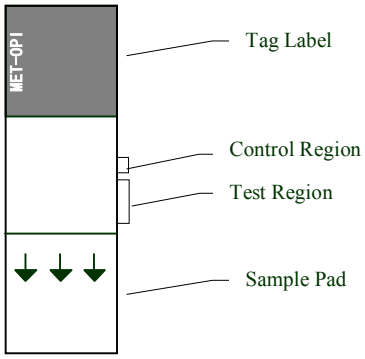
Multi-In-One 2 Panel Test (Cassette) (RAP-4336)
Methamphetamine (MET) /Opiate (OPI)

As of 16 July 2004 **RUO in the USA**

INTENDED USE

The LiveSure™ Multi-In-One Drugs of Abuse 2 Panel Test is a qualitative lateral flow immunochromatographic urinary assay for the rapid detection of drugs of abuse in human urine at cut-off levels specified by SAMHSA in a convenient one step multiple test strip format. Two test strips included in the LiveSure™ Multi-In-One Drug of Abuse 2 Panel Test are Methamphetamine(MET) /Opiate(OPI). This test is designed to obtain a visual, qualitative result and intended for professional use only. It is not intended for quantitative results, or for Over The Counter (OTC) sale to lay persons. The test provides only preliminary analytical data. A more specific alternative method must be used in order to obtain a confirmed analytical result. Substance Abuse and Mental Health Services Administration (SAMHSA) have established gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method. Clinical considerations and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.



SUMMARY AND EXPLANATION OF TEST

The LiveSure™ Multi-In-One Drugs of Abuse 2 Panel Test is a convenient holder, which permits 2 individual determinations in one dipstick using LiveSure™'s drugs of abuse test strips. It is the easy, fast and visually read competitive binding immunoassay methods for screening without the need for instrumentation to arrive at a determination. There is no inter-communication between strips and each test strip functions completely independently. Each individual test employs unique specific antibodies to selectively identify the individual drug of abuse in test sample.

PRINCIPLE OF THE PROCEDURE

The LiveSure™ Multi-In-One Drugs of Abuse 2 Panel Test contains sample reaction units, colloidal gold conjugate color units pre-labeled with specific antibodies, and chromatographic membrane units pre-coated with drug conjugates in the test region. When the free drug is absent or less than the detection cut-off level in the urine, the colored antibody-colloidal gold conjugate is free to bind to the immobilized drug conjugate pre-coated on the chromatographic membrane test region. Pink band(s) will form in the test region indicating the negative result. When the drug is present in the urine at or exceeding the detection cut-off level, it will bind to the limited epitopes on the colored antibody-colloidal gold conjugate, which completely competes with drug conjugate in the test region. As a result, it appears as the absence of the color band(s) in the test region indicating the positive result. A control band in each strip is designed to indicate that the test has been performed properly. It should always show up in the control region regardless of the drug and metabolite presence, demonstrating that the assay system is functioning correctly.

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REAGENTS AND MATERIALS SUPPLIED

1. Test Device, containing one Multi-In-One strips, Marijuana-Cocaine.
2. Test Instruction

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container.
2. Timer or Clock

PRECAUTIONS

1. For in vitro diagnostic use. In the United States, this kit is intended for Research Use Only.
2. Avoid cross contamination of urine samples by using a new specimen collection container for each urine sample.
3. Urine specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and dispose of all tested device in an approved biohazard container.
4. Do not use a test device beyond the expiration date imprinted on the outside of the foil pouch.

STORAGE AND STABILITY

The test devices supplied can be stored at room temperature or refrigerated (2-28°C) and will be stable until the expiration date. Do Not Freeze.

SAMPLE COLLECTION AND PREPARATION

The fresh urine samples should be collected in a clean dry container such that testing may be performed during the same day. Urine specimen may be refrigerated at 2-8°C for 48 hours, or frozen at -20°C for longer period of time to assaying. Specimens that have been refrigerated or frozen must be equilibrated to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

ASSAY PROCEDURE

1. Do not open foil pouch until ready to begin testing. Refrigerated test device should be allowed to come to room temperature (15-28°C) before opening the pouch.
2. Remove the test device from the sealed foil pouch by tearing along the notch.
3. Immerse the strips in urine with the arrow end pointing towards the urine. Do not introduce urine above the maximum level line as indicated by the arrows.
4. Read and record the result at 5 to 8 minutes.

