

**TEST MONOFASE MARIJUANA STRISCE URINA
ONE STEP MARIJUANA TEST STRIP (URINE)
1 ETAPE TEST DE CANNABIS SUR BANDELETTE (URINE)
EINSTUFEN MARIHUANA TESTSTREIFEN (URIN)
PRUEBA DE MARIHUANA EN UN SOLO PASO EN TIRA (ORINA)
TIRA PARA TESTE DE MACONHA EM UM SÓ PASSO (URINA)
ΤΕΣΤ ΜΑΡΙΧΟΥΑΝΑΣ ΤΑΙΝΙΑΣ ΕΝΟΣ ΣΤΑΔΙΟΥ (ΟΥΡΩΝ)**
فحص أحادي الطور ماريوانا شرائح بول

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

PER USO PROFESSIONALE
FOR PROFESSIONAL USE
FÜR DEN PROFESSIONELLEN GEBRAUCH
PARA USO PROFESIONAL
PARA USO PROFISSIONAL
ΓΙΑ ΕΠΑΓΓΕΛΜΑΤΙΚΗ 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.

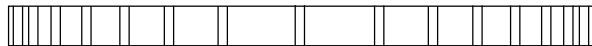
الحذر: على العمال قراءة وفهم هذا الدليل بكامله قبل البدء باستعمال المنتج

REF 24541



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





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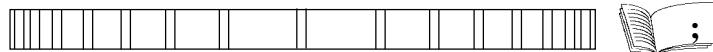
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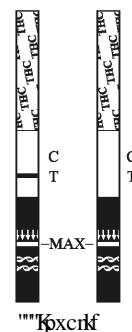
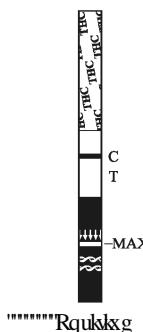
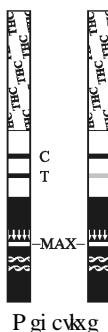
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INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Marijuana concentration is below the detectable level (50 ng/mL).

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

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Marijuana concentration is above the detectable level (50 ng/mL).

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 with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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 testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The THC One Step Marijuana Test Strip (Urine) provides only a quantitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.^{1,2}
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 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. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A three way side-by-side comparison was conducted using the THC One Step Marijuana Test Strip (Urine) and a leading commercially available THC rapid test. Testing was performed on 300 clinical specimens previously collected from subjects present for Drug Screen Testing. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 50 ng/mL 11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other THC Rapid Test		Total Results
THC One Step Test Strip	Results	Positive	Negative	
	Positive	140	0	140
	Negative	3	157	160
Total Results		143	157	300
% Agreement		98%	>99%	99%

When compared to GC/MS at 50 ng/mL, the following results were tabulated:

Method	Results	GC/MS		Total Results
		Positive	Negative	
THC One Step Test Strip	Positive	118	22	140
	Negative	4	156	160
Total Results		122	178	300
% Agreement		97%	88%	91%

When compared to GC/MS at 25 ng/mL, the following results were tabulated:

Method	Results	GC/MS		Total Results
		Positive	Negative	
THC One Step Test Strip	Positive	135	5	140
	Negative	6	154	160
Total Results		141	159	300
% Agreement		96%	97%	96%

Analytical Sensitivity

A drug-free urine pool was spiked with 11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid at the following concentrations: 0 ng/mL, 25 ng/mL, 37.5 ng/mL, 50 ng/mL, 62.5 ng/mL and 75 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below.

11-nor- Δ^9 -THC-9 COOH Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
37.5	-25%	30	12	18
50	Cut-off	30	1	29
62.5	+25%	30	1	29
75	+50%	30	0	30

Analytical Specificity

The following table lists compounds and their respective concentrations in urine that yield a positive result in the THC One Step Marijuana Test Strip (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
Cannabinol	20,000
11-nor- Δ^8 -THC-9 COOH	30
11-nor- Δ^9 -THC-9 COOH	50
Δ^8 -THC	15,000
Δ^9 -THC	15,000

Precision

A study was conducted at three physicians' offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no 11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid, 25% 11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid above and below the cut-off, and 50% 11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid above and below the 50 ng/mL cut-off was provided to each site. The following results were tabulated:

11-nor- Δ^9 -THC-9 COOH Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	14	1
37.5	15	9	6	14	1	9	6
62.5	15	2	13	0	15	0	15
75	15	0	15	0	15	0	15



Effect of Urinary Specific Gravity

Twenty-six urine specimens of normal, high, and low specific gravity ranges were spiked with 25 ng/mL and 75 ng/mL of 11-nor-D⁹-Tetrahydrocannabinol-9-carboxylic acid. The THC One Step Marijuana Test Strip(Urine) was tested in duplicate using the twenty-six neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with 11-nor-D⁹-Tetrahydrocannabinol-9-carboxylic acid to 25 ng/mL and 75 ng/mL. The spiked, pH-adjusted urine was tested with the THC One Step Marijuana Test Strip (Urine) in duplicate.

