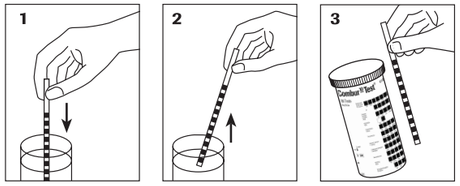
Combur[10] Test M

cobas®

REF 11379208

100



English

Intended use: Ten-patch test strip for the semi-quantitative determination of specific gravity, pH, leukocytes, nitrite, protein, glucose, ketone bodies, urobilinogen, bilirubin and blood in urine with the Miditron M, Miditron Junior II, **cobas u** 411 and Urisys 1800 urinalysis instruments.

For professional use only.

Summary:

Urine test strips are used to measure certain constituents in urine which are significant of renal, urinary, hepatic and metabolic disorders.

The reagents provided with the Combur 10 Test M test strips are identical with the proven test papers of the Combur-Test product line for visual reading.

Test principle

Specific gravity (SG): The test detects the ion concentration of the urine. In the presence of cations, protons are released by a complexing agent and produce a color change in the indicator bromothymol blue from blue via blue-green to yellow.

pH: The test paper contains the indicators methyl red, phenolphthalein and bromothymol blue and reacts specifically with H^+-ions. The most frequent pH values of fresh urine from healthy subjects lie between 5 and 6.

Leukocytes (LEU): Leukocytes in urine are detected by the action of esterase, present in granulocytic leukocytes, which catalyzes the hydrolysis of an indoxylcarbonic acid ester to indoxyl. The indoxyl formed reacts with a diazonium salt to produce a purple color.

Nitrite (NIT): The test is based on the principle of the Griess test and is specific for nitrite. The reaction reveals the presence of nitrite and hence indirectly nitrite-forming bacteria in the urine by a pink-to-red coloration of the test patch. Even a slight pink coloration is indicative of significant bacteriuria.

Protein (PRO): The test is based on the principle of the protein error of a pH indicator. It is particularly sensitive to albumin. An elevated pH (up to 9) does not affect the test.

Glucose (GLU): The glucose determination is based on the specific glucose-oxidase/peroxidase reaction (GOD/POD method). The test is independent of the pH and specific gravity of the urine and is not affected by the presence of ketone bodies.

Ketone bodies (KET): This test is based on the principle of Legal's test and is more sensitive to acetoacetic acid than to acetone.

Urobilinogen (UBG): A stable diazonium salt reacts almost immediately with urobilinogen to give a red azo dye. The test is specific for urobilinogen and is not susceptible to the interfering factors known to affect the Ehrlich's test.

Bilirubin (BIL): The test is based on the coupling of bilirubin with a diazonium salt. Even the slightest pink coloration constitutes a positive, i.e. pathologic, result. Other urinary constituents produce a more or less intense yellow coloration.

Blood (ERY/Hb): The peroxidase-like action of hemoglobin and myoglobin specifically catalyzes the oxidation of the indicator by means of the organic hydroperoxide contained in the test paper to give a blue-green coloration.

Compensation area (COMP): This white area, which is not impregnated with reagents, allows instrumental compensation for the intrinsic color of the urine while testing leukocytes, nitrite, protein, glucose, ketone bodies, urobilinogen, bilirubin and erythrocytes.

Reagents:

Each test contains per 1 cm^2 test patch area the following:

Specific gravity: Ethyleneglycol-bis(diaminoethylether)tetraacetic acid 182.8 µg; bromothymol blue 36 µg

pH: Bromothymol blue 13.9 µg; methyl red 1.2 µg; phenolphthalein 8.6 µg

Leukocytes: Indoxylcarbonic acid ester 15.5 µg; methoxymorpholinobenzene diazonium salt 5.5 µg

Nitrite: 3-hydroxy-1,2,3,4-tetrahydro-7,8-benzoquinoline 33.5 µg; sulfanilamide 29.1 µg

Protein: 3',3'',5',5''-tetrachlorophenol-3,4,5,6-tetrabromosulfophthalein 13.9 µg

