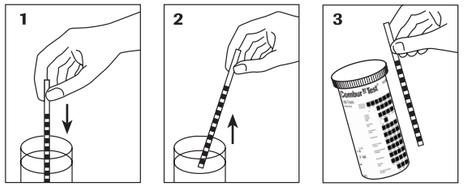
Combur[10] Test UX

cobas®

REF		SYSTEM
11544373191	100	Urisys 1100, visual reading
11544373173	100	
11544373049	100	
11544373170	100	
11544373243	100	
11544373171	100	
11544373005	100	
11544373053	100	
11544373343	100	
11544373370	100	



English

Intended use
The Combur[10] Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur[10] Test UX are test strips for single use only. Combur[10] Test UX are screening tests and can aid in the diagnosis of pathological conditions.
Not for self-testing.
The test is intended for near-patient testing.

Summary
The Combur[10] Test UX can be used in noncritical healthcare environments such as hospital wards and general practitioner's offices.

User Training
The operation of the Urisys 1100 urine analyzer and the execution of the Combur[10] Test UX is described in the Urisys 1100 urine analyzer Operator's Manual. No dedicated training is required.

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, o-cresolphthalein and bromothymol blue and reacts specifically with H+ 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^2 reactive paper 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 1.1 µg; o-cresolphthalein 7.3 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: Sodium nitroprusside 96.5 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 for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.
Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.
Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.
Safety data sheet available for professional user on request.
All components of the pack can be discarded in domestic waste.
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.

Operating conditions:
For a proper function of the test, it has to be used in the following temperature and relative humidity range.
Visual reading
Temperature: +18 °C to +32 °C
Relative humidity: 30 % to 80 %

Urisys 1100
Temperature: +15 °C to +32 °C
Relative humidity: 20 % to 80 %

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.[1] 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.[1] Using midstream urine is recommended to avoid contamination by commensal urethral flora in both sexes.[2] Do not expose urine specimens to sunlight as this induces oxidation of bilirubin and urobilinogen and hence leads to artificially low results for these 2 parameters.[2] Vaginal secretion or menstrual blood may contaminate urine from females.[2]
Diagnosis or therapy should never be based on 1 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. In case of a positive result it is advisable to use a follow up investigation.

Materials provided
For details see material table in header section.

Materials required (but not provided)
- REF 03617548xxx, 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.
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 some test areas may become discolored due to environmental influences such as moisture or nitrite gases in the air and incorrect results may be obtained. Do not use discolored strips. In case of doubt perform a quality control test.
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 (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®
- KOVA Liqua-Trol®

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.
Run a positive and negative control at least after each weekly calibration on the Urisys 1100 and when a new vial of strips is opened.
Follow the applicable government regulations and local guidelines for quality control.

Calibration
Control-Test M calibration strips are used for the calibration of the photometer unit of the Urisys 1100 urine analyzer. For details see Operator's Manual of the Urisys 1100 urine analyzer.

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
Therapeutic drugs and endogenous substances were tested for a potential interference to the test parameters of the Combur Tests. All parameters were tested with negative urine samples and samples spiked to the first positive concentration range. Therapeutic drugs were tested at concentrations in urine occurring under medication with the therapeutic dosage and above.
There are no significant therapeutic drug interferences up to the concentrations as presented below:

Parameter	Therapeutic drug	On Urisys 1100		Visual reading	
		No interference up to	Effect above stated concentration	No interference up to	Effect above stated concentration
LEU	N-Acetylcysteine	190 mg/L	false negative results	80 mg/L	false negative results
	Amoxicillin	900 mg/L	elevated positive results	8000 mg/L	false negative results
	Furosemide	1200 mg/L	false negative results	-	-
	Gabapentin	11000 mg/L	elevated positive results	-	-
	Methyldopa	1900 mg/L	elevated positive results	-	-
	Phenazopyridine	-	-	5 mg/L	False negative and not assessable results[a)]
	Salicyluric acid	3000 mg/L	false negative results	5000 mg/L	false negative results
NIT	Ascorbic acid	800 mg/L	false negative results	1000 mg/L	false negative results
	Phenazopyridine	100 mg/L	false positive results	10 mg/L	not assessable results[a)]
	Salicyluric acid	-	-	90 mg/L	false negative results
PRO	Amoxicillin	800 mg/L	elevated positive results	-	-
	Furosemide	800 mg/L	false negative results	-	-
	Gabapentin	11000 mg/L	false positive results	-	-
	Levodopa	1000 mg/L	elevated positive results	-	-
	Metformin	5000 mg/L	elevated positive results	-	-
	Ofloxacin	800 mg/L	elevated positive results	-	-
	Phenazopyridine	250 mg/L	false positive and elevated positive results	-	-
GLU	Ascorbic acid	700 mg/L	false normal results	750 mg/L	false normal results
KET	N-Acetylcysteine	50 mg/L	false positive and elevated positive results	110 mg/L	false positive results
	Levodopa	75 mg/L	false positive and elevated positive results	1000 mg/L	false positive results
	Methyldopa	75 mg/L	false positive and elevated positive results	750 mg/L	false positive results
	Phenazopyridine	-	-	100 mg/L	not assessable results[a)]
UBG	Ascorbic acid	3600 mg/L	false normal results	-	-
	Cefoxitin	6000 mg/L	false normal results	-	-
	Furosemide	1600 mg/L	false normal results	-	-
	Gabapentin	4000 mg/L	false normal results	-	-
	Gentamycine sulfate	75 mg/L	elevated positive results	-	-
	Ibuprofen	500 mg/L	false normal results	-	-
	Phenazopyridine	50 mg/L	elevated positive results	50 mg/L	not assessable results[a)]
BIL	Amoxicillin	13000 mg/L	elevated positive results	-	-
	Ascorbic acid	250 mg/L	false negative results	750 mg/L	false negative results
	Cefoxitin	11500 mg/L	elevated positive results	-	-
	Gabapentin	6000 mg/L	elevated positive results	-	-
	Levodopa	-	-	1100 mg/L	false positive results
	Methyldopa	50 mg/L	elevated positive results	-	-
	Phenazopyridine	10 mg/L	elevated positive results	-	-
	Salicyluric acid	-	-	2000 mg/L	false negative results
	Tetracycline	450 mg/L	elevated positive results	-	-
ERY	Acetaminophen	2500 mg/L	false negative results	-	-
	Amoxicillin	-	-	2250 mg/L	false negative results
	Ascorbic acid	750 mg/L	false negative results	500 mg/L	false negative results
	Biotin	900 mg/L	false negative results	-	-
	Cefoxitin	250 mg/L	false negative results	-	-
	Furosemide	300 mg/L	false negative results	-	-
	Gabapentin	6000 mg/L	false negative results	10000 mg/L	false negative results
	Gentamycine sulfate	350 mg/L	false negative results	-	-
	Ibuprofen	500 mg/L	false negative results	750 mg/L	false negative results
	Levodopa	300 mg/L	false positive and elevated positive results	-	-
	Metformin	8000 mg/L	false negative results	-	-
	Methyldopa	750 mg/L	false positive and elevated positive results	-	-
	Ofloxacin	800 mg/L	false negative results	-	-
	Phenazopyridine	250 mg/L	elevated positive results	-	-
LEU	Bilirubin	10 mg/L	false positive and elevated positive results	10 mg/L	not assessable results[b)]
	Calcium chloride	-	-	2650 mg/L	false negative results
	Glucose	10000 mg/L	false negative results	50000 mg/L	false negative results
	Hemoglobin	200 mg/L	false positive and elevated positive results	-	-
	Nitrite	18 mg/L	elevated positive results	-	-
	Urea	46930 mg/L	false positive and elevated positive results	-	-
	Urobilinogen	120 mg/L	false positive and elevated positive results	100 mg/L	not assessable results[b)]
NIT	Bilirubin	600 mg/L	false positive results	10 mg/L	not assessable results[b)]
	Creatinine	-	-	11500 mg/L	false negative results
	Hemoglobin	450 mg/L	false positive results	-	-
	Urobilinogen	1000 mg/L	false positive results	100 mg/L	false positive and not assessable results[b)]
PRO	Ammonium chloride	15000 mg/L	false negative results	-	-
	Creatinine	7500 mg/L	elevated positive results	-	-
	Hemoglobin	10 mg/L	false positive and elevated positive results	100 mg/L	false positive and elevated positive results
	Nitrite	90 mg/L	elevated positive results	-	-
	Urea	26480 mg/L	elevated positive results	115000 mg/L	false positive results
	Urobilinogen	200 mg/L	false positive and elevated positive results	500 mg/L	not assessable results[b)]
GLU	Urea	113510 mg/L	false normal results	165000 mg/L	false normal results
	Urobilinogen	-	-	500 mg/L	false normal and not assessable results[b)]

