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TEST MULTIDROGHE ONE STEP (URINA)
ONE STEP SCREEN TEST PANEL (URINE)
ESSAI MULTI-DROGUE ONE STEP (URINE)
MULTI-DROGEN-TEST ONE STEP (URIN)
PRUEBA DE MULTIDROGAS EN UN SOLO PASO (ORINA)
TESTE TOXICOGÓGICO ONE STEP (URINA)
EΞΕΤΑΣΗ ΠΟΛΛΑΠΛΩΝ ΦΑΡΜΑΚΩΝ ΕΝΟΣ ΣΤΑΔΙΟΥ (ΟΥΡΑ)
(Jet) نحص متعدد خاص بالمخدرات أحادي الطور (بول)

Manuale d'uso - User manual Manuel de l'utilisateur - Guía de uso Guia para utilização Gebrauchs- und instandhaltungsanleitung Οδηγίες χρήσης - دليل الإستعمال والرعاية

PER USO PROFESSIONALE
FOR PROFESSIONAL USE
FÜR DEN PROFESSIONELLEN GEBRAUCH
PARA USO PROFESIONAL
PARA USO PROFISSIONAL
FIA EΠΑΓΓΕΛΜΑΤΙΚΗ ΧΡΗΣΗ

للاستخدام المهني

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.

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit. ACHTUNG: Diese Anleitung muss vor dem Einsatz des Produkts aufmerksam gelesen und vollständig verstanden werden.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto. ATENÇÃO: Os operadores devem ler e entender completamente este manual antes de usar o produto. ΠΡΟΣΟΧΗ: Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εγχειριδίου πριν από την χρήση του.

الحذر: على العمال قراءة وفهم هذا الدليل بكامله قبل البدء باستعمال المنتج.



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Gima S.p.A. Via Marconi, 1 20060 Gessate (MI) Italy Made in China (P.R.C.)



















One Step Screen Test Panel (Urine)

Package insert for testing of any combination of the following drugs:

Amphetamine 300, Amphetamine 500, Amphetamine, Barbiturates, Benzodiazepines 200, Benzodiazepines, Buprenorphine, Clonazepam, Cocaine 150, Cocaine, Cotinine, Fentanyl, Heroin (6-acetylmorphine), Ketamine, Marijuana 20, Marijuana, Marijuana 150, Methadone, EDDP 100 (Methadone metabolite), EDDP 300 (Methadone metabolite), Methamphetamine 300, Methamphetamine 500, Methamphetamine, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and Tricyclic Antidepressants.

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 (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 300)	d-Amphetamine	300
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP)	d-Amphetamine	1 000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO 200)	Oxazepam	200
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10
Clonazepam (ACL)	7-Aminoclonazepam	100
Cocaine (COC 150)	Benzoylecgonine	150
Cocaine (COC)	Benzoylecgonine	300
Cotinine (COT)	Cotinine	100
Fentanyl (FTY)	Norfentanyl	20
Heroin (HRN)	6-Acetylmorphine	10
Ketamine (KET)	Ketamine	1 000
Marijuana (THC 20)	11-nor-Δ ⁰ -THC-9 COOH	20
Marijuana (THC)	11-nor-Δ ⁹ -THC-9 COOH	50
Marijuana (THC 150)	11-nor-Δ ⁹ -THC-9 COOH	150
Methadone (MTD)	Methadone	300
Methadone metabolite (EDDP 100)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	100
Methadone metabolite (EDDP 300)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300
Methamphetamine (MET 300)	d-Methamphetamine	300
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET)	d-Methamphetamine	1 000
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP 300)	Morphine	300
Opiate (OPI 2000)	Morphine	2 000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tramadol (TRA)	Tramadol	100
Tricyclic Antidepressants (TCA)	Nortriptyline	1 000

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert. Configurations of the Multi-Drug One Step Screen Test Panel (Urine) come with any combination of the above listed drug analytes with or without S.V.T. 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 (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

• Test panels • SVT/Adulterant color chart (if applicable) • Package insert

Materials Required But Not Provided

Specimen collection container
 Timer

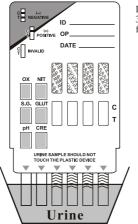
DIRECTIONS FOR USE

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

1. Remove the test card from the sealed pouch and use it as soon as possible. Remove the cap from the end of the test card. With arrows pointing toward the urine specimen, immerse the strip(s) of the test card vertically in the urine specimen for at least 10-15 seconds. Immerse the strip(s) to at least the

Immerse the strip(s) to at least the level of the wavy lines, but not above the arrow(s) on the test card.