Glucose: 3,3',5,5'-tetramethylbenzidine 103.5 µg; GOD 6 U, POD 35 U

Ketone bodies: Sodium nitroprusside 157.2 µg

Urobilinogen: 4-methoxybenzene-diazonium-tetrafluoroborate 67.7 µg

Bilirubin: 2,6-dichlorobenzene-diazonium-tetrafluoroborate 16.7 µg

Blood: 3,3',5,5'-tetramethylbenzidine 52.8 µg; 2,5-dimethyl-2,5-dihydroperoxyhexane 297.2 µg

Precautions and warnings:

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

The stopper of the test strip vial contains a non-toxic silicate-based desiccant which must not be removed. If ingested by accident, drink large quantities of water.

Reagent handling:

Test strips are ready for use.

Storage and stability:

Store the package at 2-30 °C. The test strips are stable up to the expiration date specified on the box, when stored in the original container.

Do not use the test strip after the specified expiration date.

Tightly re-cap the container immediately after removing a test strip.

Specimen collection and preparation:

For specimen collection and preparation only use suitable tubes or collection containers.

Use fresh urine that has not been centrifuged. The urine specimen should not stand for more than 2 hours before testing. In case of longer standing, mix before use.

Use only clean, well-rinsed vessels to collect urine.

Do not add preservatives to the urine.

Materials provided

- REF 11379208, package with 100 test strips

Materials required (but not provided)

- Miditron M, Miditron Junior II, **cobas u** 411 or Urisys 1800 urinalysis analyzer
- REF 11379194263, Control-Test M calibration strip
- Controls as indicated below
- General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document. Refer to the appropriate operator´s manual for instrument-specific instructions.

1. Use fresh urine that has not been centrifuged. Thoroughly mix the urine sample. The sample should be at room temperature when the test is performed and should not have been standing for more than 2 hours.
2. Take a test strip out of the container. Close the container again with the original desiccant stopper immediately after removal of the strip. This is important as otherwise the test areas may become discolored due to moisture and incorrect results may be obtained.
3. Briefly (about 1 second) dip the test strip into the urine making sure that all test areas are moistened.
4. When withdrawing the test strip, wipe the edge against the rim of the vessel to remove excess urine
5. Immediately after doing this, insert the test strip in the instrument as directed in the operator's manual. If the test is to be read visually, wait 60 seconds (60-120 seconds for the leukocyte test area) and then compare the reaction colors of the test areas with the colors on the label and assign always the value of the nearest color block. Compare the blood test area with both color scales as separate color scales are given for erythrocytes and hemoglobin.

Any color changes appearing only along the edges of the test areas, or developing after more than 2 minutes, do not have any diagnostic significance.

Calibration

Control-Test M calibration strips are used for the calibration of the photometer unit of the instrument. For details see operator's manual of the instrument.

Quality control:

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

For quality control, use commercially available urine controls, or other suitable control material.

Important note for reporting results (for professional users).
According to the regulations from the German Medical Association for quality assurance of medical laboratory analyses dated 11/23/2007, the decision to classify a laboratory test result to either part B1 or B2 depends on the way the test results are expressed in the report (scale level).

The specification in the report defines whether a determination is quantitative or qualitative and therefore which legal requirements for quality assurance (B1 for quantitative or B2 for qualitative) need to be followed. Examples of qualitative characteristics include titer levels, concentrations/color ranges (+ to +++) or a defined range of values. A characteristic of a quantitative value is when the value has a corresponding measured unit value.

Calculation

After the test strip has been accepted by the instrument, it is measured by means of reflectance photometry. The results are automatically calculated and printed on the report form in terms of "normal", "neg.", "pos." or as concentration values.

Like the results obtained by visual color comparison, each value appearing on the printout corresponds to a definite concentration range. However, as a result of the differing spectral sensitivities of the human eye and the optical system of the instrument, it is not always possible to obtain precise agreement between the values obtained by visual reading and those obtained with the instrument.

