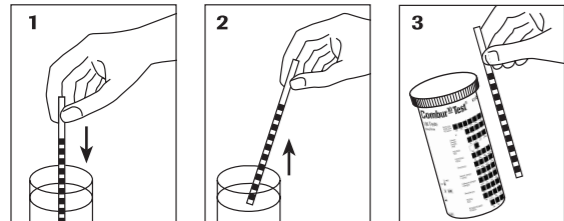


# Combur<sup>10</sup> Test UX cobas<sup>®</sup>

REF	▽	SYSTEM
11544373191	100	Urisys 1100, visual reading
11544373173	100	
11544373049	100	
11544373170	100	
11544373243	100	
11544373171	100	
11544373005	100	
11544373053	100	
11544373343	100	



## English

### Intended use

Ten-parameter test strip for the semi-quantitative determination of specific gravity (SG), pH, leukocytes (LEU), nitrite (NIT), protein (PRO), glucose (GLU), ketones (KET), urobilinogen (UBG), bilirubin (BIL) and blood (ERY/Hb) in urine for evaluation by reflectance photometry with Urisys 1100 analyzer and by visual reading.

For professional use only.

Not for self-testing.

### Summary

Combur<sup>10</sup> Test UX test strips are used to measure certain constituents in urine which are significant of renal, urinary, hepatic and metabolic disorders.

### 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<sup>+</sup>ions.

**Leukocytes (LEU):** The test reveals the presence of granulocyte esterases. These esterases cleave an indoxyl ester, and the indoxyl so liberated reacts with a diazonium salt to produce a violet dye.

**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 parameter. 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.

**Glucose (GLU):** The glucose determination is based on the specific glucose-oxidase/peroxidase reaction (GOD/POD method).

**Ketone (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.

**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, glucose, protein, ketone bodies, urobilinogen and bilirubin.

### Reagents

Each test contains per 1 cm<sup>2</sup> reactive paper area the following:

**Specific gravity:** Ethyleneglycol-bis(diaminoethyl ether)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-tetrabromosulphophthalein 13.9 µg  
**Glucose:** 3,3',5,5'-tetramethylbenzidine 103.5 µg; GOD 6 U, POD 35 U

**Ketone:** 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

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

Do not add preservatives to the urine.

Use fresh urine that has not been centrifuged.<sup>1</sup> The urine specimen should not stand for more than 2 hours before testing. For specimen collection and preparation only use suitable tubes or collection containers, as false-positive readings, particularly for glucose and protein, can result from residues of detergent or strongly oxidizing disinfectants in the specimen collection vessel.<sup>1</sup>

Using midstream urine is recommended to avoid contamination by commensal urethral flora in both sexes.<sup>1</sup> 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.<sup>1</sup> Vaginal secretion or menstrual blood may contaminate urine from females.<sup>1</sup>

Diagnosis or therapy should never be based on one test result alone but should be established in the context of all other medical findings. In doubtful cases, it is therefore advisable to repeat the test after discontinuation of the medication.

### Materials provided

For details see material table in header section.

### Materials required (but not provided)

- [REF] 03617548001, Urisys 1100 urine analyzer
- [REF] 11379194263, Control-Test M calibration strips
- Quality controls
- General laboratory equipment

### Assay

For optimum performance of the visual reading assay follow the directions given in this document. Refer to the appropriate operator's manual for analyzer-specific instructions.

- 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.
- 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 some test areas may become discolored due to moisture and incorrect results may be obtained. Do not use discolored strips. In case of doubt perform a quality control test.
- Briefly (about 1 second) dip the test strip into the urine making sure that all test areas are moistened.
- When withdrawing the test strip, wipe the edge against the rim of the vessel to remove excess urine.
- 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 (up to 120 seconds for the leukocyte test area for not clearly assignable results) 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.

### Quality control

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

Following quality controls are recommended to use:

- Bio-Rad Liquichek Urinalysis Control
- KOVA-Trol<sup>®</sup>
- KOVA Liqua-Trol<sup>®</sup>

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.