- Replace the cap and place the test card on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear.
- 3. Read the adulteration strip between 3 and 5 minutes by comparing the colors on the adulteration strip to the enclosed



Interpret adulteration strips between 3-5 minutes. See enclosed color chart for interpretation.



Interpret drug results at 5 minutes.





POSITIVE



color chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen.

4. Read the drug strip results at 5 minutes. Do not read results after 10 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 (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 (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 300	AMP 500	AMP	BAR	BZO 200	BZO	BUP**	ACL	COC 150	coc	СОТ	FTY	KET	HRN	THC 20	THC
Positive	>99%	*	97%	>99%	*	90%	88%	*	>99%	95%	>99%	*	*	*	*	98%
Negative	>99%	*	>99%	99%	*	97%	>99%	*	>99%	>99%	>99%	*	*	*	*	>99%
Total	>99%	*	98%	99%	*	94%	97%	*	>99%	98%	>99%	*	*	*	*	99%

Specimen	THC 150	MTD	EDDP 100	EDDP 300	MET 300	MET 500	MET	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TRA	TCA
Positive	*	>99%	*	*	*	>99%	98%	>99%	>99%	99%	96%	98%	>99%	*	95%
Negative	*	>99%	*	*	*	80%	>99%	99%	>99%	>99%	99%	>99%	>99%	*	>99%
Total	*	>99%	*	*	*	87%	99%	99%	>99%	>99%	98%	>99%	>99%	*	99%

* NOTE: Commercial kit unavailable for comparison testing.

^{**} NOTE: BUP was compared to the self-reported use of Buprenorphine.



% Agreement with GC/MS

Specimen	AMP 300	AMP 500	AMP	BAR	BZO 200	BZO	BUP*	ACL	COC 150	coc	COT*	FTY*	HRN	KET	THC 20	THC
Positive	>99%	98%	97%	92%	98%	97%	98%	>99%	99%	96%	>99%	99%	99%	>99%	87%	96%
Negative	99%	>99%	95%	98%	99%	95%	>99%	>99%	>99%	90%	>99%	90%	>99%	95%	99%	97%
Total	99%	>99%	96%	95%	99%	96%	>99%	>99%	99%	93%	>99%	93%	>99%	95%	95%	96%

Specimen	THC 150	MTD	EDDP 100	EDDP 300	MET 300	MET 500	MET	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TRA*	TCA**
Positive	91%	99%	98%	>99%	97%	>99%	99%	>99%	>99%	98%	98%	>99%	94%	99%	>99%
Negative	96%	94%	>99%	94%	>99%	96%	94%	98%	94%	97%	99%	96%	99%	96%	89%
Total	96%	96%	99%	96%	98%	98%	96%	99%	97%	98%	99%	97%	96%	97%	91%

^{*} NOTE: BUP, COT, FTY and TRA were based on LC/MS data instead of GC/MS.

Analytical Sensitivity

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

Drug Conc. (Cut-off range)		MP 00		MP 00	Al	MP	В	AR	BZC	200	BZ	ZO	В	JP	A	CL		OC 50	C	С	C	тс
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	60	0	30	0	90	0	90	0	30	0	30	0	90	0
-50% Cut-off	30	0	30	0	30	0	30	0	60	0	30	0	90	0	90	0	30	0	30	0	90	0
-25% Cut-off	27	3	30	0	22	8	27	3	60	0	27	3	75	15	82	8	24	6	30	0	90	0
Cut-off	13	17	24	6	12	18	22	8	22	38	11	19	60	30	39	51	14	16	4	26	46	44
+25% Cut-off	4	26	0	30	2	28	8	22	2	58	5	25	31	59	0	90	7	23	0	30	5	85
+50% Cut-off	0	30	0	30	0	30	2	28	0	60	0	30	0	90	0	90	0	30	0	30	0	90