The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Marijuana positive urine. The following compounds show no cross-reactivity when tested with the THC One Step Marijuana Test Strip (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Aacetamidophenol	Deoxycorticosterone	(+)-3,4-Methylenedioxy-	Prednisolone
Acetophenetidin	Dextromethorphan	amphetamine	Prednisone
N-Acetylprocainamide	Diazepam	(+)-3,4-Methylenedioxy-	Procaine
Acetylsalicylic acid	Diclofenac	methamphetamine	Promazine
Aminopyrine	Diflunisal	Methylphenidate	Promethazine
Amitriptyline	Digoxin	Methyprylon	D,L-Propanolol
Amobarbital	Diphenhydramine	Morphine-3-	D-Propoxyphene
Amoxicillin	Doxylamine	β-D-glucuronide	D-Pseudoephedrine
Ampicillin	Econidine hydrochloride	Nalidixic acid	Quinidine
L-Ascorbic acid	Econidine methylester	Nalorphine	Quinine
D,L-Amphetamine	(-)-Ψ-Ephedrine	Naloxone	Ranitidine
L-Amphetamine	Erythromycin	Naltrexone	Salicylic acid
Apomorphine	β-Estradiol	Naproxen	Secobarbital
Aspartame	Estrone-3-sulfate	Niacinamide	Serotonin (5-Hydroxytryptamine)
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Sulfamethazine
Benzilic acid	Fenoprofen	Norcodein	Sulindac
Benzoic acid	Furosemide	Norethindrone	Temazepam
Benzoylegconine	Gentisic acid	D-Norpseudoephedrine	Tetracycline
Benzphetamine	Hemoglobin	Noscapine	Tetrahydrocortisone
Bilirubin	Hydralazine	D,L-Octopamine	3-acetate
(±)-Brompheniramine	Hydrochlorothiazide	Oxalic acid	Tetrahydrocortisone
Caffeine	Hydrocodone	Oxazepam	3 (β-D glucuronide)
Cannabidiol	Hydrocortisone	Oxolinic acid	Tetrahydrozoline
Chloralhydrate	O-Hydroxyhippuric acid	Oxycodone	Thebaine
Chloramphenicol	3-Hydroxytyramine	Oxymetazoline	Thiamine
Chlordiazepoxide	Ibuprofen	p-Hydroxy-	Thioridazine
Chlorothiazide	Imipramine	methamphetamine	D,L-Thyroxine
(±)-Chlorpheniramine	Iproniazid	Papaverine	Tolbutamine
Chlorpromazine	(±)-Isoproterenol	Penicillin-G	Triamterene
Chlorquine	Isoxsuprine	Pentazocine	Trifluoperazine
Cholesterol	Ketamine	Pentobarbital	Trimethoprim
Clomipramine	Ketoprofen	Perphenazine	Trimipramine
Clonidine	Labetalol	Phencyclidine	Tryptamine



Cocaine hydrochloride	Levorphanol	Phenelzine	D,L-Tryptophan
Codeine	Loperamide	Phenobarbital	Tyramine
Cortisone	Maprotiline	Phentermine	D,L-Tyrosine
(-)Cotinine	Meprobamate	L-Phenylephrine	Uric acid
Creatinine	Methadone	β -Phenylethylamine	Verapamil
	Methoxyphenamine	Phenylpropanolamine	Zomepirac

Indice dei Simboli / Index of symbols / Liste des symboles/ Symbole / Indice de simbolas / Indice de Simbolos / Πίνακας συμβόλων

