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 population.

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®.

Roche
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
- **Average body tissue of an adult stores** 1.2-2.0 g presumably maintained by taking 60-75 mg per day \(^3\) \(^5\) \(^8\)

### 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\(^8\)

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*Recommended daily allowance*

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### References

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Roche Diagnostics Ltd.
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Switzerland
www.roche.com
cobas u 411 analyzer
Fast, flexible and competent

Considered for workloads of approximately 80 samples per day … and what it takes to further optimize workflow

Define your own pace
Impact workload with flexibility of continuous test strip loading

Judge at one glance
Differentiate quickly normal and abnormal results or samples to sieve for microscopy examination with availability of user-definable flags

Consolidate your analysis
Work parallel on the cobas u 411 analyzer and its sediment terminal as a result of a consolidated work- and dataflow for strip analysis and microscopy. Ease documentation and improve overview of patient records with single print-out for strip and microscopic information

Ensure comparability
Standardize microscopy result reporting with selection of pre-defined result ranges on the sediment terminal

Ease workload
Reduce manual work with sample identification via barcode reader or download from host, electronic transfer of sediment work list and printable QC results

Secure your investment
Stay easily up-to-date with simplified software upload via USB slot
# Technical specifications

## Instrument System
- **Type**: Semi-automated urine test strip analyzer
- **Type**: Reflectance photometer
- **Measuring system**: Wave lengths: 470 nm, 555 nm, 620 nm
- **Throughput**: Approx. 600 test strips/h
- **Memory**: 1000 sample results, 300 control results (3 levels)
- **User interface**: LCD touch screen (90x120 mm)
- **Printer**: Thermal printer
- **Certificates**: CE, UL, CB, CUL
- **Physical dimensions**
  - Width: 42.5 cm
  - Depth: 34.0 cm
  - Height: 26.0 cm
- **Weight**: Approx. 12 kg

## Strips*
- **Test strips**: Combur® Test® M
- **Parameters**: Specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood (erythrocytes/hemoglobin), color

## Connectivity
- **System interfaces**: Serial interfaces to barcode reader, sediment terminal and PC/Host; USB Slot
- **Host protocols**: ASTM + and Urivsys® 2400 ASTM
- **Sample identification**: Sample ID via manual entry, barcode reader or download from host

## Accessories
- **Type**: Barcode reader, Sediment Terminal
- **Supported barcode types**: Code 39, Code 128, NW 7 (Codabar), ITF (Interleaved 2 of 5)

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

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Roche Diagnostics Ltd.
CH-6343 Rotkreuz
Switzerland
www.roche.com
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.
Combur-Test® strip technology
Specifications

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nylon mesh fixing of components – unique sealing technology</td>
<td>No interference with glue components, Avoidance of contamination by protective function, Uniform liquid penetration and color development, No run over of reaction color</td>
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<td>Stable reaction colors</td>
<td>Synchronized reaction time, All in 60 seconds</td>
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<tr>
<td>Sturdy plastic carrier foil</td>
<td>No splashing of urine, hygienic strip reading, Absorbent paper</td>
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<tr>
<td>Iodate impregnated component</td>
<td>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 concentrations^1:</td>
</tr>
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</table>

### Ascorbic acid interference in routine analysis

#### Hemoglobin
(Target value of 0.075 mg/dL = 25 Ery/µL)

- 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/L^1.

#### Glucose
(Target value of 300 mg/dL)

- At a glucose concentration of 300 mg/dL, Combur-Test® strips were the only brand to show consistently accurate results, even at an ascorbic acid level of 1000 mg/L^1.

### 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, respectively^1.

### Reliable visual evaluation
Colorfast printing colors on the label, Reading of all test pads at once at a consistent reading time

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References

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 an unique sealing technology

Be accurate
Detect even low concentrations of erythrocytes/hemoglobin (5-10 Ery/μL)

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
## Combur-Test® strips*
### Technical specifications

### Parameter combinations

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Name</th>
<th>SG</th>
<th>pH</th>
<th>LEU</th>
<th>NIT</th>
<th>PRO</th>
<th>GLU</th>
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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.

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* Combur Test® strips are marketed under Chemstrip® in United States and Canada.
** Only available for instrument tests.