Drug Conc. (Cut-off range)	F	ſΥ	HF	RN	KI	ΞT	THO	20	TH	IC	THC	150	M	ΓD	ED 10	DP 00	ED 30	DP 00	MET	300	MET	500
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	90	0	90	0	90	0	30	0	30	0	90	0	30	0	90	0	90	0	30	0	30	0
-50% Cut-off	90	0	90	0	90	0	30	0	30	0	90	0	29	1	90	0	90	0	30	0	30	0
-25% Cut-off	85	5	N/A	N/A	90	0	27	3	12	18	90	0	24	6	90	0	90	0	27	3	23	7
Cut-off	49	41	N/A	N/A	57	33	24	6	1	29	46	44	21	9	37	53	51	39	15	15	13	17
+25% Cut-off	13	77	N/A	N/A	3	87	17	13	1	29	5	85	2	28	8	82	14	76	4	26	8	22
+50% Cut-off	0	90	0	90	0	90	5	25	0	30	0	90	0	30	0	90	0	90	0	30	0	30

Drug Conc. (Cut-off range)	МІ	ET	MD	MA	l .	OP 00	O 20		0	ΚΥ	P	CP	PI	×	TO	A	TF	RA
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	90	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	90	0
-25% Cut-off	30	0	26	4	25	5	25	5	30	0	19	11	24	6	29	1	90	0
Cut-off	18	12	17	13	17	13	15	15	18	12	16	14	17	13	18	12	61	29
+25% Cut-off	1	29	4	26	1	29	6	24	6	24	6	24	7	23	5	25	21	69
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	2	88

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 (Urine) at 5 minutes.

AMPHETAMINE 300	
d-Amphetamine	300
d,l-Amphetamine	390
I-Amphetamine	50 000
p-Hydroxyamphetamine	1 560
p-Hydroxynorephedrine	100 000
3,4-Methylenedioxyamphetamine (MDA)	1 560
β-Phenylethylamine	100 000
Phenylpropanolamine (d,l- Norephedrine)	100 000
Tyramine	100 000

AMPHETAMINE 500	
d-Amphetamine	500
d,I-Amphetamine	1 500
I-Amphetamine	50 000
p-Hydroxyamphetamine	190
3,4-Methylenedioxyamphetamine	781
(MDA)	
Phentermine	1 500
AMPHETAMINE	
d-Amphetamine	1 000
d,l-Amphetamine	3 000
I-Amphetamine	50 000

d,l-3,4-Methylenedioxyamphetamine (MDA)	2 000
Phentermine	3 000
BARBITURATES	
Secobarbital	300
Alphenal	150
Amobarbital	300
Aprobarbital	200
Butabarbital	75
Butalbital	2 500
Butethal	100
Cyclopentobarbital	600

^{**} NOTE: TCA was based on HPLC data instead of GC/MS.



Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES 200	100
Oxazepam Oxazepam	200
Alprazolam	30
7-Aminoclonazepam	4 000
7-Aminocionazepam 7-Aminoflunitrazepam	390
7-Aminonumirazepam	625
Bromazepam	390
Chlordiazepoxide	300
Clobazam	48
Clorazepate	97
Desalkylflurazepam	1 560
Diazepam	97
Estazolam	125
Flunitrazepam	25 000
α-Hydroxyalprazolam	30
d-Lorazepam	3 125
Midazolam	195
Nitrazepam	780
Norchlordiazepoxide	780
Nordiazepam	780
Temazepam	33
Triazolam	150
BENZODIAZEPINES	
Oxazepam	300
Alprazolam	196
Bromazepam	1 562
Chlordiazepoxide	1 562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1 562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2 500
Flunitrazepam	390
α-Hydroxyalprazolam	1 262
d,I-Lorazepam	1 562
RS-Lorazepam glucuronide	156
Midazolam	12 500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2 500
BUPRENORPHINE	
Buprenorphine	10
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine	20
Norbuprenorphine	200
3-D-glucuronide	
CLONAZEPAM	
7-Aminoclonazepam	100
Alprazolam	6
7-Aminoflunitrazepam	6
7-Aminonitrazepam	5
Bromazepam	6
Chlordiazepoxide	24
Clobazam	6
	49
Clonazepam	40
Clonazepam Clorazepate	50

