GIMA
PROFESSIONAL MEDICAL PRODUCTS

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Test delle urine multi-strisce (1-10 parametri)
Urinalysis Multistrips (1-10 parameters)
Bandelettes urinaires multi-paramètres (1-10 paramètres)
Multistreifen-Urintest (1-10 Parameter)
Prueba de orina multi-tiras (1-10 parámetros)
Teste das urinas multi-tiras (1-10 parâmetros)
Τέστ ούρων πολλαπλών-λωρίδων (1-10 παράμετροι)
فحص للبول متعدد الشرائح (1-10 قيم)

PER USO PROFESSIONALE
FOR PROFESSIONAL USE

MANUALE D'USO
OPERATOR'S MANUAL
MANUEL D'UTILIZATION
BEDIENUNGSANLEITUNG
MANUAL DE USO
MANUAL DE UO
Εγχειρίδιο χρήσης
دليل للإرشادات

REF **24069**

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: *Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.*
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.*

CE

M24069-M-Rev.3-06.16

For the Semi-quantitative and qualitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in Urine

INTENDED USE

The Urine Test Strips contains solid phase reagent area affixed to a plastic stick. They are provided as a dry reagent. The Urine Test Strips provide tests for the semi-quantitative determinations of glucose, ketone, pH, blood, nitrite, urobilinogen, bilirubin, protein, specific gravity and leukocytes in human urine.
The test results may provide information regarding the status of carbohydrate metabolism, kidney function, liver function, acid-base balance and urinary track infection.

TEST PRINCIPLES

The test principles are based on various dyes and reagent reactions with components of the urine that lead to colored components, which can be visually detected and/or measured by the instrument.

SUMMARY AND EXPLANATION

The urinalysis test strips are ready to use upon removal from the bottle. The entire reagent strip is disposable. No additional laboratory equipment is necessary for testing. The directions must be followed exactly. Accurate timing is essential to provide optimal results. The strips are packaged in a plastic bottle, containing desiccant. The bottle must be capped tightly to maintain reagent activity.

MATERIALS PROVIDED

1. Urine test strips.
2. Color label chart.
3. Instructions for use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Urine collection cup.
2. Clock or timer.

PRECAUTIONS

1. For in Vitro diagnostic use.
2. Do not touch test areas of strip.
3. After removing a test strip, replace cap on bottle promptly.
4. Working area should be free of detergents and other contaminants.

STORAGE

1. Store at room temperature 4-30°C (40-86°F), out of direct sun light.
2. Do not use after expiration date.
3. Do not refrigerate or freeze.
4. Store all test strips in the original bottle. Do not remove the desiccant from bottle.
5. Close the bottle cap tightly after each use.

SPECIMEN COLLECTION

1. Urine should be collected in a clean container, either plastic or glass. Do not centrifuge.
2. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately. Return to room temperature before testing.

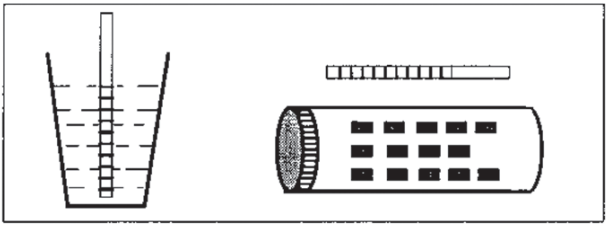
3. It is especially important to use fresh urine to obtain optimal test results for bilirubin and urobilinogen.

RECOMMENDED HANDLING PROCEDURE

All unused strips must remain in the original bottle, Transfer to any other container may cause reagent strips to deteriorate and become unreactive. Do not remove strip from the bottle until immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip.

GOOD LABORATORY PRACTICE

1. Urine collection containers are to be cleaned with no contamination.
2. The urine chemistry analyzer is to be cleaned daily. The instrument is first turned on, an optical calibration and self-test procedure must be performed.
3. Each day, the laboratory must run a negative and positive control before each routine test.



