 ng/ml of urine.

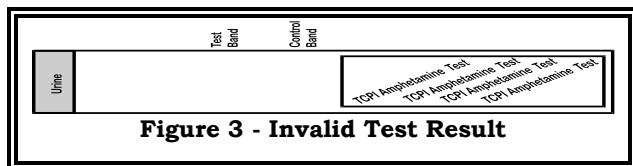


Figure 3 - Invalid Test Result

3. **INVALID:** If there is no distinct color bands in both the upper and lower portions of the read area, (lower portion of the strip), or no band in the control region (upper portion of the read area), then the test results are invalid. It is recommended that the specimen be retested.

QUALITY CONTROL

Each reaction strip has its own built-in quality control indicator. If after performing the test no line is visible on the strip, the strip may have been placed into the tube incorrectly or the test device may have deteriorated. The assay will have to be repeated using a new **One Step Methadone Test Strip™**. Re-read the instructions carefully or call for assistance (800-482-2907).

Good laboratory practice recommends the use of control material to test each product shipment or whenever it is necessary to validate reagent performance and reliability. Commercial controls from BioRad, Uro-Qual Abutrol, Utak, and Alltech are available for validation of the device functionality. NIDA recommended guidelines for drugs of abuse screening indicate that controls should contain the drug of abuse analyte at levels at least 20% above the NIDA cut off values.

ATER TESTING

Urine specimens may be infectious. Properly handle and dispose of all used reaction devices in an approved biohazard container. Residual urine should be disposed of in a medically approved manner after completion of all testing including the confirmatory testing. Sample disposal may be controlled by legal chain of custody considerations.

PERFORMANCE CHARACTERISTICS

Sensitivity:

Currently being determined by Clinical Trials.

Specificity:

Currently being determined by Clinical Trials.

Table 1 - Results of In House Testing

Reference	HCD (+)	HCD (-)	Row Totals
(+)			
(-)			
Col. Totals			

Table 2 - Compounds which produce a positive reaction

Currently being determined by Clinical Trials

Compound	Level or Concentration
Methadone Hydrochloride	300 µg/ml
Meperidine	10 µg/ml
d-Methamphetamine	10 µg/ml

TABLE 3 - Compounds which produce no reaction

4-Acetamidophenol	Isoproterenol
Acetylsalicylic Acid	Ketamine
Amikacin	Lidocaine
Amitriptyline	Morphine
d,l-Amphetamine	Naloxane
Arterenol	Neomycin
Aspartame	Niacinamide
Atropine Sulfate	11-norDelta-8-THC-9-COOH(10µg/ml)
Benzoylcegonine	1-norDelta-THC-COOH(10µg/ml)
Caffeine	Oxazepam
Camphor	Perphenazine
Chlorpheniramine	Phencyclidine
Cortisone	Phenobarbital
Deoxyepinephrine	Phenylethylamine-a
Dextromethorphan	Phenylpropanolamine
Digitoxin	Promethazine
Digoxin	Pseudoephedrine
(±) Epinephrine	Rantidine
Ephedrine	Salicylic Acid
Gentisic Acid	Secobarbital
Glucose	Tetracycline
Guaiacol Glyceryl Ether	Tetrahydrozoline
Histamine	Theophylline
Homatropine	Thiothiazine
Imipramine	Trifluoperazine

Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC,
POMPANO BEACH, FLORIDA
Website: www.healthchemdiagnostics.com

**THIS TEST IS FOR INVESTIGATIONAL USE ONLY. NOT
FOR SALE IN THE UNITED STATES OR ITS
PROTECTORATES.**

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of Methadone at its metabolites in human urine only.
2. Although HCD's **One Step Methadone Test Strip™** test is very accurate in detecting the urine Methadone level, there is a possibility of false results due to the presence of interfering substances in the urine.
3. The test is a qualitative screening assay and is not suggested for determining the quantitative Methadone level of urine.
4. Adulterants, such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

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