Desalkylflurazepam	12
Diazepam	25
Estazolam	2
Flunitrazepam	100
α-Hydroxyalprazolam	5
α-Hydroxymidazolam	10
α-Hydroxytriazolam	1
d,I-Lorazepam	400
Lorazepam glucuronide	10 000
Midazolam	200
Nitrazepam	12
	50
Norchlordiazepoxide Nordiazepam	6
	98
Oxazepam	
Oxazepam glucuronide	10 000
Temazepam	12
Temazepam glucuronide	5 000
Triazolam	24
COCAINE 150	
Benzoylecgonine	150
Cocaethylene	6 250
Cocaine	400
Ecgonine	12 500
Ecgonine methylester	50 000
COCAINE	
Benzoylecgonine	300
Cocaethylene	12 500
Cocaine	780
Ecgonine	32 000
COTININE	
I-Cotinine	100
S-I-Nicotine	12 500
FENTANYI	
FENTANYL Norfentanyl	20
Norfentanyl	20 562 500
Norfentanyl Alfentanyl	562 500
Norfentanyl Alfentanyl Buspirone	562 500 12 500
Norfentanyl Alfentanyl Buspirone Fenfluramine	562 500 12 500 37 500
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl	562 500 12 500 37 500 100
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl	562 500 12 500 37 500 100 57 500
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone	562 500 12 500 37 500 100 57 500 1 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone	562 500 12 500 37 500 100 57 500
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN	562 500 12 500 37 500 100 57 500 1 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine	562 500 12 500 37 500 100 57 500 1 000 1 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine	562 500 12 500 37 500 100 57 500 1 000 1 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine	562 500 12 500 37 500 100 57 500 1 000 1 000 1 562 10
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine	562 500 12 500 37 500 100 57 500 1 000 1 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin	562 500 12 500 37 500 100 57 500 1 000 1 000 1 562 10
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine	562 500 12 500 37 500 100 57 500 1 000 1 000 1 562 10
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE	562 500 12 500 37 500 100 57 500 1 000 1 000 1 562 10 500 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine	562 500 12 500 37 500 100 57 500 1 000 1 000 1 500 1 500 1 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine	562 500 12 500 37 500 100 57 500 1 000 1 000 1 562 10 500 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital	562 500 12 500 37 500 100 57 500 1 000 1 000 1 562 10 500 000 1 000 50 000 50 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARIJUANA 20	562 500 12 500 37 500 100 57 500 1 000 1 000 1 562 10 500 000 1 000 50 000 50 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital	562 500 12 500 37 500 100 57 500 1 000 1 000 1 562 10 500 000 1 000 50 000 50 000 100 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARJUJANA 20 11-nor-Δ®-THC-9 COOH	562 500 12 500 37 500 100 57 500 1 000 1 000 1 562 10 500 000 50 000 50 000 20 20
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARIJUANA 20 11-nor-Δ®-THC-9 COOH Cannabinol	562 500 12 500 37 500 100 57 500 1 000 1 000 1 500 1 000 2 00 2 0 1 2 500
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARIJUANA 20 11-nor-Δ°-THC-9 COOH 11-nor-Δ°-THC-9 COOH Cannabinol Δ°-THC	562 500 12 500 12 500 37 500 100 100 1 000 1 000 1 57 500 1 000 1 000 1 000 1 50 000 1 000 20 12 500 10 000 10 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARIJUANA 20 11-nor-Δ®-THC-9 COOH 11-nor-Δ®-THC-9 COOH Cannabinol Δ®-THC Δ®-THC	562 500 12 500 37 500 100 57 500 1 000 1 000 1 500 1 000 2 00 2 0 1 2 500
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARIJUANA 20 11-nor-Δ®-THC-9 COOH 11-nor-Δ®-THC-9 COOH Cannabinol Δ®- THC Δ®- THC MARIJUANA	562 500 12 500 37 500 100 1000 1 000 1 000 1 500 1 000 20 20 12 500 10000 12 500
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARIJUANA 20 11-nor-Δ®-THC-9 COOH 11-nor-Δ®-THC-9 COOH Cannabinol Δ®- THC Δ®- THC MARIJUANA 11-nor-Δ®-THC-9 COOH	562 500 12 500 37 500 100 100 1 000 1 000 1 562 10 500 000 1 000 2 0 2 0 1 2 500 1 0000 1 2 500 1 0000 1 50 000
Norfentanyl Alfentanyl Buspirone Fenfluramine Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARIJUANA 20 11-nor-Δ®-THC-9 COOH Cannabinol Δ®- THC MARIJUANA 11-nor-Δ®-THC-9 COOH 11-nor-Δ®-THC-9 COOH	562 500 12 500 37 500 100 100 1 000 1 000 1 000 1 000 1 000 50 000 50 000 20 20 12 500 10 000 12 500 50 30
Norfentanyl Alfentanyl Buspirone Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylmorphine 6-Acetylmorphine Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARIJJANA 20 11-nor-Δ*-THC-9 COOH Cannabinol Δ*- THC MARIJJANA 11-nor-Δ*-THC-9 COOH Cannabinol	562 500 12 500 12 500 37 500 100 100 1 000 1 000 1 57 500 1 000 1
Norfentanyl Alfentanyl Buspirone Fenfluramine Fenfluramine Fentanyl Sufentanyl Risperidone 9-hydroxyrisperidone HEROIN 6-Acetylcodeine Heroin Morphine KETAMINE Ketamine Norketamine Pentobarbital Secobarbital MARIJUANA 20 11-nor-Δ®-THC-9 COOH Cannabinol Δ®- THC MARIJUANA 11-nor-Δ®-THC-9 COOH 11-nor-Δ®-THC-9 COOH	562 500 12 500 37 500 100 100 1 000 1 000 1 000 1 000 1 000 50 000 50 000 20 20 12 500 10 000 12 500 50 30

