

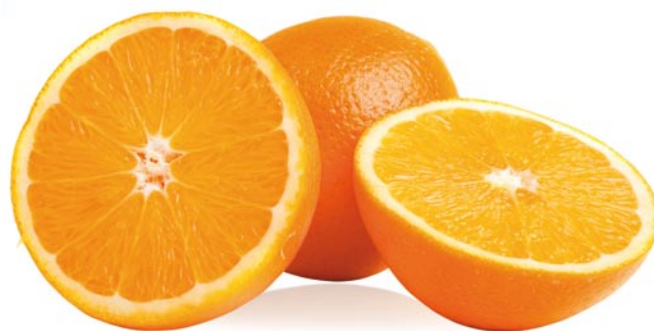


Urinalysis from Roche
What else...



Ascorbic acid - Vitamin C

Healthy, powerful and interfering



Be attentive

Consider that laboratories testing urine samples regularly found high amounts of ascorbic acid (≥ 400 mg/L) in a significant proportion of a routinely tested population¹

Identify the problem

Recognize the potential of ascorbic acid interference on urine test strips based on the peroxidase redox indicator test principle

Diminish adulterating influences

Eliminate the interference of ascorbic acid in urine test strips and prevent false negative results, which necessitate a retesting of patients or a more expensive microscopic examination

Find the answer

Do not miss the opportunity to detect symptoms of a potentially serious disease. Use ascorbic acid resistant urine test strips and detect immediately reliable and precise results

Solve the problem

Use iodate impregnated components to minimize the influence of ascorbic acid on blood and glucose test pads even under high levels of ascorbic acid (up to 750 mg/L)

Feel safe

Avoid potentially serious and costly consequences of false negative results for doctor and patient using iodate impregnated urine strips such as applied in Combur-Test®



Life needs answers

Ascorbic acid - Vitamin C

Specifications

Definition	Water soluble vitamin Chemical name: 2-oxo-L-threo-hexono-1,4-lactone-2,3-enediol A six-carbon compound, structurally related to glucose
Characteristics	Average half life: 10-20 days ² Elimination via the urine Renal threshold: plasma ascorbate concentrations of about 1.2-1.8 mg/dL corresponding to 60 mg doses per day ³⁻⁶ Average body tissue of an adult stores 1.2-2.0 g presumably maintained by taking 60-75 mg per day ^{3-5,7,8}
RDA*	90 mg per day for an adult male (set by the US Food and Nutrition Board in 2000) ⁹ Ingestion of 60 mg/day prevents the development of scurvy for 30-45 days with a diet lacking vitamin C ^{3,4,7,8}
Sources	Natural: fresh fruits and vegetables, e.g., oranges, lemons, grapefruits, watermelons, papayas, strawberries, green leafy vegetables, tomatoes, broccoli, etc. Synthetic: used in vitamin preparation, as preservative and antioxidant (e.g., E300, E301, E302, E303, E304), discoloration inhibitor, supplement in tablets, food additive
Consumption	The most frequently used vitamin supplement in the world ¹⁰ Worldwide annual demand in 1995 was evaluated at 60.000 tons ¹¹
Functions	Required for many metabolic functions in humans and cofactor for lots of metabolic reactions Potent reducing agent playing an important role in the antioxidant defense system, immune competence, and in strengthening resistance to infection Vitamin C prevents DNA mutations and might be important in treating certain cancers, heart disease and other chronic diseases
Interference	Ascorbic acid has the ability to prevent oxidization of indicator substances in urine test strips e.g. in peroxidase redox indicator test principle. Interference can be removed using iodate test components such as applied in Combur-Test®