Limitations - interference

Specific gravity: On visual reading, 0.005 should be added to the result if the urine has a pH of 7 or more. The instruments automatically carry out this correction. In the presence of small amounts of protein (100-500 mg/dL) or ketoacidosis the specific gravity measurements tend to be elevated.

An increase in the specific gravity due to glucose concentrations > 1000 mg/dL (> 56 mmol/L) is not indicated by the test.

Leukocytes: Formaldehyde (stabilizer) and medication with imipenem, meropenem and clavulanic acid may cause false-positive reactions. If the urine specimen has a pronounced intrinsic color (for example due to the presence of bilirubin or nitrofurantoin), the reaction color may be intensified due to an additive effect. Urinary protein excretions in excess of 500 mg/dL and urinary glucose excretions in excess of 1 g/dL may diminish the intensity of the reaction color, as can cephalexin and gentamicin if administered in high daily doses, or boric acid if used as a preservative.

Nitrite: Prolonged urinary retention in the bladder (4-8 hours) is essential in order to obtain an accurate result. Administration of antibiotics or chemical drugs should be discontinued 3 days before the test. Large amounts of ascorbic acid decrease the sensitivity of the test. *Attention:* Nitrogen oxides present in the atmosphere may have an influence on the stability of the nitrite test pad.

Protein: False-positive readings may be found after infusion of polyvinylpyrrolidone (blood substitute), or when the urine collection vessel contains chlorohexidine or traces of disinfectants possessing quaternary ammonium groups.

Glucose: The effect of ascorbic acid has been largely eliminated so that at glucose concentrations of 100 mg/dL and above even high ascorbic acid concentrations are not likely to give false-negative results.

Ketone bodies: Phenylketones and phthalein compounds produce red colors on the test patch; they are, however, quite distinct from the violet colors produced by ketone bodies and can lead to false-positive results. Captopril, mesna (2-Mercaptoethanesulfonic acid sodium salt) and other substances containing sulfhydryl groups may produce false-positive results.

Urobilinogen: Nitrite concentrations above 5 mg/dL or formaldehyde (stabilizer) above 200 mg/dL may cause a decrease in the color reaction.

Bilirubin: Large amounts of ascorbic acid lower the sensitivity of the test.

Do not expose urine specimens to sunlight as this induces oxidation of bilirubin and urobilinogen and hence leads to artificially low results for these two parameters.

Drugs that turn red in an acid environment (e.g. phenazopyridine) may produce false-positive readings or reddish colorations on the test patches for nitrite, protein, urobilinogen and bilirubin.

Blood: The values appearing on the printout refer to intact erythrocytes. At concentrations of about 5-50 Ery/µL, significant hemolysis (such as may occur on prolonged standing of the urine) leads to values which are higher than the corresponding concentrations given for intact erythrocytes. Ascorbic acid has virtually no effect on the test. In women the test for blood may be falsified from 3 days before to 3 days after a period. It is therefore advisable not to perform the test during this time. After physical activity, e.g. strenuous jogging, raised values for erythrocytes and protein may occur without being signs of disease.

False-positive readings for erythrocytes, glucose and protein can result from residues of strongly oxidizing disinfectants in the specimen collection vessel.

Knowledge of the effects of drugs or their metabolites upon the individual tests is not yet complete. In doubtful cases, it is therefore advisable to repeat the test after discontinuing a particular drug.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Expected values:

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

For Miditron M, Miditron Junior II, **cobas u** 411 and Urisys 1800 see Appendix 1.

For visual reading see color label on the test strip vial.

Specific performance data

For the instruments see Appendix 2.

The values specified for the analytical sensitivity are defined as the concentration of the analyte which leads to a positive result in > 90 % of the examined urines. The method comparison data for Miditron M are based on the comparison with visual reading, the data for Miditron Junior II, **cobas u** 411 and Urisys 1800 are based on the comparison with Miditron M. The values for NEG and POS indicate the rate of concordant negative or positive results. For performance characteristics using visual reading of the test strip see Method Sheet of Combur[10] Test, REF 04510062.