### 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 semi quantitative 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

The following drugs and substances were tested with Combur-Test technology test strips in the latest interference study from November 2013.

Therapeutic drugs		Endogenous substances
Acetaminophen	Hydrochlorothiazide	Ammonium
N-Acetylcysteine	Hydroxychloroquine	Calcium chloride
Amoxicillin	Ibuprofen	Creatinine

Therapeutic drugs		Endogenous substances
Amlodipine besylate	Levodopa	α-D(+)-Glucose
Ascorbic acid	Levothyroxine	Hemoglobin
Cefoxitin	Lisinopril	β-3-Hydroxybutyrate
Cetirizine	Methyldopa	Immunoglobulin G
Cotrimoxazol	Ofloxacin	Nitrite
Cyclosporine	Phenazopyridine	Urea
Furosemide	Salicylic acid	Uric acid
Gentamycin sulfate	Tetracycline	Urobilinogen
		pH 4.5-9

In case of doubt, please check if a repetition is reasonable after discontinuation of the medication.

For more detailed information on interfering substances, please contact our support via the Roche homepage [www.roche.com/contact.htm](http://www.roche.com/contact.htm).

### Common limitations

**Specific gravity:** In the presence of small amounts of protein (> 100 mg/dL) or ketoacids the specific gravity measurements tend to be elevated.<sup>2</sup> High levels of glucose or other abnormal substances can also result in high SG values.<sup>3</sup>

**Leukocytes:** Formaldehyde (stabilizer) and medication with imipenem, meropenem and clavulanic acid may cause false-positive reactions.<sup>4</sup> 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.<sup>1</sup> Urinary protein excretions in excess of 500 mg/dL and urinary glucose excretions in excess of 3 g/dL<sup>5</sup> may diminish the intensity of the reaction color, as may cephalalexin and drugs belonging to the group of cephalosporins, if administered in high daily doses, or boric acid if used as a preservative.<sup>1</sup>

**Nitrite:** Prolonged urinary retention in the bladder (4-8 hours) is essential in order to obtain an accurate result.<sup>1</sup> Administration of antibiotics or chemical drugs should be discontinued 3 days before the test.<sup>6</sup> More than 80 % of all bacteria responsible for urinary tract infections are gram-negative rods (E.coli, Klebsiella, Enterobacter and Proteus species).<sup>7</sup> Most gram-negative bacteria have the ability to reduce urinary nitrate to nitrite and can therefore be detected indirectly with the test strips.<sup>1</sup> Normal nutrition as a rule ensures a sufficiently high content of nitrate in the urine for the detection of bacteria.<sup>8</sup> Some common uropathogens, e.g. Enterococcus spp. and Staphylococcus spp. (5-15 % of bacteria responsible for urinary tract infections),<sup>7</sup> do not reduce urinary nitrate to nitrite and will therefore not be detected whatever their urinary concentration.<sup>1</sup> False-negative results may occur as a result of strong diuresis with frequent voiding of urine, insufficient intake or too short retention of urine in the bladder.<sup>1</sup> Large amounts of ascorbic acid decrease the sensitivity of the test.<sup>1</sup> Drugs that turn red in an acid environment (e.g. phenazopyridine) may produce false-positive readings or reddish colorations on the test parameter for nitrite.<sup>9</sup> Attention: Nitrogen oxides present in the atmosphere may have an influence on the stability of the nitrite test parameter.<sup>9</sup>

**Protein:** False-positive readings may be found after infusion of polyvinylpyrrolidone (blood substitute), or when the urine collection vessel contains chlorhexidine or traces of disinfectants possessing quaternary ammonium groups.<sup>1</sup>

**Glucose:** The effect of ascorbic acid has been largely eliminated so that glucose concentrations of 100 mg/dL and ascorbic acid concentrations up to 400 mg/L are not likely to give false-negative results.<sup>10</sup>

**Ketones:** Phenylketones and phthalein compounds produce red colors on the test parameter; they are, however, quite distinct from the violet colors produced by ketone bodies and can lead to false-positive results.<sup>11</sup> Captopril,<sup>1</sup> mesna (2-mercaptoethanesulfonic acid sodium salt)<sup>12</sup> and other substances containing sulfhydryl groups may produce false-positive results.