	<p>Leggere e seguire attentamente le istruzioni per l'uso <i>Read instructions carefully</i> Lire et suivre attentivement la notice <i>Gebrauchsanweisung sorgfältig lesen und befolgen</i></p>	<p>Leer y seguir atentamente las instrucciones de uso <i>Ler e seguir atentamente as instruções de uso</i> Διαβάστε και ακολουθήστε προσεχτικά τις οδηγίες χρήσης</p> <p style="text-align: right;">اقرأ بدقة وحرص تعليمات الاستخدام</p>
	<p>Solo per uso diagnostico in vitro <i>For in vitro diagnostic use only</i> Uniquement pour usage diagnostique in vitro <i>Nur zum Gebrauch für In-vitro-Diagnostik</i></p>	<p>Solo para uso diagnóstivo in vitro <i>Apenas para diagnóstico in vitro</i> Μόνο για διαγνωστική χρήση σε δοκιμαστικό σωλήνων</p> <p style="text-align: right;">فقط للاستخدام التشخيصي المجهري</p>
	<p>Conservare tra _ e _ °C <i>Store between _ and _ °C</i> À conserver entre _ et _ °C <i>Lagern bei _ °C</i></p>	<p>Conservar entre _ y _ °C <i>Guardar entre _ e _ °C</i> Διατηρείται μεταξύ _ και _ °C</p> <p style="text-align: right;">يحفظ بين و درجة مئوية</p>
	<p>Conservare in luogo fresco ed asciutto <i>Keep in a cool, dry place</i> À conserver dans un endroit frais et sec. <i>An einem kühlen und trockenen Ort lagern</i></p>	<p>Conservar en un lugar fresco y seco <i>Armazenar em local fresco e seco</i> Διατηρείται σε δροσερό και στεγνό περιβάλλον</p> <p style="text-align: right;">يحفظ في مكان بارد وجاف</p>
	<p>Fabbricante <i>Manufacturer</i> Fabricant <i>Hersteller</i></p>	<p>Fabricante <i>Fabricante</i> Παραγωγός</p> <p style="text-align: right;">الشركة المصنعة</p>
	<p>Dispositivo monouso, non riutilizzare <i>Disposable device, do not re-use</i> Dispositif pour usage unique, ne pas réutiliser <i>Für einmaligen Gebrauch, nicht wiederverwenden</i></p>	<p>Dispositivo monouso, no reutilizable <i>Dispositivo descartável, não reutilizar</i> Προϊόν μιας χρήσεως. Μην το χρησιμοποιείται εκ νέου</p> <p style="text-align: right;">أداة أحادية الاستخدام، لا تستخدم من جديد</p>
	<p>Data di scadenza (vedi scatola / bustina) <i>Expiration date (see box / package)</i> Date d'échéance (voir boîte/sachet) <i>Ablaufdatum (siehe Schachtel / Beutel)</i></p>	<p>Fecha de caducidad (ver caja / sobre) <i>Data de validade (ver caixa/saquetă)</i> Ημερομηνία λήξεως (βλέπε συσκευασία/ σακουλάκι)</p> <p style="text-align: right;">تاريخ انتهاء الصلاحية (انظر العبوة / المغلف)</p>
	<p>Numero di lotto (vedi scatola / bustina) <i>Lot number (see box / package)</i> Numéro de lot (voir boîte/sachet) <i>Chargennummer (siehe Schachtel / Beutel)</i></p>	<p>Número de lote (ver caja / sobre) <i>Número de lote (ver caixa/saquetă)</i> Αριθμός παρτίδας (βλέπε συσκευασία/ σακουλάκι)</p> <p style="text-align: right;">رقم الدفعه (انظر العبوة / المغلف)</p>
	<p>Leggere attentamente le istruzioni per l'uso <i>Please read instructions carefully</i> Lire attentivement la notice <i>Gebrauchsanweisung sorgfältig lesen</i></p>	<p>Leer atentamente las instrucciones de uso <i>Ler atentamente as instruções de uso</i> Διαβάστε προσεχτικά τις οδηγίες χρήσης</p> <p style="text-align: right;">اقرأ بدقة وحرص تعليمات الاستخدام</p>

	<p>Contiene <n> di test <i>Contains sufficient for "n" tests</i> Contient <n> de test <i>Enthält <n> Tests</i></p>	<p>Contiene <n> de test <i>Contém <n> de teste</i> Περιέχει <n> τέστ</p>	يحتوي على <n> من اختبار
	<p>Prodotto conforme alla Direttiva Europea n. 98/79/CE sui dispositivi diagnostici in vitro <i>Product complies with European Directive no. 98/79/EC on In Vitro diagnostic devices</i> Ce produit est conforme à la directive européenne n. 98/79 /CE relative aux dispositifs de diagnostic in vitro <i>Produkt gemäß EU-Richtlinie Nr. 98/79/CE über Geräte für In-vitro-Diagnostik</i></p>	<p>Producto conforme a la Directiva Europea nº 98/79/CE sobre los dispositivos diagnósticos in vitro <i>Produto em conformidade com a Diretiva Europeia n.º 98/79/CE sobre dispositivos de diagnóstico em vidro</i> Προϊόν σύμφωνο με την Ευρωπαϊκή Οδηγία αρ. 98/79/CE περί διαγνωστικών μέσων σε δοκιμαστικό</p>	منتج يتوافق مع توجيهات الاتحاد الأوروبي رقم EC/79/98 في يتعلق أجهزة وأدوات التشخيص المجهري
	<p>Codice prodotto <i>Product code</i> <i>Code produit</i> <i>Erzeugniscode</i></p>	<p>Código producto <i>Código produto</i> <i>Κωδικός προϊόντος</i></p>	كود المنتج
	<p>Conservare al riparo dalla luce solare <i>Keep away from sunlight</i> À conserver à l'abri de la lumière du soleil <i>Vor Sonneneinstrahlung geschützt lagern</i></p>	<p>Conservar al amparo de la luz solar <i>Guardar ao abrigo da luz solar</i> Κρατήστε το μακριά από ηλιακή ακτινοβολία</p>	يحفظ بعيداً عن ضوء الشمس

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