



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					
Parameter	Control <sup>0)</sup>	Repeatability		Intermediate precision	
		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<sup>10</sup> Test M using at least 198 clinical samples.

Parameter	Limit of Detection	Method comparison <sup>0)</sup>
SG	N.A.	ident. <sup>10)</sup> : 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.: 81 %, pos.: 90 %
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					
Parameter	Control <sup>0)</sup>	Repeatability		Intermediate precision	
		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 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**

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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):

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

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