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

reaction.<sup>5,13</sup> Drugs that turn red in an acid environment (e.g. phenazopyridine) may produce false-positive readings or reddish colorations on the test parameter for urobilinogen.<sup>9</sup>

**Bilirubin:** Large amounts of ascorbic acid lower the sensitivity of the test.<sup>14</sup> Drugs that turn red in an acid environment (e.g. phenazopyridine) may produce false-positive readings or reddish colorations on the test parameter for bilirubin.<sup>9</sup>

**Blood/ERY:** Ascorbic acid has virtually no effect on the test.<sup>15</sup> 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.<sup>16</sup>

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

### Expected values (visual reading and instrumental reading with Urisys 1100)

Based on literature. Current medical guidelines are leading.

Parameter	Expected values	Additional information
SG	1.003-1.035 g/mL <sup>17</sup>	
pH	5-9 <sup>18</sup>	
LEU	< 10 LEU/µL <sup>1</sup>	10-100 LEU/µL borderline <sup>1</sup>
NIT	< 1 µmol (< 0.005 mg/dL) <sup>19</sup>	A positive result is indicative of urinary tract infection, but a negative result does not rule out UTI. <sup>9</sup>
PRO	≤ 30 mg/dL <sup>20</sup>	> 30 mg/dL proteinuria <sup>20</sup>
GLU	< 25 mg/dL, < 1.4 mmol/L <sup>21</sup>	For daytime urine
KET	≤ 2 mg acetoacetic acid/dL <sup>17</sup>	Borderline > 2 mg up to 50 mg acetoacetic acid/dL <sup>17</sup>
UBG	< 1 mg/dL <sup>a),8</sup>	1-4 mg/dL borderline (4 mg/dL corresponding to 2+, indicating liver damage) <sup>8</sup>
BIL	neg. <sup>17</sup>	When this method is used, normal urine contains no detectable bilirubin.
ERY	< 18 ERY/µL (< 3 ERY/HPF) <sup>17</sup>	Hematuria ≥ 18 ERY/µL (≥ 3 ERY/HPF) <sup>22,23</sup>
	Conversion factor 5.8 to translate chamber counting HPF into µL <sup>1</sup>	

a) Values displayed by the instrument are rounded compared to conventional values.

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

### Result values (visual reading)

Parameter	Result values
SG	1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 g/mL
pH	5, 6, 7, 8, 9
LEU	neg., ~ 10-25, ~ 75, ~ 500 LEU/µL neg., 1+, 2+, 3+
NIT	neg., pos.
PRO	neg., 30, 100, 500 mg/dL neg., 0.3, 1, 5 g/L neg., 1+, 2+, 3+
GLU	norm., 50, 100, 300, 1000 mg/dL norm., 2.8, 5.5, 17, 56 mmol/L norm., 1+, 2+, 3+, 4+



Parameter	Result values
KET	neg., 10, 50, 150 mg/dL neg., 1, 5, 15 mmol/L neg., 1+, 2+, 3+
UBG	norm., 1, 4, 8, 12 mg/dL norm., 17, 68, 135, 203 µmol/L norm., 1+, 2+, 3+, 4+
BIL	neg., 1, 3, 6 mg/dL neg., 17, 50, 100 µmol/L neg., 1+, 2+, 3+
ERY/Hb	neg., ~ 5-10, ~ 25, ~ 50, ~ 250 ERY/µL neg., 1+, 2+, 3+, 4+

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

#### Specific performance data (visual reading)

Representative performance data are given below. Results obtained in individual laboratories may differ. The values for neg. and pos. indicate the proportion of concordant negative or positive results.

The values specified for the **limit of detection** are defined as the concentration of the analyte which leads to a positive result in ≥ 90 % of the examined urines. For specific gravity and pH, limit of detection is not applicable (N.A.).