* Recommended daily allowance

References

1. Nagel, D., Seiler, D., Hohenberger, E.F., Ziegler, M. (2006). Investigations of ascorbic acid interference in urine test strips. *Clin Lab*; 52:149-153.
2. Hellman, L., Burns, J.J. (1958). Metabolism of L-ascorbic acid-1-C14 in man. *J Biol Chem*; 230:923-930.
3. Baker, E.M., Hodges, R.E., Hood, J., Sauberlich, H.E., March, S.C. (1969). Metabolism of ascorbic-1-14C acid in experimental human scurvy. *Am J Clin Nutr*; 22:549-558.
4. Baker, E.M., Hodges, R.E., Hood, J., Sauberlich, H.E., March, S.C., Canham, J.E. (1971). Metabolism of 14C- and 3H-labeled L-ascorbic acid in human scurvy. *Am J Clin Nutr*; 24:444-454.
5. Kallner, A., Hartmann, D., Hornig, D. (1979). Steady-state turnover and body pool of ascorbic acid in man. *Am J Clin Nutr*; 32:530-539.
6. Pietrzik, K., Loew, D., Golly, I. (2008). Vitamin C. In: *Handbuch Vitamine. Für Prophylaxe, Therapie und Beratung*. Munich: Urban & Fischer, Elsevier GmbH; 173-185.
7. Hodges, R.E., Baker, E.M., Hood, J., Sauberlich, H.E., March, S.C. (1969). Experimental scurvy in man. *Am J Clin Nutr*; 22:535-548.
8. Hodges, R.E., Hood, J., Canham, J.E., Sauberlich, H.E., Baker, E.M. (1971). Clinical manifestations of ascorbic acid deficiency in man. *Am J Clin Nutr*; 24:432-443.
9. Food and Nutrition Board IoM, National Academies. (2008). Dietary Reference Intakes: *Recommended Intakes for Individuals, Vitamins*. Washington D.C.
10. Naidu, K.A. (2003). Vitamin C in human health and disease is still a mystery? *An overview. Nutr J*; 2:7.
11. Elvers, B., Hawkinds, S. (1996). *Ullmann's Encyclopedia of Industrial Chemistry*.

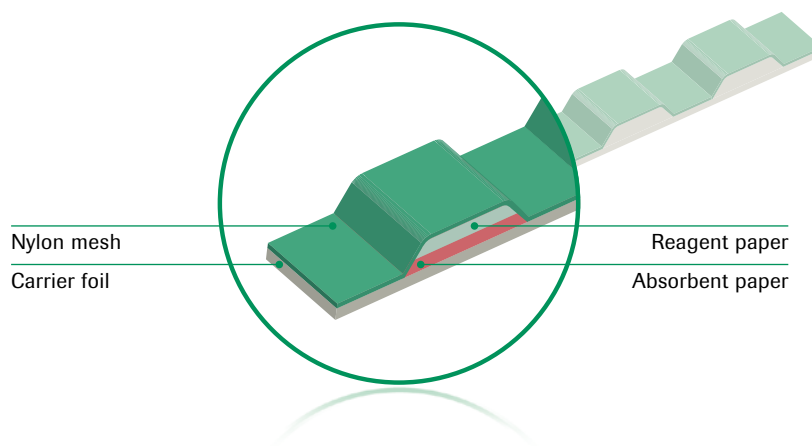
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Combur-Test® strip technology

Accurate, safe and protective



Be confident with the results

Count on protection and stable performance since sensitive areas are protected against contact, contamination or abrasion with the application of a nylon mesh

Have no doubts

Benefit from a uniform color development of test pads due to the usage of a fine porous nylon mesh

Believe in what you see

Be convinced of your diagnosis. Identify even slight pathological changes in the urine as a result of high sensitivity and clear color changes in the test area

Detect UTI for sure

Prevent false leukocyte results through improved reagent stability in the leukocyte test pad

Don't worry with ascorbic acid

Avoid patient revisits just because of vitamin C interference with iodate impregnated components protecting blood and glucose detection even from high levels of ascorbic acid

Rely on quality

Provide a basis for standardized diagnostic procedures with the application of high-quality urine test strips based on years of research and development



Life needs answers

Combur-Test® strip technology

Specifications

Nylon mesh fixing of components – unique sealing technology

No interference with glue components
Avoidance of contamination by protective function
Uniform liquid penetration and color development
No run over of reaction color