a) not assessable results: A visual determination might not be possible for negative or low positive results due to intrinsic color of the specimen.

There are no significant endogenous substance interferences up to the concentrations as presented below:

Parameter	Endogenous substance	On Urisys 1100		Visual reading	
		No interference up to	Effect above stated concentration	No interference up to	Effect above stated concentration
KET	Bilirubin	700 mg/L	false positive results	750 mg/L	not assessable results[b)]
	Hemoglobin	650 mg/L	false positive results	-	-
	Urobilinogen	-	-	1000 mg/L	false negative and not assessable results[b)]
UBG	Bilirubin	150 mg/L	elevated positive results	10 mg/L	not assessable results[b)]
	Creatinine	12000 mg/L	false normal results	-	-
	Nitrite	2 mg/L	false normal results	30 mg/L	false normal results
BIL	Nitrite	5 mg/L	false negative results	25 mg/L	false negative results
	Urea	87610 mg/L	elevated positive results	-	-
	Urobilinogen	70 mg/L	false positive and elevated positive results	80 mg/L	false negative and not assessable results[b)]
ERY	Bilirubin	500 mg/L	elevated positive results	-	-
	Creatinine	3567 mg/L	false negative results	-	-
	Nitrite	20 mg/L	false negative results	-	-
	Urobilinogen	80 mg/L	false negative and false positive results	80 mg/L	false negative and not assessable results[b)]

b) not assessable results: A visual determination might not be possible for negative or low positive results due to intrinsic color of the specimen.
On instrument evaluation, a strong intrinsic coloration of the urine, may lead to false positive or elevated positive result.

Common limitations
Specific gravity: On visual reading, 0.005 should be added to the result if the urine has a pH of 7 or more.
Nitrite: Prolonged urinary retention in the bladder (4-8 hours) is essential in order to obtain an accurate result.[2] Administration of antibiotics or chemical drugs should be discontinued 3 days before the test.[3] More than 80 % of all bacteria responsible for urinary tract infections are gram-negative rods (E.coli, Klebsiella, Enterobacter and Proteus species).[4] Most gram-negative bacteria have the ability to reduce urinary nitrate to nitrite and can therefore be detected indirectly with the test strips.[2] Normal nutrition as a rule ensures a sufficiently high content of nitrate in the urine for the detection of bacteria.[5] Some common uropathogens, e.g. Enterococcus spp. and Staphylococcus spp. (5-15 % of bacteria responsible for urinary tract infections)[4], do not reduce urinary nitrate to nitrite and will therefore not be detected whatever their urinary concentration.[2] 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.[2]
Attention: Nitrogen oxides present in the atmosphere may have an influence on the stability of the nitrite test parameter.[6]
Protein: False-positive readings may be found after infusion of polyvinylpyrrolidone (blood substitute).
Urobilinogen: 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.[6]
Bilirubin: 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.[6]
Blood/ERY: 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.[7]
Note:
A selection of relevant commercially available drugs or their metabolites were tested. For questionable results, 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 (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[8]	
pH	5-9[9]	
LEU	< 10 Leu/µL[2]	10-100 Leu/µL borderline[2]
NIT	< 1 µmol/L (< 0.005 mg/dL)[10]	A positive result is indicative of urinary tract infection, but a negative result does not rule out UTI.[6]
PRO	≤ 30 mg/dL[11]	> 30 mg/dL proteinuria[11]
GLU	< 25 mg/dL, < 1.4 mmol/L[12]	For daytime urine Using semi-quantitative reagent strips, expected values in a healthy population are negative.[13]
KET	≤ 2 mg acetoacetic acid/dL[8]	Borderline > 2 mg up to 50 mg acetoacetic acid/dL[8]
UBG	< 1 mg/dL[c),5]	1-4 mg/dL borderline (4 mg/dL corresponding to 2+, indicating liver damage)[13]
BIL	neg.[8]	When this method is used, normal urine contains no detectable bilirubin.
ERY	< 18 Ery/µL (< 3 Ery/HPF)[8]	Hematuria ≥ 18 Ery/µL (≥ 3 Ery/HPF)[14,15]
	Conversion factor 5.8 to translate chamber counting HPF into µL[2]	