The **method comparison** data for visual reading are based on the comparison with the instrument **cobas u 411** with Combur<sup>10</sup> Test M using at least 210 clinical samples per parameter. All concentration ranges were covered.

Parameter	Limit of detection	Method comparison <sup>b)</sup>
SG	N.A.	ident. <sup>c)</sup> : 100 %
pH	N.A.	ident.: 94 % pH 5-6: ≥ 100 %, pH 8-9: ≥ 100 %
LEU	10 LEU/µL	neg.: 100 %, pos.: 98 %
NIT	0.05 mg/dL	neg.: 100 %, pos.: 100 %
PRO	14 mg/dL	neg.: 100 %, pos.: 98 %
GLU	30 mg/dL	neg.: 96 %, pos.: 100 %
KET	5 mg/dL	neg.: 100 %, pos.: 90 %
UBG	1.6 mg/dL	neg.: 100 %, pos.: 96 %
BIL	0.4 mg/dL	neg.: 100 %, pos.: 97 %
ERY/Hb	6 ERY/µL	neg.: 99 %, pos.: 96 %

b) The values for neg. and pos. indicate the proportion of concordant negative or positive results.

c) for ± 1 colour block

#### Precision (visual reading)

Precision experiments comprised an assessment of repeatability (within-run precision) and intermediate precision using control material.

**Repeatability** was checked for 3 test strip lots in 3 separate runs with 21 measurements per run and lot.

**Intermediate precision** was assessed for 3 test strip lots over 20 days with 1 run per day and four-fold measurements per used control. In total there were 80 measurements performed per used control and test strip lot. Data refers to the minimal performance obtained with 1 lot. For details see table below.

Parameter	Control <sup>d)</sup>	Precision		Intermediate precision	
		Result	Exact agreement	Result	Exact agreement
SG	Level 1	1.015 mg/dL	100 %	1.015 mg/dL	80 %
	Level 2	1.010 mg/dL	100 %	1.010 mg/dL	80 %
pH	Level 1	5	100 %	6	60 %
	Level 2	7	100 %	7	100 %
LEU	Level 1	neg.	100 %	neg.	100 %
	Level 2	~ 10-25 LEU/µL	100 %	~ 10-25 LEU/µL	95 %
NIT	Level 1	neg.	100 %	neg.	100 %
	Level 2	pos.	100 %	pos.	100 %
PRO	Level 1	neg.	100 %	neg.	100 %
	Level 2	100 mg/dL	100 %	100 mg/dL	80 %
GLU	Level 1	norm.	100 %	norm.	100 %
	Level 2	1000 mg/dL	100 %	1000 mg/dL	100 %
KET	Level 1	neg.	100 %	neg.	100 %
	Level 2	150 mg/dL	100 %	150 mg/dL	76 %
UBG	Level 1	norm.	100 %	norm.	100 %
	Level 2	8 mg/dL	76 %	8 mg/dL	95 %
BIL	Level 1	neg.	100 %	neg.	100 %
	Level 2	6 mg/dL	100 %	6 mg/dL	100 %
ERY/Hb	Level 1	neg.	100 %	neg.	100 %
	Level 2	~ 250 ERY/µL	100 %	~ 250 ERY/µL	100 %

d) Bio-Rad Liquichek Urinalysis Control

#### Result values (instrumental reading with Urisys 1100)

Parameter	Result values
SG	1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 g/mL
pH	5, 6, 6.5, 7, 8, 9
LEU	neg., 25, 100, 500 LEU/µL neg., 1+, 2+, 3+
NIT	neg., pos.
PRO	neg., 25, 75, 150, 500 mg/dL neg., 0.25, 0.75, 1.5, 5.0 g/L neg., 1+, 2+, 3+, 4+

Parameter	Result values
GLU	norm., 50, 100, 300, 1000 mg/dL norm., 3, 6, 17, 56 mmol/L norm., 1+, 2+, 3+, 4+
KET	neg., 5, 15, 50, 150 mg/dL neg., 0.5, 1.5, 5, 15 mmol/L neg., (+), 1+, 2+, 3+
UBG	norm., 1, 4, 8, 12 mg/dL norm., 17, 70, 140, 200 µmol/L norm., 1+, 2+, 3+, 4+
BIL	neg., 1, 3, 6 mg/dL neg., 17, 50, 100 µmol/L neg., 1+, 2+, 3+
ERY	neg., 10, 25, 50, 250 ERY/µL neg., 1+, 2+, 3+, 4+

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

#### Specific performance data (instrumental reading with Urisys 1100)

Representative performance data are given below. Results obtained in individual laboratories may differ. The values for neg. and pos. indicate the proportion of concordant negative or positive results. See table below.