IMPORTANT: In order to prevent an incorrect reading, do not read the test results after more than 8 minutes. If the test is read after 8 minutes, the intensity of the colored lines may change or a new line may appear.

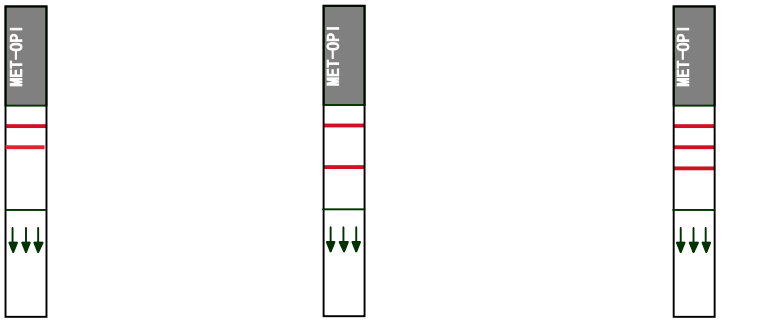
INTERPRETATION OF RESULTS

Negative: Colored lines appear in both Control and Test Regions. Negative results indicate that the free drug substances are absent or less than the detection level of the test.

Positive: Only colored band appears in the control region with no apparent band in the test region. Positive results indicates that the free drug substance are present in the urine at or exceeding the detection level of the test

Invalid: No colored line appear in control region, even there are colored lines appear in the test region. Invalid result may be due to improper assay procedures or damage of the device. The assay is inconclusive and the specimen should be retested using a new test device.
Note: The intensity of colored line may be varied between test and control lines.

TEST DEVICE



POSITIVE For MET

POSITIVE For OPI

NEGATIVE For All Drugs

QUALITY CONTROL
Good laboratory practice recommends the use of control materials to ensure proper test device performance and reliability. When testing the quality control standards, use the same assay procedure as with a urine sample. The SAMHSA recommended guidelines for drug of abuse screening test device indicate that controls should contain the drug of abuse substance at levels at least 25% above the SAMHSA cut-off values.

AFTER TESTING
Urine specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and dispose of all tested device in an approved biohazard container. The residual urine should be disposed of in a medically approve manner after the completion of all testing including the confirmatory assay.

PERFORMANCE CHARACTERISTICS
SENSITIVITY
The LiveSure™ Multi-In-One Drugs of Abuse 2 Panel Test has been designed for the detection of drugs of abuse and their metabolites in urine at the following detection sensitivity levels:

Methamphetamine(MET)	1000 ng/ml
Opiate(OPI)	2000 ng/m

PRECISION
The results of within-lot reproducibility analytical studies clearly showed excellent repeatability for all 3 batches of positive and negative urine samples, using one lot of the LiveSure™ Multi-In-One Drugs of Abuse 2 Panel Test. The results of lot-to-lot reproducibility studies clearly demonstrate that there is no appreciable inter-lot variation when testing both positive and negative spiked samples across three (3) different lots of LiveSure™ Multi-In-One Drugs of Abuse 2 Panel Test.

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SPECIFICITY STUDY

The specificity of devices was tested by the compounds related or not associated with drugs of abuse prepared in the drug-free normal human urine. The following compounds produced positive results in the test device at or greater than the concentrations listed below:

Methamphetamine	(+)-Methamphetamine	1,000ng/ml
	(±) 3,4-Methylenedioxymethamphetamine	2,500ng/ml
	Procaine	10,000ng/ml
	(-)-Methamphetamine	25,000ng/ml
	D-(+)-Amphetamine	50,000ng/ml
	Chloroquine	50,000ng/ml
	(±)-Ephedrine	50,000ng/ml
	β-Phenylethylamine	50,000ng/ml
	Ranitidine	50,000ng/ml
Morphine(OPI)	Morphine	2000ng/ml
	Codeine	2000ng/ml
	Ethyl morphine	2000ng/ml

The following compounds were found not to have any impact on the negative results when tested at concentrations up to 100 µg/ml.

