INSTRUCTIONS FOR USE

DOA 6 PANEL URINE TEST
(AMP / COC / MET / MOR/OPi / THC / XTC)

Morphine (MOR, MOR300)
Morphine is a popular marketed drug for treatment of moderate to severe pain. It is also a common metabolite of opiates [morphine, codeine (methyl-morphine), and heroin (a semi-synthetic derivative of morphine)]. Opiates are administered by smoking, intravenous injection, intramuscular injection or oral ingestion. Adverse or toxic effects of opiates usage include pupillary constriction, constipation, urinary retention, nausea, vomiting, hypothermia, drowsiness, dizziness, apathy, confusion, respiratory depression, hypotension, cold and clammy skin, coma and pulmonary edema. Death may occur following an overdose.

The duration of effect of morphine is 3-6 hours. Morphine is metabolized extensively, with only 2-12% excreted as unchanged morphine in the urine. Heroin is rapidly metabolized to morphine in the liver; the principal urinary excretion of heroin is similar to that of morphine. Codeine is also extensively metabolized, with 10-15% of the dose demethylated to form morphine and norcodeine. It has been reported that unchanged morphine may remain detectable in urine for up to one week, which makes morphine a useful marker of opiates abuse.

Marijuana (THC)
Tetrahydrocannabinols (THC, ∆9-THC, ∆1-THC) are the most active principal constituents and major metabolites of cannabinoids such as marijuana and hashish. Cannabinoids have been used as central nervous system depressants. Overdose and extended usage of cannabinoids may lead to substance abuse, which may cause severe and/or permanent damage to the human nervous system. The detection of THC in human urine is widely used to evaluate the abuse of cannabinoids.

MDMA (XTC)
MDMA is an abbreviation of the chemical methylenedioxymethamphetamine. It is also known by street names such as Ectasy, X-TC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamboks. MDMA is a stimulant with hallucinogenic tendencies. It is described as an empathogen since it releases mood-altering chemicals such as L-Dopa in the brain and may generate feelings of love and friendliness. MDMA is a class A drug, in the same category as heroin and cocaine. ADverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or heat stroke.

MDMA belongs to a family of manmade drugs; its relatives are MDA (methylendioxyamphetamine), the parent drug of MDMA, and MDEA (methylendioxyethamphetamine), also known as EVE. Both exhibit amphetamine-like effects. MDMA is administered either by oral ingestion or intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. The clinical dose is 50-100 mg; the threshold toxic dose is 500 mg. The effects of MDMA begin 30 minutes after use. They peak in an hour and last for 2-3 hours. Sixty five percent (65%) of MDMA is excreted unchanged in urine, and MDMA is detectable in urine for up to 3 days after use.

PRINCIPLE OF THE PROCEDURE

The Multi-Drug of Abuse Urine Test consists of any combination of between one (1) to twelve (12) individual test strip(s) for the drug(s) being tested. The assay is a one-step lateral flow chromatographic immunoassay based on the principle of competition for limited antibody binding sites between a drug or drug metabolite(s) in the sample and a drug-protein conjugate immobilized on a porous membrane support.

During testing, urine migrates to the test area of the membrane by capillary action, mobilizing the colored antibody conjugates. The antibody conjugates then move along the membrane to the test area. In the absence of drug or if the drug concentration is below the cutoff limit in the sample, the colored conjugates attach to the respective drug antigen immobilized in the test line region, forming a colored band (T line). If drug is present in the sample, the drug or drug metabolite(s) compete for the limited antibody binding sites. If the drug concentration is at or above the cutoff limit, the drug will saturate all the binding sites of the antibody, preventing the attachment of the colored conjugates to the antigen in the test line area of the membrane. Therefore no colored line will form. The control line (C line) serves as an internal quality control of the system. It should always appear as a colored band regardless of the presence of the drug.

REAGENTS AND MATERIALS SUPPLIED

• 25 Test devices, each sealed in a foil pouch with a desiccant and a dropper pipette (20 devices for 7-12 test panel)
• 1 Package insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen collection container
• Time
• External positive and negative controls
PRECAUTIONS
- The instructions must be followed exactly to obtain accurate results.
- Do not open the sealed pouch until ready to conduct the assay.
- Do not use expired devices.
- Dispose of all specimens and used assay materials as potentially biohazardous.

STORAGE AND STABILITY
- Store the product at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.
- Do not freeze and/or expose this kit to temperatures over 30°C.

SPECIMEN COLLECTION
- Each urine specimen must be collected in a clean container. Do not combine specimens.
- Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or below for long term storage.

