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PROFESSIONAL MEDICAL PRODUCTS

TEST MONOFASE COCAINA STRISCE URINA
ONE STEP COCAINE TEST STRIP (URINE)
1 ETAPE TEST DE COCAÏNE SUR BANDELETTE (URINE)
EINSTUFEN KOKAIN TESTSTREIFEN (URIN)
PRUEBA DE COCAÍNA EN UN SOLO PASO EN TIRA (ORINA)
TIRA PARA TESTE DE COCAÍNA EM UM SÓ PASSO (URINA)
ΤΕΣΤ ΚΟΚΑΪΝΗΣ ΤΑΙΝΙΑΣ ΕΝΟΣ ΣΤΑΔΙΟΥ (ΟΥΡΩΝ)
فحص أحادي الطور كوكاينا شرائح بول

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

PER USO PROFESSIONALE
FOR PROFESSIONAL USE
POUR USAGE PROFESSIONNEL
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 **24540**

Gima S.p.A.
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Made in China

M-24540-M-Rev.5-01.19

One Step Cocaine Test Strip (Urine)

A rapid, one step test for the qualitative detection of Cocaine metabolites in human urine. For professional IVD (In Vitro Diagnostics) use only.

INTENDED USE

Urine based tests for 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 drugs of abuse.

The COC One Step Cocaine Test Strip (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of drugs and drug metabolites in urine at the following cut-off concentrations in urine:[1]

Test	Calibrator	Cut-off (ng/mL)
Cocaine (COC)	Benzoylecgonine	300

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a qualitative, 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 used.

PRINCIPLE

The COC One Step Cocaine Test Strip (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. A drug-positive urine specimen will not generate a colored line in the test line region 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.

REAGENTS

The test contains mouse monoclonal anti-Benzoylecgonine antibody-coupled particles and Benzoylecgonine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For professional IVD (In Vitro Diagnostics) use only. Do not use after the expiration date.
- The test 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 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 is stable through the expiration date printed on the sealed pouch. The test 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.

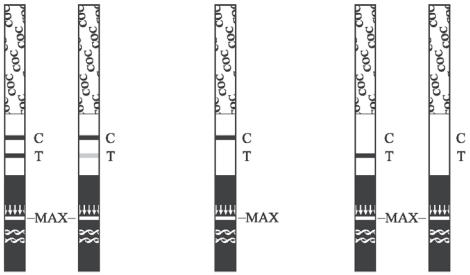
Specimen Storage
Urine specimens may be stored at 2-8ºC for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20ºC. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided
- Test strips
- Package insert

Materials Required But Not Provided
- Specimen collection container
- Timer

DIRECTIONS FOR USE
Allow the test, urine specimen, and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing it. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



Negative **Positive** **Invalid**

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 Benzoylecgonine concentration is below the detectable level (300 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 This positive result indicates that the Benzoylecgonine concentration is above the detectable level (300 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

1. The COC One Step Cocaine Test Strip (Urine) provides only a qualitative, preliminary analytical result. A secondary quantitative analytical method must be used to obtain a confirmed result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method.[2,3]
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.
7. Certain foods and food supplements can give a positive result.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the COC One Step Cocaine Test Strip (Urine) and a commercially available drug rapid test. Testing was performed on a minimum of 200 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. Negative urine specimens were screened initially by Predicate test, 10% negative specimens were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

Specimen	COC
Positive	95%
Negative	>99%
Total	98%

% Agreement with GC/MS

Specimen	COC
Positive	96%
Negative	90%
Total	93%

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)	COC	
	-	+
0% Cut-off	30	0
-50% Cut-off	30	0
-25% Cut-off	30	0
Cut-off	4	26
+25% Cut-off	0	30
+50% Cut-off	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the COC One Step Cocaine Test Strip (Urine) at 5 minutes.

COCAINE	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12 500
Ecgonine	32 000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug- negative urine or Benzoylecgonine positive urine. The following compounds show no interference when tested with the COC One Step Cocaine Test Strip (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
(-)Cotinine
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

BIBLIOGRAPHY

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735
2. Baselt RC. Disposition of Toxic Multi-Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols

	Attention, see instructions for use		Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog **24540**
	Keep in a cool, dry place		Keep away from sunlight		Please read instructions carefully