The values specified for the **limit of detection** (analytical sensitivity) are defined as the concentration of the analyte which leads to a positive result in ≥ 90 % of the examined urines. For specific gravity and pH, limit of detection is not applicable (N.A.).

The **method comparison** data for Urisys 1100 are based on the comparison with **cobas u 411** with Combur<sup>10</sup> Test M using at least 198 clinical samples.

Parameter	Limit of Detection	Method comparison <sup>e)</sup>
SG	N.A.	ident. <sup>f)</sup> : 98 %
pH	N.A.	ident.: 83 %, pH 5-6: 98 %, pH 8-9: 100 %
LEU	35 Leu/µL	neg.: 96 %, pos.: 92 %
NIT	0.06 mg/dL	neg.: 87 %, pos.: 98 %
PRO	24 mg/dL	neg.: 99 %, pos.: 84 %
GLU	40 mg/dL	neg.: 99 %, pos.: 100 %
KET	5 mg/dL	neg.: 81 %, pos.: 90 %
UBG	2 mg/dL	neg.: 97 %, pos.: 96 %
BIL	0.8 mg/dL	neg.: 100 %, pos.: 76 %
ERY	18 ERY/µL	neg.: 100 %, pos.: 85 %

e) The values for neg. and pos. indicate the proportion of concordant negative or positive results.

f) for ± 1 colour block

#### Precision (instrumental reading with Urisys 1100)

Precision experiments comprised an assessment of repeatability (within run precision) and intermediate precision.

**Repeatability** was checked for 3 test strip lots in 3 separate runs with 21 measurements each for the tested controls. In total there were 63 measurements performed per used control.

**Intermediate precision** was assessed for 3 test strip lots over 20 days with 2 runs per day and duplicate measurements per used control. In total there were 80 measurements performed per used control. Values have to be found within 2 adjacent concentration ranges. Refer to target ranges of the controls. For details see table below.

Parameter	Control <sup>g)</sup>	Precision		Intermediate precision	
		Result	Exact Agreement	Result	Exact Agreement
SG	Level 1	1.010 mg/dL	90 %	1.010 mg/dL	71 %
	Level 2	1.000 mg/dL	62 %	1.005 mg/dL	74 %
pH	Level 1	6	86 %	6.5	60 %
	Level 2	7	100 %	7	99 %
LEU	Level 1	neg.	100 %	neg.	99 %
	Level 2	500 Leu/µL	100 %	500 Leu/µL	100 %
NIT	Level 1	neg.	100 %	neg.	99 %
	Level 2	pos.	100 %	pos.	100 %
PRO	Level 1	neg.	100 %	neg.	100 %
	Level 2	500 mg/dL	67 %	500 mg/dL	100 %
GLU	Level 1	norm.	100 %	norm.	100 %
	Level 2	1000 mg/dL	100 %	1000 mg/dL	100 %
KET	Level 1	neg.	100 %	neg.	100 %
	Level 2	150 mg/dL	100 %	150 mg/dL	98 %
UBG	Level 1	norm.	100 %	norm.	100 %
	Level 2	12 mg/dL	100 %	12 mg/dL	100 %
BIL	Level 1	neg.	100 %	neg.	100 %
	Level 2	6 mg/dL	100 %	6 mg/dL	100 %
ERY	Level 1	neg.	100 %	neg.	100 %
	Level 2	250 ERY/µL	100 %	250 ERY/µL	100 %

g) Bio-Rad Liquichek Urinalysis Control

For further information, please refer to the appropriate operator's manual for the analyzer 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

