



## ADVANCED QUALITY™ ONE STEP Methadone(MTD) TEST

(Urine)

FOR *IN VITRO* DIAGNOSTIC USE ONLY

### INTENDED USE

THE ADVANCED QUALITY™ ONE STEP METHADONE TEST IS A RAPID, QUALITATIVE IMMUNOASSAY FOR THE DETERMINATION OF METHADONE AND ITS METABOLITE IN HUMAN URINE. THE TEST IS USED TO SCREEN URINE FOR THE PRESENCE OF METHADON AT A CUT OFF CONCENTRATION OF 300NG/ML. THE TEST IS FOR USE BY HEALTH CARE PROFESSIONALS ONLY.

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

### PRINCIPLE OF THE ASSAY

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, dipheylpyrrodine derivatives, methadol, normethadol and conjugates.

The Advanced Quality One Step Methadone 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, it competes 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.

### REAGENTS AND MATERIALS SUPPLIED

1. Test strips individually foil pouched with a desiccant
2. Package insert

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Positive and negative urine controls available from commercial distributors.

### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Avoid cross contamination of urine samples by using a new urine specimen cup for each sample.

3. Do not use the kit beyond the expiration date printed on the outside of the foil pouch.
4. Do not open the foil pouch until urine specimen is collected and ready to be tested.
5. Urine specimens may be infectious. Handle and dispose of all used specimens and devices in an approved biohazard container.

### STORAGE AND STABILITY

The test device can be stored under refrigeration and at room temperature (2 - 30° C) and will be stable until the expiration date. **Do not** open foil pouch until ready to test.

### SAMPLE COLLECTION AND PREPARATION

10 ml of urine must be collected in a clean, dry, plastic or glass container, that does not contain preservative. Some plastics may adsorb drugs. If not tested immediately, urine specimens may be stored refrigerated at 2-8°C for up to 7 days and then frozen(-20° C or colder) prior to assaying. Refrigerated or frozen samples must be warmed to room temperature and gently mixed before testing. Urine samples exhibiting visible precipitates or turbidity should be centrifuged or allowed to settle so a clear aliquot may be sampled for this assay. Collection of samples may require mandatory procedures and custody and control records. Poppy seed ingestion has been associated with positive test results in some samples.

### ASSAY PROCEDURES

1. Bring all materials and specimens to room temperature.
2. Remove test strip from the sealed foil pouch.
3. Dip the test strip into the urine sample with the arrows pointing toward the specimen.
4. The urine level should reach the maximum line marked on the strip, but must not exceed the maximum line.
5. Hold the strip in the urine until a reddish color appears at the lower edge of the test membrane (approximately 10 seconds).
6. Withdraw the strip and place it face up on a clean, dry surface.
7. Read the result between 3 - 8 minutes after adding the sample.

### READING THE TEST RESULTS

*Read test results between 3 - 8 minutes.*

**Do not interpret results after 8 minutes.**

**NEGATIVE** Two (2) pink/purple bands form. In addition to the control band, a pink/purple band also appears in the test region.

*Note: This immunoassay is a screening test. A negative result indicates the drug level is below the detection sensitivity. It is important to understand that concentrations of the drug below cut off may cause a faint "ghost line" to form in the test region. This "ghost line" should be considered a negative result.*

**POSITIVE** One (1) pink/purple band appears in the control region. No band is found in the test region. This is an indication that the drug level is above the detection sensitivity level.

**INVALID** If there is no pink/purple band in the control area of the strip, the test result is invalid. Retest the sample using a new device.

*Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive. Positive results should be confirmed by an alternate method such as GC/MS.*

### QUALITY CONTROL

1. Each test device has a control band to indicate that the sample volume and migration is adequate, and that the colloidal gold is dissolving as expected. An invalid result must be repeated using a new test device.
2. Positive and negative, drug free urine controls can be used to validate reagent performance and establish test reliability. Commercial drug urine controls are available, but not provided with this test. NIDA recommended guidelines for drugs of abuse screening indicate controls should contain the drug at a level at least 20% above the NIDA cutoff value. If control values do not fall within the established limits, assay results are invalid.

#### EXPECTED RESULTS

The Advanced Quality Methadone Test identifies Methadone in human urine at a cut off concentration of 300ng/mL. The concentration of the drug can not be determined using this test. The test is intended to screen urine to separate a negative result from a presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

#### CHARACTERISTICS & SPECIFICITY

The Advanced Quality Methadone Test detects an average of 300 ng/ml of methadone in human urine.

#### COMPOUNDS DETECTED:

(±) Methadone 300 ng/ml

#### COMPOUNDS GIVING NEGATIVE RESULT:

4-acetamidophenol	ketamine
acetylsalicylic acid	lidocaine
amikacin	meperidine
amitriptyline	methamphetamine
d,l-amphetamine	morphine
arterenol	naloxane
aspartame	neomycin
atropine sulfate	niacinamide
benzoylecgonine	11-nor-delta-8-THC-9-COOH (10 ug/ml)
caffeine	1-nor-delta-THC-COOH (10 ug/ml) oxazepam
camphor	perphenazine
chlorpheniramine	phencyclidine
cortisone	phenobarbital
deoxyepinephrine	phenylethylamine-α
dextromethorphan	phenylpropanolamine
digitoxin	promethazine
digoxin	pseudoephedrine
(±)epinephrine	rantidine
ephedrine	salicylic acid
gentisic acid	secobarbital
glucose	tetracycline
histamine	tetrahydrozoline
guaiacol glyceryl ether	theophylline
homatropine	thioridazine
imipramine	trifluoperazine
isoproterenol	

#### LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of Methadone in human urine only.
2. Although the Advanced Quality One Step Methadone Test is very accurate in detecting Methadone in urine, there is a possibility of false results due to the presence of interfering substances.
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.
5. There is the possibility that other substances and/or factors not listed may interfere with the test and cause false results, e.g. technical or procedural errors.
6. A positive result indicates the presence of Methadone in urine. This result does not indicate the level of intoxication nor is it intended to monitor drug levels.
7. Results should be confirmed using an alternate method. GC/MS is the preferred confirmatory method.

#### BIBLIOGRAPHY

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3. R.C.Baselt, Disposition of Toxic Drugs and Chemicals in Man, 2nd ed., Biomedical publ., Davis, CA, 1982, p.488.



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