TEST PROCEDURE

1. Bring specimens to room temperature before use.
2. Remove a test strip from the bottle. Replace cap immediately.
3. Inspect the strip. (Discoloration or darkening of reagent test areas may indicate deterioration. Do not use the strip.).
4. Immerse test areas of the strip completely in urine and remove immediately to avoid dissolving of reagents.
5. Remove excess urine by the following steps, otherwise the test results may be inaccurate.
    A: Run the edge of the strip against the rim of the urine container.
    B: Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas.
    C: Gently blotting the lengthwise edge of the strip on absorbent paper.
6. Compare the test results carefully with the color chart on the bottle label in good light.
7. **Note**: The optimal reading time of each test parameter varies from 30 seconds up to 2 minutes. Changes in color that appear only on the edges of the test areas or after more than 2 minutes are of no clinical significance.

RESULTS

The results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label at the specified times.

REAGENT COMPOSITION

Glucose: 10.54% w/w glucose oxidase (aspergillus, 250 IU), 0.2% w/w peroxidase (horseradish, 2,500 IU), 5.0% w/w potassium iodide and 84.3% non-reactive ingredients.

Bilirubin: 1 % w/w 2,4-dichloroaniline diazonium salt and 99 % w/w non-reactive ingredients.
Ketone: 4.5% w/w sodium nitroprusside and 95.5% w/w buffer.
Specific Gravity: 5.0 % w/w bromothymol blue, 58.0% w/w poly (methy vinyl ether), 15.0% w/w sodium hydroxide and 22.0% w/w non-reactive ingredients.
Blood: 6.6% w/w cumen hydroperoxide, 2.0% w/w 3,3',5,5' tetramethylbenzidine, and 91.4% w/w non-reactive ingredients.
pH: 0.1% w/w methyl red, 1.5% w/w bromthymol blue, and 98.4% w/w non-reactive ingredients.
Protein: 1.5% w/w tetrabromphenol blue and 98.5% w/w non-reactive ingredients.
Urobilinogen: 0.6% w/w p-diethylaminobenzaldehyde and 99.4% w/w buffer.
Nitrite: 2.0% w/w p-arsanilic acid, 2.2% w/w a-naphthylamine and 95.8% w/w buffer.
Leukocytes: 0.1% w/w ester, 0.6% w/w diazonium salt, 40% w/w buffer and 59.3% w/w non-reactive ingredients.

LIMITATIONS

Glucose: Large amounts of ketone bodies (50 mg/dl or greater) may decrease color development.
Ketone: Color reactions that could be interpreted as „positive“ may be obtained with urine specimens containing medium or large amounts of phenylketones .
pH: Excessive urine on the test strip may wash the acid buffer from the neighboring protein reagent onto the pH area and change the pH reading to an acid pH.
Blood: A false positive can sometimes occur when bacteria are present in the urine. Ascorbic acid or protein may reduce the reactivity of the blood test. Strong oxidizing substances, such as hypochlorite, may produce false positive results.
Nitrite: Any degree of uniform pink color development should be considered positive, however, pink spots or pink edges should not be interpreted as a positive result.
Urobilinogen: Atypical color reactions may be obtained in the presence of high concentrations of p-aminobenzoic acid. Also false negative results may be obtained if formalin is present.
Bilirubin: Reactions may occur with urine specimens containing large doses of chlorpromazine, which might be mistaken for positive bilirubin.
Protein: False positive results may be obtained with alkaline urine.
Specific gravity: Elevated specific gravity readings may be obtained in the presence of moderate quantities of protein (100 - 700 mg/dl). Specific gravity is increased with glucose in the urine.
Leukocytes: Elevated glucose concentrations or high specific gravity may cause decreased test sensitivity.

EXPECTED VALUES

False negative and week reaction of Glucose, Blood and Bilirubin may be observed if:

- **Glucose**: more than 30mg/dl ascorbic acid in the sa.mple
- **Bilirubin**: more than 50 mg/dl ascorbic acid in the sample.
- **Blood**: more than 10 mg/dl ascorbic acid in the sample.

