


ADVANCED QUALITY™ ONE STEP Methamphetamine(MET) TEST
(Urine)FOR *IN VITRO* DIAGNOSTIC USE ONLY**INTENDED USE**

THE ADVANCED QUALITY™ ONE STEP METHAMPHETAMINE TEST IS A RAPID, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF METHAMPHETAMINE AND ITS METABOLITES IN HUMAN URINE. THE TEST IS USED TO SCREEN URINE FOR THE PRESENCE OF METHAMPHETAMINE AND ITS METABOLITES AT A CUTOFF CONCENTRATION OF 500NG/ML. THE TEST IS INTENDED FOR USE BY HEALTHCARE 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.

SUMMARY AND EXPLANATION OF THE TEST

Methamphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of methamphetamine could develop tolerances and physiological dependency and lead to its abuse. Both d(+) and l(-) forms of the isomers are controlled substances. The legally allowable level for Methamphetamine is set by the National Institute on Drug Abuse at 500 ng/ml in urine as measured by GC/MS.

The test is a qualitative, visual screening immunoassay. The method employs unique antibodies to selectively identify the drug in the test urine with a high degree of sensitivity and specificity.

PRINCIPLE OF THE PROCEDURE

The test device 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 immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level 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 (2) distinct color bands, one in the test area and one in the control region.

A **positive** specimen produces only one (1) color band in the control region.

REAGENTS AND MATERIALS SUPPLIED**FOR STRIP TEST**

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

FOR CARD TEST

1. Test cards individually foil pouched with a desiccant
2. Plastic dropper
3. Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Urine collection containers (for card test)

2. Clock or Timer
3. 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 mls 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**FOR STRIP TEST:**

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.

FOR CARD TEST:

1. Bring all materials and specimens to room temperature.
2. Remove test card from the sealed foil pouch.
3. Place the test card on a flat dry surface.
4. Using the provided plastic dropper, dispense 3 drops of urine sample to the sample well of the test card. Start timing.
5. Read 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 Methamphetamine Test identifies methamphetamine and its metabolites in human urine at a cutoff concentration of 500ng/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.

PERFORMANCE CHARACTERISTICS

The Advanced Quality One Step Methamphetamine Test was compared to a commercially available reference screening method using 280 human urine samples (See Table 1).

Sensitivity:

The Advanced Quality One Step Methamphetamine test is designed for the detection of Methamphetamine in human urine at 500 ng/mL, as suggested for the immunoassay method. Based on the data collected in this study, the sensitivity was 142/142 or 1.00.

Specificity:

The Advanced Quality One Step Methamphetamine test can specifically detect both d and l forms of methamphetamine and a mixture. The test has proven positive with 500 ng/mL or greater concentrations of both Methamphetamine and Methylenedioxyamphetamines. Using the data presented in Table 1 the specificity was calculated to be 138/138 or 1.00.

TABLE 1 – Evaluation Summary

Reference Screen	AQ(+)	AQ(-)	Row Totals
(+)	142	0	142
(-)	0	138	138
Col. Totals	142	138	280

TABLE 2 – Compounds which produce a positive result

Compound	Level or Concentration
d-Amphetamine	5 ul/mL
Δ ₁ -Amphetamine	10 ul/mL
(+) Methamphetamine	500 ng/mL
± 3,4-Methylenedioxyamphetamine	10 ul/mL
± 3,4-Methylenedioxyamphetamine	1 ul/mL
Pseudoephedrine	10 ul/mL
Ephedrine	25 ul/mL
Phenyl propanolamine (PPA)	50 ul/mL

TABLE 3 – Compounds that give negative results

Acetaminophen	Ketoprofen
Acetylsalicylic Acid	Levorphanol
Amikacin	Meperidine
Amitriptyline	Methylphenidate
d-Amphetamine	Methadone
Ampicillin	3,4-Methylenedioxyamphetamine
Acetaminophen	Δ ₉ -THC

Acetylsalicylic acid	11-nor-Δ ₉ -carboxy-THC-9-COOH
Amikacin	Meperidine
Amitriptyline	Methylphenidate
Ampicillin	Methadone
Arterenol	Methaqualone Morphine Glucuronide
Aspartame	Morphine Sulfate Oxazepam Oxycodone
Atropine Sulfate	Pendimetrazine Penicillin G Pentobarbital
Benzoic Acid	d-Propoxyphene Hydrochlorothiazide
Benzoylcegonine HCl	Propanol Phencyclidine Phenobarbital
Caffeine	Phentermine Phenylpropanolamine L-
Chlorpheniramine	Phenylephrine Quinine Ranitidine Sodium
Chlorpropamazine HCl	Salicylate
Cimetidine	Tryptophan Tetracycline Tetrahydrozoline
Codeine	Theophylline Thioridazine Trifluoperazine
Deoxyephedrine	
Dextromethorphan	
Diazepam	
Diethylpropion	
Diphenylhydantoin	
Doxylamine	Ecgonine HCl
Ecgonine Methyl Ester	
Glucose	Histamine
Hydrocodone	Hydromorphone
Indomethacin	Ketoprofen
Levorphanol	

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of Methamphetamine in human urine only.
2. Although The Advanced Quality One Step Methamphetamine Test is very accurate in detecting the level of Methamphetamine in urine, 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 level of Amphetamine in 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 above may interfere with the test and cause false results, e.g. technical or procedural errors.

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