MARIJUANA 150	
11-nor-Δ ⁹ -THC-9 COOH	150
11-nor-Δ ⁸ -THC-9 COOH	500
Cannabinol	25 000
Δ ⁸ - THC	25 000
Δº- THC	25 000
METHADONE	000
Methadone	300
Doxylamine	50 000
EDDP 100	400
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	100
EDDP 300	
2-Ethylidene-1,5-dimethyl-3,3-	300
diphenylpyrrolidine (EDDP)	000
METHAMPHETAMINE 300	
d-Methamphetamine	300
d,I-Amphetamine	100 000
Chloroquine	25 000
Ephedrine	100 000
(1R,2S)-I-Ephedrine	100 000
I-Epinephrine	50 000
Fenfluramine	12 500
p-Hydroxymethamphetamine	25 000
Mephentermine	50 000
I-Methamphetamine	3 125
3,4-Methylenedioxymetham-	780
phetamine (MDMA)	
Trimethobenzamide	25 000
METHAMPHETAMINE 500	
d-Methamphetamine	500
d,l-Amphetamine	75 000
d-Amphetamine	50 000
Chloroquine	12 500
(1R,2S)-I-Ephedrine	50 000
p-Hydroxymethamphetamine	15 000
Mephentermine	25 000
I-Methamphetamine	4 000
3,4-Methylenedioxymetham- phetamine (MDMA)	1 000
I-Phenylephrine	100 000
β-Phenylethylamine	75 000
METHAMPHETAMINE	73 000
d-Methamphetamine	1 000
p-Hydroxymethamphetamine	30 000
Mephentermine	50 000
I-Methamphetamine	8 000
d,I-3,4-Methylenedioxy-	2 000
methamphetamine (MDMA)	
METHYLENEDIOXYMETHAMPH	ETAMINE
(MDMA)	
d,I-3,4-Methylenedioxy-	500
methamphetamine (MDMA)	0.000
d,l-3,4-Methylenedioxy-	3 000
amphetamine (MDA) 3,4-Methylenedioxyethylampheta-	300
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
OPIATE 2000	
Morphine	2 000
Codeine	2 000
Ethylmorphine	5 000
Hydrocodone	12 500
Hydromorphone	5 000
Levorphanol	75 000
6-Acetylmorphine	5 000
Morphine 3-β-D-glucuronide	2 000
Norcodeine	12 500
Normorphine	50 000

Oxycodone	25 000
Oxymorphone	25 000
Procaine	150 000
Thebaine	100 000
OXYCODONE	
Oxycodone	100
Hydrocodone	6 250
Hydromorphone	50 000
Levorphanol	50 000
Naloxone	37 500
Naltrexone	37 500
Oxymorphone	200
PHENCYCLIDINE	
Phencyclidine	25
4-Hydroxyphencyclidine	12 500
PROPOXYPHENE	
d-Propoxyphene	300
d-Norpropoxyphene	300