Stable reaction colors

Synchronized reaction time
All in 60 seconds

Sturdy plastic carrier foil

No splashing of urine, hygienic strip reading
Absorbent paper

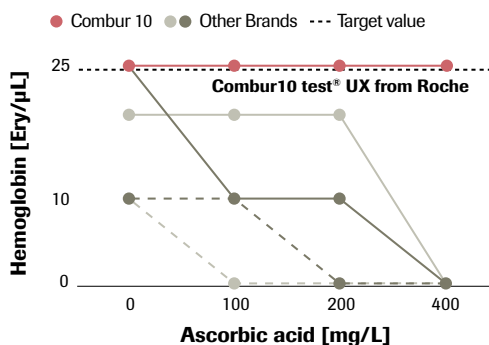
Iodate impregnated component

Protects blood and glucose test areas efficiently from ascorbic acid interference and false-negative results by oxidation even at high concentrations of vitamin C. When five common 10 parameter urine test strips are compared, Combur-Test® strip showed the highest resistance to ascorbic acid interference at higher hemoglobin or glucose concentrations¹:

Ascorbic acid interference in routine analysis

Hemoglobin

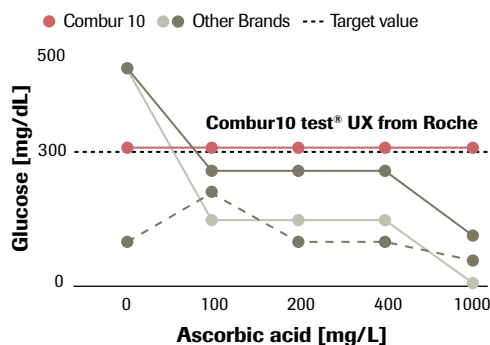
(Target value of 0.075 mg/dL = 25 Ery/ μ L)



At a hemoglobin concentration of 0.075 mg/dL, Combur-Test® strips were the only brand to register a correct analysis with ascorbic acid levels as high as 400 mg/L¹

Glucose

(Target value of 300 mg/dL)



At a glucose concentration of 300 mg/L, Combur-Test® strips were the only brand to show consistently accurate results, even at an ascorbic acid level of 1000 mg/L¹

Additional diazonium salt impregnated mesh

Improves reagent stability in the leukocyte test pad

Absorbent paper

Prevents chemical interference

Low test detection limits

High sensitivity and specificity
With no ascorbic acid present, only three out of five tests were able to detect pathologically relevant low hemoglobin and glucose concentrations of 0.03 mg/dL and 50 mg/dL, respectively¹

Reliable visual evaluation

Colorfast printing colors on the label
Reading of all test pads at once at a consistent reading time

References

1. Nagel, D., Seiler, D., Hohenberger, E.F., Ziegler, M. (2006). Investigations of ascorbic acid interference in urine test strips. *Clin Lab*; 52:149-153.

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Combur-Test® strips*

Precise, secure and easy



A quality choice for professional use.

Be on the safe side

Be independent from interferences of glued components as a result of a unique sealing technology

Be accurate

Detect even low concentrations of erythrocytes/hemoglobin (5-10 Ery/ μ L)

Be specific

Stop test area colors from running through an absorbent paper

Find an immediate answer to ascorbic acid

Avoid retesting and prevent false-negative results in glucose and blood even under high levels of ascorbic acid (up to 750 mg/L) with the application of an iodate impregnated mesh layer

Results you can trust

Reduce risk of false results through compensation of strong intrinsic urine coloration with the availability of a color compensation pad **

Choose the easy way

Ease analysis of results with a consistent reading time of 60 seconds for all parameters. Benefit from advanced and hygienic strip handling with possibility of reading tip down



cobas®

Life needs answers

Combur-Test® strips*

Technical specifications

Parameter combinations

Parameters

Name
Combur ² Test
Combur ³ Test
Combur ³ Test E
Combur ⁴ Test
Combur ⁵ Test
Combur ⁶ Test
Combur ⁷ Test
Combur ⁹ Test
Combur ¹⁰ Test

