Multi-Drug 2 Panel Test (Dip Card) (RAP-4149)
Methamphetamine (MET) / Marijuana (THC)

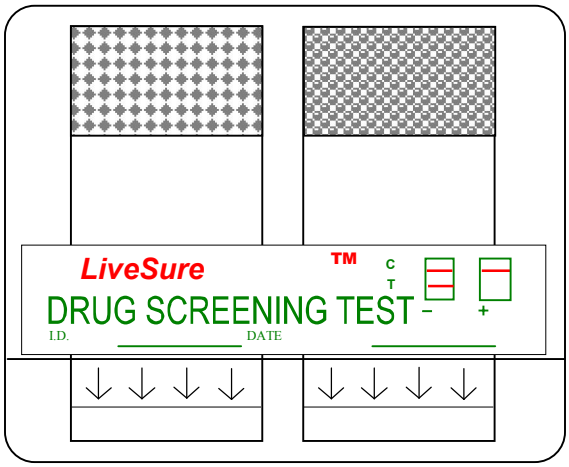
As of 16 July 2004 **RUO in the USA**

INTENDED USE

The LiveSure™ Multi-Drug 2 Panel Test is a diagnostic qualitative lateral flow immuno-chromatographic urinary assay for the rapid detection of drug of abuse in human urine at SAMSA cut-off levels specified by SAMHSA in a convenient one step multiple test strip format. Test strip included in the LiveSure™ Multi-Drug 2 Panel Test are Methamphetamine and Marijuana (THC). 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. National Institute on Drug Abuse (NIDA) and SAMSA has 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 LiveSureTM Multi-Drug 2 Panel Test is a convenient holder which permits 2 individual determinations in one dip using LiveSureTM ‘s drugs of abuse test strips easy, fast and visually read competitive binding immunoassay methods for screening without the need for instrumentation to arrive at a determination. There is no intercommunication 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 samples.



PRINCIPLE OF THE PROCEDURE

The LiveSure™ Multi-Drug 2 Panel Test contains sample reaction unit, colloidal gold conjugate color unit pre-labeled with specific antibody, and a chromatographic membrane unit pre-coated with drug conjugate 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. A pink band will form in the test region indicating a 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 an absence of the color band in the test region indicating a positive result. A control band 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. Summarizing, negative urine will produce two colored bands, one in both the control region and test region, while positive urine produces only one band in the control region.

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REAGENTS AND MATERIALS SUPPLIED

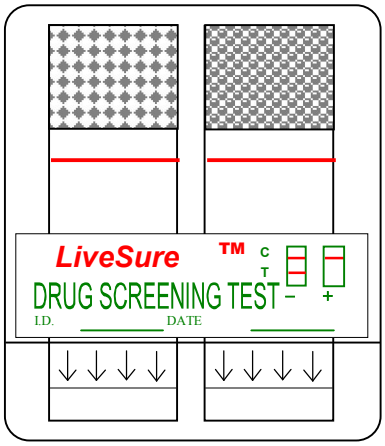
1.Test Device, containing sample reaction unit, colloidal gold conjugate color unit, and a chromatographic membrane unit.
2.Test Instruction

MATERIALS REQUIRED BUT NOT PROVIDED

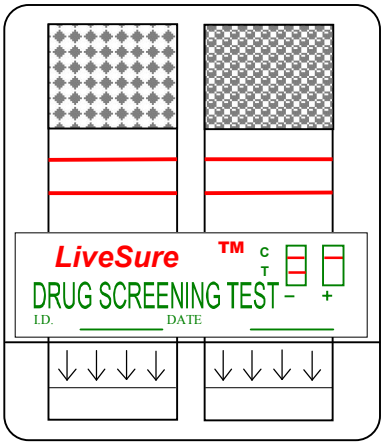
1.Specimen collection container.
2.Timer or Clock

PRECAUTIONS

1 For in vitro 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.



POSITIVE (+)



NEGATIVE (-)

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. Remove the protective cap and immerse the strips in urine with the arrow end pointing towards the urine sample for at least 10 seconds. Do not introduce urine above the maximum level line as indicated by the arrows.
4. Replace the protective cap over the exposed strips and lay the test device on a clean flat surface. Read the test result at 5 minutes.

