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PROFESSIONAL MEDICAL PRODUCTS

TEST MULTIDROGHE ONE STEP CON BICCHIERINO INTEGRATO (URINA)

ONE STEP SCREEN TEST PANEL WITH INTEGRATED CUP (URINE)

Manuale d'uso - User manual

PER USO PROFESSIONALE
FOR PROFESSIONAL USE

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

REF **24546**

Innovacon, Inc.
9975 Summers Ridge Road
San Diego, CA 92121, USA
Made in China (P.R.C.)

EC REP MDSS GmbH
Schiffgraben, 41 - 30175 Hannover, Germany

M-24546-M-Rev.2-07.18

Multi-Drug One Step Screen Test Panel with integrated cup (Urine)
Package insert for testing of any combination of the following drugs:
Amphetamine 500, Cocaine, Marijuana, Methadone, Methamphetamine 500, Methylenedioxymethamphetamine, Morphine 300.
Including Specimen Validity Tests (S.V.T.) for Oxidants/ Pyridinium Chlorochromate (OX/PCC), Specific Gravity (S.G.), pH, Nitrite (NIT), Glutaraldehyde (GLUT) and Creatinine (CRE).
A rapid, one step screen test for the simultaneous, qualitative detection of multiple drugs and metabolites in human urine. For medical and other professional in vitro diagnostic use only.

INTENDED USE & SUMMARY

Urine based screen tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.
The Multi-Drug One Step Screen Test Panel with integrated cup (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of following drugs without the need of instruments.[1]

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP 500)	d-Amphetamine	500
Cocaine (COC)	Benzoylecgonine	300
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Methadone (MTD)	Methadone	300
Methamphetamine (MET 500)	d-Methamphetamine	500
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP 300)	Morphine	300

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.
This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

S.V.T. SUMMARY

Each S.V.T. strip contains chemically treated reagent pads. Three to five minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help assess the integrity of the urine sample.

PRINCIPLE

The Multi-Drug One Step Screen Test Panel with integrated cup (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.
During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.
A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

S.V.T. PRINCIPLE

Adulteration is the tampering of a urine specimen with the intention of altering the test results.
The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/ or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.
One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH and specific gravity and to detect the presence of oxidants/PCC, specific gravity, pH, nitrite, glutaraldehyde and creatinine in urine.
• **Oxidants/PCC** (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant.[2] Normal human urine should not contain oxidants or PCC.

• **Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.
• **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
• **Nitrite** tests for commonly used commercial adulterants such as Klear or Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.[3] Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.
• **Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative screening results by disrupting the enzyme used in some immunoassay tests.[2] Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
• **Creatinine** is a waste product of creatine, an amino acid contained in muscle tissue and found in urine.[1] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to "flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (< 5 mg/dL) is indicative of a specimen not consistent with human urine.

REAGENTS
Each test contains specific drug antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants/PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

PRECAUTIONS
• For medical and other professional in vitro diagnostic use only. Do not use after the expiration date.
• The test panel should remain in the sealed pouch until use.
• All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
• The used test panel should be discarded according to local regulations.

STORAGE AND STABILITY
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test panel is stable through the expiration date printed on the sealed pouch. The test panel must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

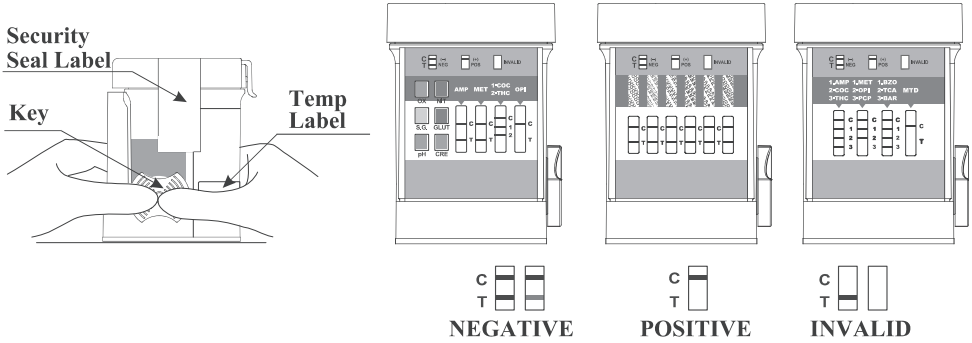
SPECIMEN COLLECTION AND PREPARATION
Urine Assay
The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.
Specimen Storage
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing. When tests include S.V.T., storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing. For best results, test specimens immediately following collection.