Appendices

Appendix 1

Test strip parameter	Expected values	Result values
SG	1.016 – 1.022	1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030
pH	4.8 – 7.4	5, 6, 6.5, 7, 8, 9
LEU	< 10 Leu/µL	NEG, 25, 100, 500 Leu/µL
NIT	–	NEG, POS
PRO	< 10 mg/dL < 0.1 g/L	NEG, 25, 75, 150, 500 mg/dL NEG, 0.25, 0.75, 1.5, 5.0 g/L
GLU	< 30 mg/dL < 1.7 mmol/L	NORM, 50, 100, 300, 1000 mg/dL NORM, 3, 6, 17, 56 mmol/L
KET	< 5 mg/dL < 0.5 mmol/L	NEG, 5, 15, 50, 150 mg/dL NEG, 0.5, 1.5, 5, 15 mmol/L
UBG	< 1 mg/dL < 17 µmol/L	NORM, 1, 4, 8, 12 mg/dL NORM, 17, 68, 135, 203 µmol/L
BIL	< 0.2 mg/dL < 3.4 µmol/L	NEG, 1, 3, 6 mg/dL NEG, 17, 50, 100 µmol/L
ERY	0 – 5 Ery/µL	NEG, 10, 25, 50, 150, 250 Ery/µL

Appendix 2

Test strip parameter	Analytical sensitivity		
	Miditron M	Miditron Junior II	**cobas u** 411 Urisys 1800
SG	N. A.[a)]	N. A.	N. A.
pH	N. A.	N. A.	N. A.
LEU	20 Leu/µL	25 Leu/µL	20 – 25 Leu/µL
NIT	0.05 mg/dL	0.05 mg/dL	0.05 – 0.07 mg/dL
PRO	18 mg/dL	18 mg/dL	12 – 18 mg/dL
GLU	40 mg/dL	40 mg/dL	30 – 40 mg/dL
KET	5 mg/dL	5 mg/dL	3 – 6 mg/dL
UBG	1.0 mg/dL[b)]	1.0 mg/dL	1 – 1.6 mg/dL
BIL	0.5 mg/dL	0.5 mg/dL	0.4 – 0.6 mg/dL
ERY	5 Ery/µL	5 Ery/µL	5 – 10 Ery/µL (0.012 – 0.030 mg/dL)

a) not applicable

b) Detected in 57 % of the samples

Appendix 3

Test strip parameter	Method comparison		
	Miditron M	Miditron Junior II	**cobas u** 411 Urisys 1800
SG	Ident.: > 57 %	Ident.: > 75 %	Ident.: > 73 %
pH	Ident.: > 72 %	Ident.: > 86 %	Ident.: > 82 %
LEU	NEG: > 70 % POS: > 97 %	NEG: > 95 % POS: > 78 %	NEG: > 94 % POS: > 88 %
NIT	NEG: > 97 % POS: > 85 %	NEG: > 98 % POS: > 89 %	NEG: > 98 % POS: > 99 %
PRO	NEG: > 79 % POS: > 93 %	NEG: > 86 % POS: > 91 %	NEG: > 93 % POS: > 81 %
GLU	NEG: > 99 % POS: > 90 %	NEG: > 99 % POS: > 99 %	NEG: > 99 % POS: > 98 %
KET	NEG: > 97 % POS: > 73 %	NEG: > 96 % POS: > 92 %	NEG: > 97 % POS: > 95 %
UBG	NEG: > 93 % POS: > 92 %	NEG: > 97 % POS: > 97 %	NEG: > 97 % POS: > 96 %
BIL	NEG: > 93 % POS: > 74 %	NEG: > 96 % POS: > 85 %	NEG: > 92 % POS: > 94 %
ERY	NEG: > 77 % POS: > 97 %	NEG: > 91 % POS: > 89 %	NEG: > 97 % POS: > 88 %

For further information, please refer to the appropriate operator's manual for the instrument concerned, and the Method Sheets of all necessary components.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

References

REF 12254620, Compendium Visual Urinalysis with Test Strips

CE

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

Roche

05868998001
2016-04 **V 2.0**