

1. Interference testing

The AccuTest™ MQL test strip performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.5 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed did not interfere with the AccuTest™ MQL test strip at the listed concentrations.

Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

2. Specificity

The following table lists compounds that are detected by the AccuTest™ MQL test strip, which produced positive results when tested at levels equal or greater than the concentrations listed below:

Test	Compounds	Cut-off(ng/ml)
MQL	Methaqualone	300
	Amitriptyline	50,000
	Carbamazepine	20,000
	2'-Hydroxy-methaqualone	3,000
	3'-Hydroxy-methaqualone	500
	4'-Hydroxy-methaqualone	500
	Mecloqualone	500
	Nortriptyline	50,000
	Phenytoin	40,000
	Primidone	24,000
	Theophylline	40,000

The following compounds show no cross-reactivity at concentration up to 100 µg/ml unless specified.

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid	Amikacin
Amitriptyline	Arterenol	Aspartame	Ascorbic acid
Atrophine	Caffeine	Camphor	Chloroquine
Chlopheniramine	Cortisone	Deoxyephedrine	Dextromethorphan
Digitoxin	Digoxin	Diphenhydramine	Ecgonine
Ecgonine methyl ester	Ephedrine	Epinephrine	Gentisic acid
Guaiaaccol glycer ester	Histamine	Hydrochlorothiazide	Homatrophine
Imipramine	Ibuprofen	Isoproterenol	Ketamine
Lidocaine	Meperidine	Methaqualon	Methylphenidate
Neomycin	Niacinamide	Perphenazine	Penicillin G
Phenylethylamine-□	Phenylpropanolamine	Promethazine	Pseudoephedrine
Quinine antidine	Salicylic acid	Tetracycline	Tetrahydrozoline
Theophylline	Thioridazine	Trifluoperazine	Tryptophan

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AccuTest™ MANDRAX Test Cassette

FOR THE QUALITATIVE ASSESSMENT OF
METHAQUALONE AND THE
METABOLITES IN HUMAN URINE



For in vitro Diagnostic and Forensic Use

INTENDED USE

The AccuTest™ MQL test strip is an immunochromatography based one step in vitro test. It is designed for qualitative determination of drug substances in human urine specimens. This assay may be used in the point of care setting. The cut-off concentration using our test is as follows;

Methaqualone (MQL) 300 ng/ml

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. The Substance Abuse Mental Health Services Administration (SAMHSA) has established gas chromatography/ mass spectrometry (GC/MS) as 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 indicated.

Note: It is not for use in diagnosing disease or illness; it is for investigational use only.

SUMMARY AND EXPLANATION

Mandrax is a synthetic drug that is compiled by means of the mixing of chemicals in a chemical process and a tablet is then produced. The active ingredient in Mandrax is Methaqualone. In the sixties and early seventies these tablets were prescribed as sleeping tablets. Other medicinal uses included illnesses like high blood pressure and anxiety attacks. Mandrax was originally known as a safe and non-dependent drug. It was the drug that people reckoned was going to be the miracle cures of the world at its time. It was however found that Mandrax had various side effects, especially if it was used with marijuana and alcohol, which was life threatening because it caused psychological and physical dependency. This caused a drastic increase in burglaries, especially at pharmacies, where it was found that Mandrax specifically was stolen. Mandrax was banned in most parts of the world because of the misuse.

The banning of Mandrax caused crime syndicates to use this opportunity to continue producing it by means of clandestine laboratories. The market was already established and the need for the drug made it a profitable business.

PRINCIPLE

The test strip is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result. A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

MATERIAL PROVIDED

1. An AccuTest™ MQL test cassette.

The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti- mouse IgG antibody.

Test zone: contains drug bovine protein antigen conjugates

Control zone: contains Goat anti-mouse IgG antibody

Conjugate pad: contains mice monoclonal anti-drug antibody.

2. Dropper
3. Instruction for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection container.
2. Timer or clock.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic and professional use only.
2. Do not use the test strip beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, the integrity of the device might be compromised.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

STORAGE AND STABILITY

The test device should be stored at 2°C to 28°C; **do not freeze** and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine does not require any special handling or pretreatment. Specimen should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2- 8 °C or frozen up to 7 days. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 25% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials that are not provided with this test kit are commercially available.

The AccuTest™ MQL test kit provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test strip from sealed foil pouch.
3. Place the sample pad end of the test strip (up to the bottom blue line mark) into the urine specimen.
4. Hold the strip in the urine for 10 seconds, remove from the urine.
5. At 5 minutes, read the test strip.

Do not interpret the result after 5 minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test strip after interpreting the result.

INTERPRETATION OF RESULTS

Negative:

Two colored bands form on any strip of the card. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug in the specimen; it only indicates the level of tested drug in the specimen is less than cut-off level.

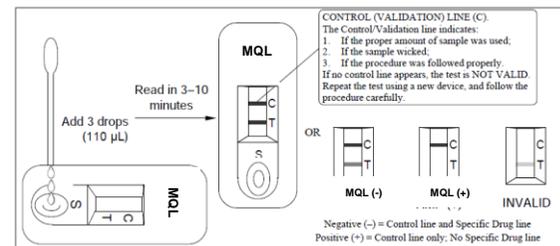
Positive:

One colored band appears in control line zone. No coloured band is found in test line zone. This is an indication the level of tested drug(s) in the specimen is above the cut- off level.

Invalid:

If there is no colored band in control line zone of any strip, the test result is invalid. Retest the sample with a new device.

Note: A borderline(+/-) in test line zone should be considered negative result.



LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or processed urine error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer "SPECIFICITY" section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED RESULTS

The AccuTest™ MQL test strip is a qualitative assay. It identifies the drug in human urine at its cut-off concentration or higher. The concentration of the drug cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the AccuTest™ MQL test strip 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. Sensitivity

The cut-off concentrations (sensitivity level) of AccuTest™ MQL test strip is determined to be:

MQL 300 ng/ml.

C. Precision

The precision of the AccuTest™ MQL test strip was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 50% above and 50% below cut-off specimens are 100% agreed by three observers:

Tested Drug	Concentration (ng/ml)	Number Tested	Corrected Result	% Corrected Result
MQL	300	40	40	100

D. Specificity

The specificity for adding various drugs, drug metabolites tested the AccuTest™ MQL test strip, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.