Multi-Drug 5 Panel Test (Dip Card) (RAP-3538)
Amphetamine (AMP) / Methamphetamine (MET) / Cocaine COC) / Marijuana (THC) / Opiate (OPI)

As of 27 Apr. 2007 **RUO in the USA**

INTENDED USE

Multi-Drug 5 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 Multi-Drug 5 Panel Test are Amphetamine, Cocaine, Marijuana (THC), Methamphetamine and Morphine (Opiates). 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.

The test provides only preliminary analytical data. A more specific alternative method must be used in order to obtain a confirmed analytical result. 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 Multi-Drug 5 Panel Test is a convenient holder allowing 5 individual determinations in one dip using Drugs of Abuse test strips. The test employs easy, fast and visually read, competitive binding immunoassay methods to arrive at a determination without the need for instrumentation. Individual strips function independently and employ unique, specific antibodies to selectively identify the individual drugs of abuse or their metabolites in human urine. There is no intercommunication between test strips.

PRINCIPLE OF THE PROCEDURE

Components of the individual Multi-Drug 5 Panel Test strips include a sample reaction unit, a pink-colored, antibody-colloidal gold conjugate unite pre-labeled with specific antibody, and a chromatographic membrane pre-coated with drug conjugate. When free drug is absent from urine or at concentrations lower than the urinary detection cut-off level, the pink-colored, antibody-colloidal gold conjugate is free to bind to the immobilized drug conjugate pre-coated on the chromatographic membrane test region. Consequently, a pink-colored band will form in the test region indicating a **negative** result. When the drug is present in urine at concentrations at or exceeding the detection cut-off level, it will bind to the limited epitomes on the pink-colored, antibody-colloidal gold conjugate, which completely competing with drug conjugate in the test region. In such cases, no band forms 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.

REAGENTS AND MATERIALS SUPPLIED

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

As of 27 Apr. 2007 **RUO in the USA**

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen (urine sample) 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 sample collection container and pipette 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 used test devices 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 assaying at a later date. 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 the pouch is opened.
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.

As of 27 Apr. 2007 **RUO in the USA**

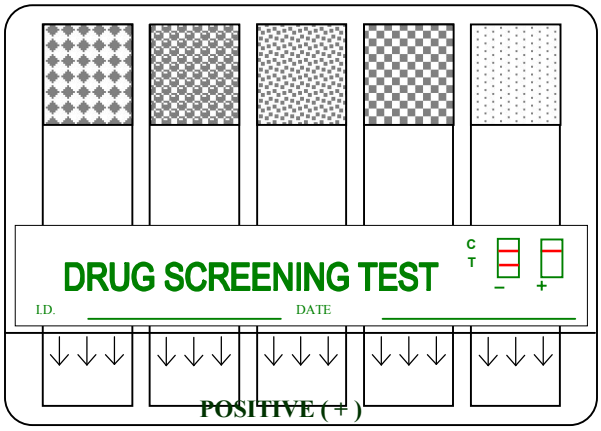
INTERPRETATION OF RESULTS

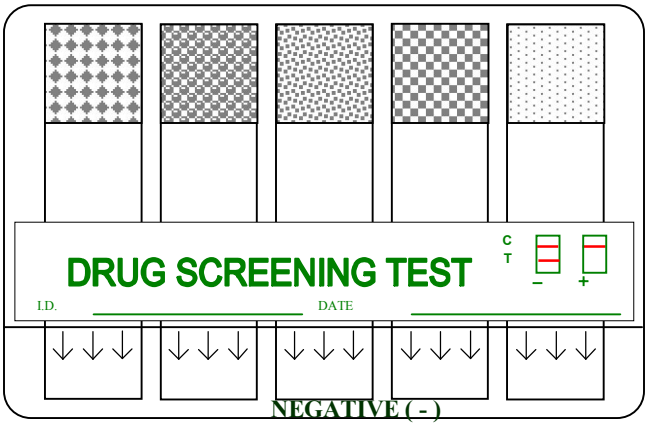
Negative: Two pink-colored bands appear, one in the control region and one in the test region. A negative result indicates that the free drug is absent or at concentrations lower than the detection cut-off level of the test.

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

Invalid: No band appears in control region, or a pink-colored 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 re-tested 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 requires 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 devices indicate that controls should contain the drug of abuse analyte at levels at least 25% above 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. Residual urine should be disposed of in a medically approve manner after the completion of all testing including the confirmatory assay.