Acetaminophen	Furosemide
Acetone	Glucose
Albumin	Guaiacol Glyceryl Ether
Amikacin	Hemoglobin
Amitriptyline	Histamine
Ampicillin	Imipramine
Arterenol	Indomathacin
Aspartame	(+/-)-Isoproterenol
Aspirin (Acetylsalicylic Acid)	Methyphenidate
Benzoic Acid	(+/-)-Norephedrine
Bilrubin	Oxalic Acid
Caffeine	Pendimetrazine
Chloroquine	Penicillin-G
(+)-Chlorpheniramine	Propanol
(+/-)-Chlorpheniramine	Phentermine
Cimetidine	Quinine
Deoxyephedrine	Quinidine
Dexbrompheniramine	Raboflavin
Dextromethorphan	Ranitidine
Diphenylhydantoin	Sodium Chloride
Doxylamine	Sulindac
Erythromycin	Tyramine
Ethanol	Vitamin C

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ASSAY COMPARISONS & EQUIVALENCY

Each of the test strips eligible for inclusion into the holder has been subjected to strict testing prior to FDA clearance of the individual test strips. In independent clinical trials each analyte strip was subjected to evaluation involving a comparison between the strip and GC/MS methodology. Accuracy and equivalency comparison study of LiveSure™ Multi-In-One Drugs of Abuse 2 Panel Test was tested in individual urine samples in-house. All positive samples were confirmed by GC/MS. The results of that testing have been tabulated below for all five analytes.

METHAMPHETAMINE

LiveSure™	EMIT II (+)	EMIT II (-)	Row Totals
(+)	**205**	**3**	**208**
(-)	**1**	**211**	**212**
Col. Totals	**206**	**214**	**420**

When compared to Emit® II Assay, the percent agreement with LiveSure™ Methamphetamine Screen Test Strip positive samples and 205/206 or 99.5%. Negative samples recovered at 211/214 or 98.6%, while the overall relative accuracy obtained was 416/420 or 99.1%.

LiveSure™	GC/MS(+)	GC/MS(-)	Row Totals
(+)	**133**	**5**	**138**
(-)	**0**	**162**	**162**
Col. Totals	**133**	**167**	**300**

When compared to the GC/MS data, the relative sensitivity or percent agreement with LiveSure™ Methamphetamine Screen Test Strip positive samples with the external clinical study was 133/133 or 100%. Negative samples recovered a relative specificity of agreement of 162/167 or 97.0%. Finally, the overall relative accuracy obtained was 295/300 or 98.3%.

OPIATES

LiveSure™	EMIT II (+)	EMIT II (-)	Row Totals
(+)	146	0	**146**
(-)	6	331	**337**
Col. Totals	**152**	**331**	**483**

When compared to Emit® II Assay, the percent agreement with LiveSure™ Morphine Screen Test strip positive samples and 146/152 or 96.1%. Negative samples recovered at 331/331 or 100%, while the overall relative accuracy obtained was 477/483 or 98.8%.

LiveSure™	GC/MS (+)	GC/MS (-)	Row Totals
(+)	100	0	**100**
(-)	0	281	**281**
Col. Totals	**100**	**281**	**381**

When compared to the GC/MS data, the relative sensitivity or percent agreement with LiveSure™ Morphine Screen Test **Strip** positive samples with the external clinical study was 100/100 or 100%. Negative samples recovered a relative specificity of agreement of

LIMITATIONS OF PROCEDURE

1. This diagnostic test is designed to be used for the forensic in vitro detection of drug of abuse in urine only. This kit is intended for Research Use Only in the United States.
2. This diagnostic test provides a qualitative screening for drugs of abuse in urine only, and is not to be used for quantitative determination of drugs concentration in urine. A positive result with this test indicates only the presence of a drug or metabolite, does not indicate intoxication, and should be confirmed by GC/MS.
3. There is a possibility of false positive results due to the assay procedural errors or other substances present in the urine as interfering factors, some of which are listed.
4. See the specificity lists of substances that will produce positive results at high levels, versus those substances that do not interfere with test performance.
5. Adulterants, such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method. If an adulteration is suspected, another urine specimen should be used.

BIBLIOGRAPHY

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