MATERIALS
Materials Provided
• Cups with multi-drug panels • Security seal labels • Keys
• SVT/Adulterant color chart (if applicable) • Package insert
Materials Required But Not Provided
• Timer

DIRECTIONS FOR USE

Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. Remove the key by twisting it from the center of the cup cap.
3. Collect specimen in the cup and secure the cap tightly by pressing down on the pull tab until an audible click is heard.
4. Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 33-38°C (91-100°F).
5. Date and initial the security seal label then place it over the cap.
6. Place the cup on a flat surface and push the key into the socket of the cup to initiate the test. Start the timer.
7. Remove the peel off label covering the test results. Read the adulteration strip between 3 and 5 minutes.
8. Compare the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen.
9. Read the drug strip results at 5 minutes. The drug strip results remain stable for up to sixty minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug.

***NOTE:** The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

SVT/ADULTERANT INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strips to the printed color blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Multi-Drug One Step Screen Test Panel with integrated cup (Urine) provides only a preliminary analytical result. A more specific chemical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[4, 5]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.

3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

S.V.T. ADULTERATION LIMITATIONS

1. The adulteration tests included with this product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an “all-inclusive” representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
5. Glutaraldehyde: Is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
6. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the Multi-Drug One Step Screen Test Panel with integrated cup (Urine) and commercially available drug rapid tests. Testing was performed on approximately 300 specimens previously collected from subjects present for drug screen testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

Specimen	AMP 500	COC	THC	MTD	MET 500	MDMA	MOP 300
Positive	*	>99%	>99%	89%	>99%	96%	95%
Negative	*	99%	99%	>99%	80%	>99%	>99%
Total	*	99%	99%	94%	87%	98%	97%

*** NOTE:** Commercial kit unavailable for comparison testing.

% Agreement with GC/MS

Specimen	AMP 500	COC	THC	MTD	MET 500	MDMA	MOP 300
Positive	95%	95%	95%	93%	99%	99%	98%
Negative	>99%	>99%	95%	>99%	>99%	99%	97%
Total	98%	98%	95%	97%	99%	99%	97%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

Drug Conc. (Cut-off range)	AMP 500		COC		THC		MTD		MET 500		MDMA		MOP 300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	90	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	90	0	30	0	30	0
-25% Cut-off	25	5	25	5	27	3	20	10	73	17	20	10	27	3
Cut-off	11	19	19	11	14	16	19	11	48	42	18	12	17	13
+25% Cut-off	5	25	3	27	6	24	7	23	15	75	10	20	10	20
+50% Cut-off	0	30	0	30	0	30	0	30	0	90	0	30	0	30

Analytical Specificity

The following tables lists the concentration of compounds (ng/mL) that are detected positive in urine by the Multi-Drug One Step Screen Test Panel with integrated cup (Urine) at 5 minutes.

AMPHETAMINE 500	
d-Amphetamine	500
d,l-Amphetamine	1 500
3,4-Methylenedioxyamphetamine (MDA)	800
Phentermine	1 500
β-Phenylethylamine	50 000
Tryptamine	50 000
Tyramine	25 000
COCAINE	
Benzoylecgonine	300
Cocaethylene	12 500
Cocaine	780
Ecgonine	32 000
MARIJUANA	
11-nor-Δ^9-THC-9 COOH	50
11-nor-Δ^8-THC-9 COOH	30
Cannabinol	20 000
Δ^8– THC	15 000
Δ^9– THC	15 000