c) 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.

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Result values (visual reading)

Parameter	Result values
SG	1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030
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+
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+

Specific performance data (visual reading)
Representative performance data are given below. Results obtained in individual laboratories may differ.
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[10] Test M using at least 210 clinical samples per parameter. All concentration ranges were covered.

Parameter	Limit of detection	Method comparison[d)]
SG	N.A.	ident.[e)]: 100 %
pH	N.A.	ident.: 94 % pH 5-6: 100 %, pH 8-9: 100 %
LEU	5-20 Leu/µL	neg.: 100 %, pos.: 98 %
NIT	0.03-0.09 mg/dL	neg.: 100 %, pos.: 100 %
PRO	10-18 mg/dL	neg.: 100 %, pos.: 98 %
GLU	25-45 mg/dL	neg.: 96 %, pos.: 100 %
KET	4-8 mg/dL	neg.: 100 %, pos.: 90 %
UBG	1.0-1.6 mg/dL	neg.: 100 %, pos.: 96 %
BIL	0.2-0.6 mg/dL	neg.: 100 %, pos.: 97 %
ERY/Hb	3-7 Ery/µL	neg.: 99 %, pos.: 96 %
Hb	5-12 Ery/µL	neg.: 99 %, pos.: 96 %

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

e) 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.

Precision					
		Repeatability		Intermediate precision	
Parameter	Control[f)]	Result	Exact agreement	Result	Exact agreement
SG	Level 1	1.015	100 %	1.015	80 %
	Level 2	1.010	100 %	1.010	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 %

f) 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
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+
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+

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** 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[10] Test M using at least 140 clinical samples.

Parameter	Limit of Detection	Method comparison[g)]
SG	N.A.	ident.[h)]: 98 %
pH	N.A.	ident.: 83 %, pH 5-6: 98 %, pH 8-9: 100 %
LEU	15-55 Leu/µL	neg.: 96 %, pos.: 92 %
NIT	0.02-0.12 mg/dL	neg.: 87 %, pos.: 98 %
PRO	18-30 mg/dL	neg.: 99 %, pos.: 84 %
GLU	30-45 mg/dL	neg.: 99 %, pos.: 100 %
KET	2-8 mg/dL	neg.: 100 %, pos.: 85 %
UBG	1.2-2.2 mg/dL	neg.: 97 %, pos.: 96 %
BIL	0.6-1.2 mg/dL	neg.: 100 %, pos.: 76 %
ERY	12-22 Ery/µL	neg.: 100 %, pos.: 85 %

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

h) 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.

Precision					
		Repeatability		Intermediate precision	
Parameter	Control[i)]	Result	Exact Agreement	Result	Exact Agreement
SG	Level 1	1.010	90 %	1.010	71 %
	Level 2	1.000	62 %	1.005	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 %

i) Bio-Rad Liquichek Urinalysis Control

For further information, please refer to the appropriate Operators 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.
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

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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):


Device for near-patient testing


Device not for self-testing

CONTENT Contents of kit

SYSTEM Analyzers/Instruments on which reagents can be used

REAGENT Reagent

CALIBRATOR Calibrator


Volume for reconstitution

GTIN Global Trade Item Number

UDI Unique Device Identifier

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

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