SILEX®

IVD

REAGENT STRIPS FOR URINALYSIS KETONE

(For both professional & self-testing use)

This package insert is to be used with Reagent Strips for Urinalysis - Ketone. The test strips enable the qualitative and semi-quantitative detection of ketone in urine.
For self-testing in vitro diagnostic use. Single use only. **Do not reuse.**

SUMMARY

Urine test strips (URS) consist of solid plastic strips with a colored test pad that can detect ketones (acetoacetic acid). Test results provide information regarding the status of carbohydrate metabolism.
Reagent strips for urinalysis are packaged along with a drying agent in a bottle with a twist-off cap. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. Results are obtained by direct comparison of the test strip with the color blocks printed on the color chart. No calculations or laboratory instruments are required.

TEST PRINCIPLE

This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" reading.

REAGENTS (Based on dried weight at time of impregnation)

7.7% w/w sodium nitroprusside balanced with buffer and non-reactive ingredients.

WARNINGS AND PRECAUTIONS

- Reagent Strips for Urinalysis are for in vitro diagnostic use. Do not touch the test area of the Urine Reagent Strips.
- Package contents may be disposed of in the normal household waste after use.
- All package contents are non-toxic and safe when used as directed.
- Do not use if the product seal is broken.
- As with all diagnostic tests, a definitive diagnosis should not be based on the result of a single test, but should only be made by your physician after all clinical and laboratory findings have been evaluated.

STORAGE

- Store at room temperature between 2°-30°C (36°-86°F) and out of direct sunlight.
- Do not use after the expiration date printed on the label.
- The expiration date is printed on the packaging and the color chart.

SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean container and test as soon as possible. The use of urine preservatives is not recommended. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately. Allow a refrigerated specimen to return to room temperature before testing.

MATERIALS

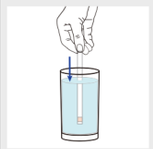
Material provided

Each box contains
1. One PET Bottle containing test strips
2. Desiccant (in PE Bottle)
3. One color chart (glued onto the bottle)

Material required but not provided

1. Timer
2. Sample container
3. Disposable glove

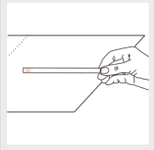
TEST PROCEDURE



1.Remove a strip from the bottle for immediate use.

2.Completely immerse reagent area of the strip in fresh urine. Remove the strip immediately to avoid dissolving out the reagent area.

3.While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine.



4. Compare the reagent area to the corresponding color block on the color chart after 40 seconds. The correct reading time is critical for optimal results.

5. Obtain results by direct color chart comparison.

Note: Immerge the strip into the urine sample and take out one second later. The correct reading times are mentioned on the color chart. If the results are read after the correct reading time, the colors shown have no diagnostic value.

RESULTS

Results are obtained by direct comparison of the color block on the test strip with the color chart. The color blocks represent nominal values; the actual values will vary around the nominal values.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new test is performed or whenever a new pouch is first opened. Each laboratory should establish its own goals for adequate standards of performance and should question handling and testing procedures if these standards are not met.

LIMITATIONS OF THE PROCEDURE

As with all tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.
Color reaction that could be interpreted as "positive" may be obtained with urine specimens containing MESNA or large amounts of phenylketones or L-dopa metabolites.

INTERPRETATION OF RESULTS (FOR NUTRITIONAL KETOSIS MONITORING)

Negative: You are likely not in ketosis. Trace/Small: Indicates light nutritional ketosis. For many diets, this means you need to further reduce carbohydrate intake. Moderate/Large: Shows a higher level of ketosis, which can be an ideal range for some weight loss programs or a result of prolonged fasting. Very Large: This may indicate a need to increase water intake or you are in a period of prolonged fasting. If you are diabetic this could suggest a need to contact a healthcare professional urgently.

Expected Concentration Range
Reagent Strips for Urinalysis Concentration Linear Range

Test Item	Test unit	Expected Test Concentrations					
		neg.	TRACE	SLIGHTLY ELEVATED	MODERATELY ELEVATED	HIGHLY ELEVATED	
Ketone	mmol/L	neg.	0.5	1.5	4.0	8.0	16.0

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of the Reagent Strips for Urinalysis (URS) have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, Urine Reagent Strips (URS) have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATIONS OF PROCEDURE)
The accuracy of visually read strips depends on how well the color blocks on the chart are determined and how effectively the human eye can discern them. Assessing precision in such tests is challenging due to the inherent variability of human vision.
The ketone test area provides semi-quantitative results and reacts with acetoacetic acid in urine. This test does not react with beta-hydroxybutyric acid or acetone.

BIBLIOGRAPHY

1.Free, A.H and Free, H.M.: Urinalysis, Critical Discipline of Clinical Science. CRC Crit. Rev. Clin. Lab. Sci. 3(4): 481-531; (1972).
2.Yoder, J.Adams, E.C., and Free. H.M.: Simultaneous Screening for Urinary Occult Blood, Protein, Glucose and pH. Amer. J. Med Tech. 31:285; (1965).
3.Tietz, N.W.: Clinical Guide to Laboratory Tests; W.B. Saunders Company, (1976).
4.Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry 2nd Ed. 2205; (1994).
5.Shchersten, B. and Fritz, H.: Subnormal Levels of Glucose in Urine. JAMA 201:129-132; (1967).
6.McGarry, J.D.: Lilly Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28: 517-523 May, (1978).
7.Williamson, D.H.: Physiological ketoses, or Why Ketone Bodies? Postgrad. Med. J. (June Suppl.): 371-375: (1971).
8.Paterson, P. et al.: Maternal and Fetal Ketone Concentrations in Plasma and Urine. Lancet: 862-865; April 22, (1967).
9.Fraser, J. et al.: Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk. Clin. Chem. Acta II: 372-378; (1965).
10.Henry, J.B. et al.: Clinical Diagnosis and Management by Laboratory Methods, 16th Ed. Philadelphia: Saunders; (1979).
11.Hayashi A.et al:Journal of Japan Diabetes Society, 35,819,1992

SYMBOLS

IVD For in vitro diagnostic use	Use By
Consult instruction for use	LOT Lot number
Temperature limits for storage	Do not reuse
Contains sufficient for <n> test	

DTS TRADING INC.LTD
Floor 3, 43-45 St. John Street, London, United Kingdom EC1M 4AN
www.silextest.com

Yercon Diagnostic Co.,Ltd.
No.2 Building, LedongIndustrial Estate 3248 Century Ave. Tech.& Economic Development Zone, Changchun, 130032 Jilin,P.R.China

EC REP **CMC Medical Devices & Drugs S.L.**
C/ Horacio Lengo N 18, CP29006, Málaga-Spain

UK REP **SUNGO Certification Company Limited**
3rd floor, 70 Gracechurch Street, London. EC3V 0HR

CE 0197