ASSAY PROCEDURE
Important: Refrigerated specimens and other test materials, including devices, must be equilibrated to room temperature before testing.

1. Bring the pouch to room temperature before opening.
2. Remove the device from the sealed pouch and label it with specimen identification.
3. Remove the cap from the device and add the urine sample to the device using either the "Dip Method (I)" or the "Dropper Method (II)" as described below:

I. DIP METHOD
   a) Dip the sample well end of the device into the specimen.
   b) Start the timer.
   c) Remove the device from the specimen after 10 seconds.
   d) Replace the cap back onto the device. Set the device on a clean and level surface.
   e) Read results between 4-7 minutes.

   Note: Immerse the sample well completely in the urine sample. Make sure the tips of the arrows in the device window are above the surface of the urine sample.

II. DROPPER METHOD (Recommended for small sample volumes)
   a) Set the device on a clean and level surface.
   b) Use the provided dropper to pick up the urine sample and fill the dropper to the mark.
   c) Transfer all of the urine sample in the dropper to the sample well.
   d) For a double-sided panel (7-12 drugs), turn the device over and add a full dropper of urine (up to the mark on the dropper) to the sample well on side 2.
   e) Start the timer.
   f) Read results between 4-7 minutes.

INTERPRETATION OF RESULTS
Each test strip is labeled with an abbreviation for its target drug. For example, "COC" indicates a cocaine test. A complete list of abbreviations can be found in the Intended Use section on Page 1.

IMPORTANT:
- Read each test independently.
- Do not compare the color intensity of one test to another.
- Do not compare the color intensity of the T line to the C line.
- Do not interpret results after 7 minutes.

PRELIMINARY POSITIVE:
If the C line appears and there is no T line, the result is a preliminary positive for that drug. More than one test may be preliminary positive.

Note: Preliminary positive results should be confirmed with a more specific method. GC/MS or HPLC are the preferred confirmatory methods.

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Note: Even a very faint T line is negative.

NEGATIVE:
If both the C and T lines appear for a test, the result is negative for that drug. If both the C and T lines appear for all tests, the urine specimen is negative for all the drugs tested.

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Invalid:
If no C line develops within 4 minutes on any test strip, the result is invalid. In this case, do not report test results. Repeat the assay with a new device. If the result is still invalid, stop using the device and contact the manufacturer.

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QUALITY CONTROL

Built-in Control Features:
Each test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If a C line does not form, the result is invalid. Review the procedure and repeat with a new device.

External Quality Control:
Users should follow local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

LIMITATIONS
1. This kit is for professional in vitro diagnostic use only.
2. This device provides only preliminary qualitative analytical test results. A more specific alternate method must be used to obtain a confirmed analytical result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results. If adulteration is suspected, collect a fresh specimen and repeat the procedure with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results.

EXPECTED VALUES
This device is capable of detecting specific drugs and/or drug metabolites in human urine at or above the cutoff concentrations in the Intended Use section on page 1.

PERFORMANCE CHARACTERISTICS

Accuracy
A comparison study was performed at two physician’s office laboratories (POL) and a reference laboratory. Samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested at each site with the Multi-Drug of Abuse Urine Test and the results were compared to GC/MS or HPLC/MS results. The test results are grouped into drug free, below 75% cutoff (negative), above 125% cutoff (positive), between 75% cutoff and cutoff, between cutoff and 125% cutoff according to the analyte concentrations from GC/MS for all analytes except BUP and TCA, which were tested with HPLC/MS. Overall, this test exhibited more than 90% agreement with the selected analytical method for each analyte. The test results are tabulated below.
Drug and spiked urine pools were tested with the Multi-Drug of Abuse Urine Test at various pH levels and specific gravities. pH ranges from pH 5 to pH 9 and specific gravity ranges from 1.002 – 1.035 g/mL did not affect the expected results in the study. There is a possibility that other substances and/or factors not listed above (e.g., technical or procedural errors) may interfere with the test and cause false results.

To determine the interference of structurally unrelated substances, various substances were tested in both drug-free urine pools and urine pools spiked with the cutoff level of each analyte. The results indicate 100% precision for replicates within each lot and no run on five consecutive days, five times per day, for a total of 25 assays for each MOR300, OXY, OXY300, THC and XTC tests, the devices were run on three production lots with four levels of samples: Drug-free, 75% cutoff, 125% cutoff and 150% cutoff to 25% cutoff.

The common substances listed in this table were found not to interfere with test results at a concentration of 100 µg/mL.

### References