METHADONE	
Methadone	300
Doxylamine	50 000
METHAMPHETAMINE 500	
d-Methamphetamine	500
d,l-Amphetamine	75 000
d-Amphetamine	50 000
Chloroquine	12 500
(1R,2S)-l-Ephedrine	50 000
p-Hydroxymethamphetamine	15 000
Mephentermine	25 000
l-Methamphetamine	4 000
3,4-Methylenedioxymethamphetamine (MDMA)	1 000
l-Phenylephrine	100 000
β-Phenylethylamine	75 000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
d,l-3,4-Methylenedioxy-methamphetamine (MDMA)	500

d,l-3,4-Methylenedioxy-amphetamine (MDA)	3 000
3,4-Methylenedioxyethylampheta-mine (MDEA)	300
MORPHINE 300	
Morphine	300
Codeine	300
Ethylmorphine	6 250
Hydrocodone	50 000
Hydromorphone	3 125
Levorphanol	1 500
6-Acetylmorphine	400
Morphine 3-β-D-glucuronide	1 000
Norcodeine	6 250
Normorphine	100 000
Oxycodone	30 000
Oxymorphone	100 000
Procaine	15 000
Thebaine	6 250

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine 500, Cocaine, Marijuana, Methadone, Methamphetamine 500, Methylenedioxymethamphetamine, Morphine 300 positive urine. The following compounds show no cross-reactivity when tested with the Multi-Drug One Step Screen Test Panel with integrated cup (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol
Acetone
Acetophenetidin
Acetylsalicylic acid
Albumin
alpha-Naphthaleneacetic Acid
Aminopyrine
Amoxapine
Amoxicillin
Ampicillin
Apomorphine
Ascorbic acid
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzydamine
Brompheniramine
Caffeine
Cannabidiol
Chloral Hydrate
Chloramphenicol
Chloroquine
Chlorothiazide
Chlorpromazine
Chlorprothixene
Cholesterol
Cimetidine
Clonidine
Cortisone
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Dicyclomine
Diflunisal
Digoxin
4-Dimethylaminoantipyrine
Diphenhydramine
5,5-Diphenylhydantoin
EMDP
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl alcohol
Ethyl-p-aminobenzoate
Etodolac
Famprofazone
Fenoprofen
Fluoxetine
Furosemide
Gentisic acid
d-Glucose
Guaiacol Glyceryl Ether
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
o-Hydroxyhippuric acid
3-Hydroxytyramine
Ibuprofen
Iproniazid
Isoproterenol
Isoxsuprine
Kanamycin
Ketoprofen
Labetalol
Lidocaine
Lindane
Lithium
Loperamide
l-Thyroxine
Meperidine
Meprobamate
Methaqualone
Methoxyphenamine
Methylphenidate
Metoprolol
N-Acetylprocainamide
Nalidixic acid
Nalorphine
Naproxen
Niacinamide
Nifedipine
Nimesulide
Norethindrone
Noscapine
d,l-Octopamine
Orphenadrine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Pemoline
Penicillin
Pentazocine
Phenelzine
Pheniramine
Phenothiazine
Prednisolone
Prednisone
d,l-Propanolol
Quinacrine
Quinidine
Quinine
R(-) Deprenyl
Riboflavin
Salicylic acid
Serotonin
Seroquel
Sertraline
Sodium Chloride
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrozoline
Theophylline
Thiamine
Thioridazine
Tolbutamide
Trans-2-phenylcyclopropylamine
Trazodone
Triamterene
Trifluoperazine
Trimethoprim
d,l-Tryptophan
d,l-Tyrosine
Uric acid
Verapamil
Zomepirac

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SVT/Adulterant Color Chart

Abnormal	Abnormal
Normal	Normal

OX PCC	Oxidants/Pyridinium chlorochromate
S.G.	Specific gravity
pH	pH

NIT	Nitrite
GLUT	Glutaraldehyde
GLUT	Creatinine

Index of Symbols

	Keep away from sunlight	CE	Product complies with European Directive no. 98/79/EC on In Vitro diagnostic devices		Expiration date (see box / package)
	Keep in a cool, dry place	IVD	For in Vitro diagnostic use only	REF	Product code
	Please read instructions carefully		Read instructions carefully	LOT	Lot number (see box / package)
	Contains sufficient for "n" tests	 2°C 30°C	Store between 2 and 30°C		Manufacturer
	Disposable device, do not re-use	EC REP	Authorized representative in the European community		