

6 Drug Screen Test

INTENDED USE

The Multi-Drug Test is an immunochromatographic assay for rapid, qualitative detection of drugs and their principal metabolites in urine at specified cut-off concentrations.

Note: The test provides only preliminary data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). 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

The Multi-drug Test is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. The method employs unique mixture of monoclonal and polyclonal antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. Opiates are among a class of heavily abused prescription drugs.

REAGENTS AND MATERIALS PROVIDED

1. Test Device in sealed foil pouch.
2. Specimen collection containers.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic and professional use only.
2. Do not use the test device beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices.
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.

STORAGE AND STABILITY

Store test kit below 28°C; do not freeze. Refer to the expiration date for stability.

TEST PROCEDURE

1. Bring a urine sample and a foil test pouch to room temperature (15°-28°C).
2. Do not break the seal of the pouch until ready to begin testing.
3. Remove a Test Device from the foil pouch.
4. Remove the protective cap and place the revealed strips into the urine sample until it is observed that a pink colour begins to migrate across each result window (approximately 30 seconds). Do not allow the urine level to touch the plastic device.
5. Replace the cap to cover the sample strips. Then place the test card on a flat surface.
6. Read the results within 3 to 8 minutes. Do not read results after 8 minutes.

Note: The result must be interpreted between 3 and 8 minutes. Waiting more than 8 minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

Negative: Two colour bands appear adjacent to each other in the result window. This indicates that no drug above the cut-off level has been detected. The test line intensity may be any shade of pink and may be weaker or stronger than that of the control line. All tests are independent of each other.

Positive: Only one coloured line appears in the control region (C). No color line appears in the appropriate test region (T).

Invalid: If no control line appears in the result window, the test should be considered void. Another test should be run to re-evaluate the specimen.

Note: There is no meaning attributed to line color intensity or width. See Test Cassette For More Details.

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
2. Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens can cause erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

KITS TEST FOR THE FOLLOWING 5 COMMONLY USED DRUG TYPES:

COC - The Cocaine Test is a one-step immunoassay for the qualitative detection of benzoylecgonine (cocaine metabolite) at a cut-off of 300ng/ml. Derived from leaves of coca plant, cocaine is a potent central nervous system stimulant and a local anesthetic.

MAMP - The Methamphetamine Test is a one-step immunoassay for the qualitative detection of methamphetamine at a cut-off of 1,000ng/ml. Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Over the counter medicine like ephedrine, cough suryp, codeine, diet pills, etc.

MOR (OPI) - The Morphine Test is a one-step immunoassay for qualitative detection of morphine and their metabolites at a cut-off of 300ng/ml. The opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide both might be found in the urine of a person who has taken only heroin. The body also changes codeine to morphine. Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the urine indicates heroin, morphine and/or codeine use.

THC - The THC Test is a lateral flow, one-step immunoassay for the qualitative detection of 11-nor-tetrahydrocannabinol-9-THC-carboxylic acid in human urine at a cut-off of 50ng/ml. Daggá/marijuana.

MDMA - The MDMA Test is a one step chromatographic immunoassay for the qualitative detection of MDMA and its metabolites in human urine. The test cut off is 500ng/ml. Ecstasy (aka MDMA, XTC) is a club drug, is a synthetic, mind-altering drug with hallucinogenic and amphetamine-like properties. MDMA, 3, 4-methylenedioxy-N-methamphetamine, was developed and patented in the early 1900's as a chemical precursor in the synthesis of pharmaceuticals. Chemically, MDMA is similar to the stimulant amphetamine and the hallucinogen mescaline.

BZO - The BZO test is for Benzodiazepines of which the so-called "date drug" falls under. Benzodiazepines are the most widely used anxiolytic drugs. They are used extensively as anti-anxiety agents, hypnotics, muscle relaxants and anti-convulsants. They are taken orally or sometimes by injection. Benzodiazepines are metabolized in the liver, some of their metabolites also exhibit pharmacological activities. Both Benzodiazepines and their metabolites are excreted in the urine.