TRAMADOL	
Cis-tramadol	100
d,I-O-Desmethyl venlafaxine	25 000
n-Desmethyl-cis-tramadol	195
o-Desmethyl-cis-tramadol	6 250
Phencyclidine	100 000
Procyclidine	100 000
TRICYCLIC ANTIDEPRESSANT	ΓS
Nortriptyline	1 000
Amitriptyline	1 500
Clomipramine	12 500
Desipramine	200
Doxepin	2 000
Imipramine	400
Maprotiline	2 000
Nordoxepin	1 000
Promazine	1 500
Promethazine	25 000
Trimipramine	3 000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine 300, Amphetamine 500, Amphetamine, Barbiturates, Benzodiazepines 200, Benzodiazepines, Buprenorphine, Clonazepam, Cocaine 150, Cocaine, Cotinine, Fentanyl, Heroin (6-acetylmorphine), Ketamine, Marijuana 20, Marijuana, Marijuana 150, Methadone, EDDP 100 (Methadone metabolite), EDDP 300 (Methadone metabolite), Methamphetamine 300, Methamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and Tricyclic Antidepressants positive urine. The following compounds show no cross-reactivity when tested with the Multi-Drug One Step Screen Test Panel (Urine) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol Labetalol Acetone Dicyclomine Lidocaine Acetophenetidin Diflunisal Lindane Acetylsalicylic acid Digoxin Lithium Albumin 4-Dimethylaminoantipyrine Loperamide alpha-Naphthaleneacetic Acid Diphenhydramine I-Thyroxine Aminopyrine 5,5-Diphenylhydantoin Meperidine **EMDP** Meprobamate Amoxanine Amoxicillin Ervthromycin Methaqualone Ampicillin β-Estradiol Methoxyphenamine Apomorphine Estrone-3-sulfate Methylphenidate Ascorbic acid Ethyl alcohol Metoprolol Ethyl-p-aminobenzoate N-Acetylprocainamide Aspartame Atropine **Ftodolac** Nalidixic acid Benzilic acid Famprofazone Nalorphine Benzoic acid Fenoprofen Naproxen Fluoxetine Niacinamide Benzydamine Brompheniramine Furosemide Nifedipine Caffeine Gentisic acid Nimesulide Cannabidiol d-Glucose Norethindrone Guaiacol Glyceryl Ether Chloral Hydrate Noscapine Chloramphenicol Hemoglobin d,I-Octopamine Chloroquine Hydralazine Orphenadrine Hydrochlorothiazide Oxalic acid Chlorothiazide Chlorpromazine Hydrocortisone Oxolinic acid Chlorprothixene o-Hydroxyhippuric acid Oxymetazoline Cholesterol 3-Hydroxytyramine Papaverine Cimetidine Ibuprofen Pemoline Clonidine Iproniazid Penicillin Cortisone Isoproterenol Pentazocine Phenelzine Creatinine Isoxsuprine Kanamycin Pheniramine Deoxycorticosterone Dextromethorphan Ketoprofen Phenothiazine

Prednisolone Prednisone d,I-Propanolol Quinacrine Quinidine Quinine R(-) Deprenyl Riboflavin Salicylic acid Serotonin Seroquel Sertraline Sodium Chloride Sulfamethazine Sulindac Tetracvcline Tetrahydrozoline Theophylline Thiamine Thioridazine Tolbutamide

Trans-2-phenylcyclopropylamine

Trazodone Triamterene Trifluoperazine Trimethoprim d,I-Tryptophan d,I-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
рН	рН

NIT	Nitrite
GLUT	Glutaraldehyde
GLUT	Creatinine

Index of Symbols

<u> </u>	Attention, see instructions for use
IVD	For <i>in vitro</i> diagnostic use only
2°C 30°C	Store between 2-30°C
Ť	Keep in a cool, dry place

Σ	Tests per kit
	Use by
LOT	Lot Number
漆	Keep away from sunlight





GIMA S.p.A. Via Marconi, 1 - 20060 Gessate (MI) - Italia Made in China (P.R.C.)