IMPORTANT: In order to prevent an incorrect reading, do not read the test results after more than 10 minutes. If the test is read after 10 minutes, the intensity of the colored lines may change or a new line may appear. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

Negative: Two colored bands appear. One in the control region and one in the test. A negative result indicates that the free drug is absent or less than the detection level of the test.

Positive: Only one colored band appears in the control region with no apparent band in the test region. A positive result indicates that the free drug is present in the urine at or exceeding the detection level of the test.

Invalid: No band appears in control region, or a band appears in the test region only. An invalid result may be due to improper assay procedures or damage of the device. The assay is inconclusive and the specimen should be repeated using a new test device. **Note:** The test band intensity may be weaker or stronger than that of the control band.

TEST DEVICE

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 NIDA recommended guidelines for drug of abuse screening test device indicate that controls should contain the drug of abuse analyte at levels at least 25% above the NIDA 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-Drug 2 Panel Test has been designed for the detection of drugs of abuse and their metabolites in urine at the detection sensitivity of levels as suggested for immunoassay methods by NIDA/SAMHSA.

Methamphetamine	**1,000** ng/ml
Marijuana(THC)	**50** ng/ml

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-Drug 2 Panel Test.

The results of these tests 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-Drug 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
Marijuana(THC)	11-nor-Δ9-THC-9-COOH	50 ng/ml
	11-nor-Δ8-THC-9-COOH	250 ng/ml
	Cannabinol	50,000 ng/ml
	Δ8-THC	25,000 ng/ml
	Δ9-THC	15,000 ng/ml
	11-hydroxy-Δ9-THC	10,000 ng/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

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 indivodual test strips. In independent clinical trials each analyte strip was subjected to evaluation involving a comparison between the strip, A predicate device (EMIT II) and GC/MS. Accuracy and equivalency comparisons of each LiveSure™ Multi-Drug 2 Panel Test was first tested in individual urine samples in-house and subsequently in a clinical trial of individual urines submitted to a NIDA certified laboratory. All positive samples by either screening method 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 141/144 or 97.9%. Negative samples recovered at 220/220 or 100%, while the overall relative accuracy obtained was 361/364 or 99.2%.

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 94/94 or 100%. Negative samples recovered a relative specificity of agreement of 161/163 or 98.8%. Finally, the overall relative accuracy obtained was 255/257 or 99.2%.

Marijuana (THC)

LiveSure™	**EMIT II (+)**	**EMIT II (-)**	**Row Totals**
(+)	160	0	**160**
(-)	8	341	**349**
Col. Totals	**168**	**341**	**509**

When compared to Emit® II Assay, the percent agreement with LiveSure™ THC Screen Test Strip positive samples and 160/148 or 95.2%. Negative samples recovered at 341/341 or 100%, while the overall relative accuracy obtained was 501/509 or 98.4%.

LiveSure™	**GC/MS (+)**	**GC/MS (-)**	**Row Totals**
(+)	107	5	**112**
(-)	0	283	**283**
Col. Totals	**107**	**288**	**395**

When compared to the GC/MS data, the relative sensitivity or percent agreement with LiveSure™ THC Screen Test Strip positive samples with the external clinical study was 107/107 or 100%. Negative samples recovered a relative specificity of agreement of 283/288 or 98.3%. Finally, the overall relative accuracy obtained was 390/395 or 98.7%.

LIMITATIONS OF PROCEDURE

1. This diagnostic test is designed to be used for the medical or forensic in vitro detection of drug of abuse in urine only.
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.

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