SG	pH	LEU	NIT	PRO	GLU	KET	UBG	BIL	BL
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Local availability might differ, please check with your local representative

Test construction

Composition

Reagent paper and underlying absorbent paper are sealed with a thin porous nylon mesh and fixed to a carrier foil

Nylon mesh features

Protection from strip contamination.
Homogenous liquid distribution and uniform color development.
Prevention from falsification of the color by glue

Practical detection limit

Detection limit is made such that even slight pathological changes in the urine are made visible by a clear color change in the test area

Vial construction

Composition

Protection of test strips from atmospheric humidity with drying agent filled cap

Color Scale

Special colorfast printing colors on the vial label allow easy and reliable evaluation of the results

* Combur Test® strips are marketed under Chemstrip® in United States and Canada.

** Only available for instrument tests

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Urisys[®] 1100 analyzer

Connected, compact and intuitive



Designed for doctor's office or ward.

Rule out your doubts

Minimize potential transcription errors through convenient data input via barcode reader

Learn at your pace

Conduct self-trainings anytime with existing training CD (available in English, German and Spanish)

Simplify your life

Eliminate manual documentation through export of data over host connection

Peace and calmness for everyone

Guarantee friendly environment with quiet operations

Be safe

Prevent unauthorized access and comply with accreditation requirements by an operator lock-out feature

Centralize initialization (cobas IT 1000 solution required)

Change general instrument settings for several analyzers from a central area



cobas[®]

Life needs answers

Urisys[®] 1100 analyzer

Technical specifications

Instrument	System	Semi-automated urine test strip analyzer																																												
	Type	Reflectance photometer																																												
	Measuring system	Wave lengths: 565 nm, 610 nm																																												
	Throughput	Approx. 50 test strips/h (normal mode) Approx. 100 test strips/h (fast mode)																																												
	Memory	100 results																																												
	User interface	Liquid Crystal Display (LCD), 2 lines of 24 characters																																												
	Printer	Thermal printer																																												
	Certificates	CE, UL, CUL																																												
	Physical dimensions	Width: 15.0 cm Depth: 29.0 cm Height: 9.5 cm																																												
	Weight	Approx. 0.8 kg																																												
Strips*	Urine test strips	Combur Test [®] Strips																																												
	Parameters																																													
		<table border="1"> <thead> <tr> <th>Name</th> <th>SG</th> <th>pH</th> <th>LEU</th> <th>NIT</th> <th>PRO</th> <th>GLU</th> <th>KET</th> <th>UBG</th> <th>BIL</th> <th>BL</th> </tr> </thead> <tbody> <tr> <td>Combur⁵ Test</td> <td></td> <td></td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td></td> <td></td> <td></td> <td>•</td> </tr> <tr> <td>Combur⁷ Test</td> <td></td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td></td> <td></td> <td>•</td> </tr> <tr> <td>Combur¹⁰ Test UX</td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> <td>•</td> </tr> </tbody> </table>	Name	SG	pH	LEU	NIT	PRO	GLU	KET	UBG	BIL	BL	Combur ⁵ Test			•	•	•	•				•	Combur ⁷ Test		•	•	•	•	•	•			•	Combur ¹⁰ Test UX	•	•	•	•	•	•	•	•	•	•
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Combur ⁷ Test		•	•	•	•	•	•			•																																				
Combur ¹⁰ Test UX	•	•	•	•	•	•	•	•	•	•																																				
Calibration	Control-Test M calibration strip																																													
Connectivity	System interfaces	5-pin DIN socket for keyboard and barcode reader Serial interface to PC and host																																												
	Host protocols	Unidirectional, bidirectional or ASTM (selectable)																																												
Accessories	Sample identification	Sample ID via keyboard entry or barcode reader																																												
	Type	Barcode reader, keyboard																																												
	Supported barcode types	Code 39, Code 128, NW 7 (Codabar), ITF (Interleaved 2 of 5)																																												

* Combur Test[®] strips are marketed under Chemstrip[®] in United States and Canada.
Combur⁷ Test[®] and Combur⁵ Test[®] are not available in some countries.

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