Glucose: The kidney normally excretes small amounts of glucose. Concentrations of as little as 0.1g/dl glucose, read either at 10 or 30 seconds, may be significantly abnormal if found consistently. (1)
Ketone: Normally no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent exercise. (2)
pH: newborn: 5 -7, thereafter: 4.5-8, average: 6. (1)
Blood: Any green spots or green color that appears on the reagent area within 60 seconds indicates blood has been detected and the need for further investigation. (3)
Nitrite: Any degree of pink color after 30 seconds indicates a positive test for nitrite suggesting

a clinically significant infection by bacteria. A negative test does not necessarily rule out bacterial infection. (1, 4)
Urobilinogen: In this test the normal range is 0.2 - 1.0 mg/dl. If results exceed the concentration of 2.0 mg/dl, the patient and/or urine specimen should be evaluated further. (5)
Bilirubin: Normally no bilirubin is detectable in urine by even the most sensitive methods. Atypical colors may indicate that bilirubin derived bile pigments are present in the urine sample and are possibly masking the bilirubin reaction. (6)
Protein: Normally urine specimens contain some protein, (0-4 mg/dl) therefore, only persistent levels of urine protein indicate kidney or urinary tract disease. (4)
Specific gravity: In normal adult random urine specific gravity may be from 1.003 to 1.040. Specific gravity will shift according to kidney disfunction. (7)
Leukocytes: Normal urine specimens generally yield negative results; positive results (small or large) are clinically significant. (1,4)

NORMAL VALUE REFERECE

Glucose	Negative
Bilirubin	Negative
Ketone	Negative
Blood	Negative
Protein	Negative
Urobilinogen	0.2 ~ 1 mg/dl (1 mg/dl =approx. 1 EU)
Nitrite	Negative
Leukocytes	Negative

PERFORMANCE CHARACTERISTICS

Studies comparing the Urinalysis.
Strips and other commercially available strips resulted in greater than 99% agreement with 60 urine samples.

REFERENCE

1. A. H. Free and H. M. Free " Urinalysis, critical discipline of clinical science" CRC Critical Reviews in Clinical Laboratory Sciences, 481-531, 1972.
2. H. Free et. al., "A comparative study of qualitative tests for ketones in urine and serum" Clin. Chem., 4, 323, 1958.
3. J. M. Wilson and G. Junger "Principles and practice of screening for disease" Public Health Papers No. 34, World Health Organization, Geneva, 1968.
4. Gershen Tield, L., "Urine and Urinalysis" 3rd ed., W.13, Saunders, Philadelphia, 1948, 17.
5. B. Balikov "Urobilinogen in urine and feces" Standard Methods of Clinical Chemistry, vol. 2, Scligson, D., Ed., Academic Press, New York, 1958, 192.
6. J. H. Ivy and J. W. Hurley. Routine urine bilirubin determinations, J.A.M.A., 176, 689, 1961.
7. PA.Castaldi et al., "Urinary specific gravity as a measure of renal function" Med. Aust., I, R47, 1960.

Simbologia / Index of symbols

REF	Codice prodotto Product code		Teme l'umidità Keep dry
LOT	Numero di lotto Lot number		Riparare da luce diretta Keep away from sunlight
	Leggere e seguire attentamente le istruzioni per l'uso Read instructions carefully		Consultare le istruzioni prima dell'uso Read instruction before use
	Fabbricante Manufacturer	MIN MAX	Temperatura di conservazione Storage temperature
CE	Simbolo per marchio CE Symbol for CE Mark		Monouso/non riutilizzare Do not reuse/single use only
Σ	Contiene <n> di test Contains sufficient for <n> tests		Data di scadenza Expiry date
IVD	Dispositivo diagnostico In Vitro In Vitro diagnostic device		

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Made in P.R.C.