As of 27 Apr. 2007 **RUO in the USA**

PERFORMANCE CHARACTERISTICS

SENSITIVITY

DRG Multi-Drug 5 Panel Test has been designed for the detection of the following drugs of abuse and their metabolites in urine at the detection sensitivity of levels as suggested for immunoassay methods by NIDA/SAMHSA.

Amphetamine	**1,000**ng/ml
Methamphetamine	**1,000** ng/ml
Cocaine	**300**ng/ml
Marijuana(THC)	**50** ng/ml
Opiate	**2,000** ng/ml

PRECISION

The results of within-lot reproducibility analytical studies clearly showed excellent repeatability for all positive and negative urine samples, using one lot of the DRG Multi-Drug 5 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 Multi-Drug 5 Panel Test.

SPECIFICITY STUDY

The specificity of devices was tested by the compounds related or not associated with the targeted 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:

Opiates	Morphine	2,000 ng/ml
	Codeine	2,000 ng/ml
	Ethyl morphine	2,000 ng/ml
Cocaine	Benzoylecgonine	300 ng/ml
	Cocaine	300 ng/ml
Amphetamine	D-(+)-Amphetamine	1,000 ng/ml
	(±) 3,4-Methylenedioxyamphetamine	5,000 ng/ml
	L-Amphetamine	10,000 ng/ml
Marijuana(THC)	11-nor-Δ9-THC-9-COOH	50 ng/ml
	11-nor-Δ8-THC-9-COOH	250 ng/ml
	Cannabinol	0,000 ng/ml
	Δ8-THC	25,000 ng/ml
	Δ9-THC	15,000 ng/ml
	11-hydroxy-Δ9-THC	10,000 ng/ml

As of 27 Apr. 2007 **RUO in the USA**

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

The following compounds were found not to have any impact on the negative results when tested at concentrations up to 100 µg/ml (100,000 ng/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

Test strips eligible for inclusion into the holder were subjected to strict testing prior to FDA clearance. In independent clinical trials, each analyte test 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 Multi-Drug

As of 27 Apr. 2007 **RUO in the USA**

5 Panel Test was first tested in individual urine samples in-house and subsequently in a clinical trial of individual urines submitted to a SAMHSA certified laboratory. Samples identified as positive by either screening method were confirmed by GC/MS. The results of that testing have been tabulated below for all five analytes.

OPIATES

DRG	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 the 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%.

DRG	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 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 281/281 or 100%. Finally, the overall relative accuracy obtained was 381/381 or 100%.

COCAINE

DRG	EMIT II (+)	EMIT II (-)	Row Totals
(+)	162	0	**162**
(-)	5	322	**327**
Col. Totals	**167**	**322**	**489**

When compared to Emit® II Assay, the percent agreement with the Cocaine Screen Test Strip positive samples was 162/167 or 97.0%. Negative samples recovered at 322/322 or 100%, while the overall relative accuracy obtained was 484/489 or 99.0%.

DRG	GC/MS (+)	GC/MS (-)	Row Totals
(+)	101	4	**105**
(-)	0	272	**272**
Col. Totals	**101**	**276**	**377**

As of 27 Apr. 2007 **RUO in the USA**

When compared to the GC/MS data, the relative sensitivity or percent agreement with the Cocaine Screen Test Strip positive samples with the external clinical study was 101/101 or 100%. Negative samples recovered a relative specificity of agreement of 272/276 or 98.6%. Finally, the overall relative accuracy obtained was 373/377 or 98.9%.

AMPHETAMINE

DRG	EMIT II (+)	EMIT II (-)	Row Totals
(+)	141	3	**141**
(-)	3	220	**223**
Col. Totals	**144**	**220**	**364**

When compared to Emit® II Assay, the percent agreement with the Amphetamine 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%.

DRG	GC/MS (+)	GC/MS (-)	Row Totals
(+)	94	2	**96**
(-)	0	161	**161**
Col. Totals	**94**	**163**	**257**

When compared to the GC/MS data, the relative sensitivity or percent agreement with the Amphetamine 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)

DRG	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 the 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%.

DRG	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 the 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%.

METHAMPHETAMINE

DRG	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 the 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%.

DRG	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 DRG 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%.

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. In the United States, this kit is intended for Research Use 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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