- ECLM, European Urinalysis Guidelines. Scand J Clin Lab Invest, 2000. 60: p. 1-96.
- Delanghe J, Speeckaert M. Preanalytical requirements of urinalysis. Biochimica Medica (2014);24(1):89-104.
- Steggall B. Nursing Standard (2007);22:42-45.
- Beer JH, Vogt A, Neftel K, et al. False positive results for leucocytes in urine dipstick test with common antibiotics. BMJ. (1996);313(7048):25.
- Brunzel NA. Fundamentals of Urine and Body Fluid Analysis, Elsevier Health Sciences (2016):102.
- Rangaiahagari A, Nyirabanzi J, Uwizeyimana JP. Comparison of urinary culture and urine dipstick nitrite test in urinary tract infection, Rwanda Medical Journal (2015);72:5-7.
- Ronald A. The Etiology of Urinary Tract Infection: Traditional and Emerging Pathogens, Dis Mon (2003);49:71-82.
- Susan King-Strasinger, M.S., Urinalysis and Body Fluids, 5th Edition. ISBN 978-0-8036-1697-4 (alk. paper), 2008.
- Simerville JA., Maxted WC and Pahira J.J., Urinalysis: a comprehensive review. Am Fam Physician, 2005. 71(6): p. 1153-62.

- Nagel D, Seiler D, Hohenberger EF, et al. Investigations of ascorbic acid interference in urine test strips. Clin Lab (2006);52:149-153.
- van Oudheusden APM, et al. Teststreifen zum Nachweis von Ketonkörpern im Harn. Diagnostic (1976);9:14.
- Csako G. False-positive results for ketone with the drug mesna and other free-sulphydryl compounds. Clin Chem. (1987);33:289-92.
- https://www.mlo-online.com/continuing-education/article/13008884/rediscovering-urine-chemistryand-understanding-its-limitations
- Wu AHB. Tietz Clinical Guide to Laboratory Tests, 4th Edition.
- Nagel D, et al. Einfluß von Ascorbinsäure auf einen neuen Harnstreifen zum Nachweis von Erythrocyten. Med Lab (1982);35:137.
- Rao PV, Jones JS. How to evaluate 'dipstick hematuria': What to do before you refer. Cleveland Clinic Journal of Medicine (2008);75(3):227-233.
- McPherson RA, M.R.P., HENRY'S Clinical Diagnosis and Management by Laboratory Methods, 23rd edition. ISBN 9780323295680, 2017.
- Thomas L. ed. Clinical Laboratory Diagnostics. Electronic ed. (2016);TH-Books GmbH.
- Pannala AS., et al., The effect of dietary nitrate on salivary, plasma, and urinary nitrate metabolism in humans. Free Radic Biol Med, 2003. 34(5): p. 576-84.
- Johnson DW. Global Proterinuria Guidelines: Are We Nearly There Yet?; Clin Biochem Rev. (2011);Vol.32.
- Cowart SL, Stachura ME. Glucosuria, Clinical Methods: The History, Physical, and Laboratory Examinations. 3rd edition., Boston 1990, Chapter 139.
- Wollin T, Laroche B and Psooy K, Canadian guidelines for the management of asymptomatic microscopic hematuria in adults. Can Urol Assoc J, 2009. 3(1): p. 77-80.
- Nielsen M, Qaseem A; High Value Care Task Force of the American College of Physicians. Hematuria as a marker of occult urinary tract cancer: advice for high-value care from the American College of Physicians. Ann Intern Med. 2016;164(7):488-497.

#### Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

	Contents of kit
	Analyzers/Instruments on which reagents can be used
	Reagent
	Calibrator
	Volume after reconstitution or mixing
	Global Trade Item Number

COBAS, COMBUR 10 TEST, URISYS 1100 and URISYS are trademarks of Roche.

All other product names and trademarks are the property of their respective owners.

Additions, deletions or changes are indicated by a change bar in the margin.

© 2019, Roche Diagnostics



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

