cobas u 601 urine analyzer

Performance Data (US)
1.1

Document information

Revision history

Manual version	Revision date	Change description
1.0	May 2019	First publication.
1.1	March 2020	New layout.

Revision history

Edition notice

This information is intended for operators and administrators of the **cobas u** 601 urine analyzer.

Every effort has been made to ensure that all the information is correct at the time of publishing. However, Roche reserves the right to make any changes necessary without notice as part of ongoing product development.

Customer modifications to the instrument may impair instrument safety and may lead to malfunction, incorrect measurements, and incorrect results. Any customer modification to the instrument will render the warranty or service agreement null and void.

Intended use

The **cobas u** 601 urine analyzer when used with the **cobas u** pack is a fully automated urinalysis system intended for the in vitro qualitative or semi-quantitative determination of urine analytes, including pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, color and erythrocytes, as well as clarity.

These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. This system is intended to be used by trained operators in clinical laboratories.

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Trademarks

The following trademarks are acknowledged:

COBAS, COBAS U, and LIFE NEEDS ANSWERS are trademarks of Roche.

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Instrument approvals

The **cobas u** 601 urine analyzer meets the requirements laid down in:

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

The **cobas u** 601 urine analyzer is manufactured and tested according to the international safety standards below:

- UL 61010-1, 2nd Edition
- IEC 61010-1, 2nd Edition
- IEC 61010-2-081, 1st Edition
- IEC 61010-2-101, 1st Edition
- CAN/CSA C22.2 No. 61010 2nd Edition
- EN IEC 61326-1 2nd Edition
- EN IEC 61326-2-6 2nd Edition

Compliance with the applicable directives is provided by means of the Declaration of Conformity. The following marks demonstrate compliance:

For in vitro diagnostic use.

Complies with the provisions of the applicable EU directives.

Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

Contact address

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany
Made in Hungary

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Performance data

The following section provides representative performance data for SG and CLA.

The performance data for urine test strips are presented in the **cobas u** pack method sheet (US).

Performance data for SG and Clarity

The measurement range of a parameter is the interval that reveals the results of the performance data evaluation (e.g. for SG this range is 1.002 - 1.050). The measuring range reflects the interval of the parameter that is technically displayed by the analyzer (e.g. for SG this range is 1.000 - 1.050).

Representative performance data on the analyzers are given below.

Results obtained in individual laboratories may differ.

Parameter	SG	Clarity[(a)]
Method comparison Versus Urisys 2400 with human urine samples	Deming regression: • y = 1.04*x - 0.0417 • Pearson's r = 0.995 Measurement range: • 1.002 - 1.050	Concordance rates: • clear: 89% • light turbid: 80% • turbid: 84%
	Number of samples measured: • n = 1334	Number of samples measured: • n = 1364
Precision Measured over 21 days with 2 aliquots per control with 2 replicates each, total n = 84	**Repeatability**: Control 1: (Bio-Rad Liquichek Level 1) • Mean: 1.013 • Standard deviation = 0.000	**Repeatability**: Control 1: (Bio-Rad Liquichek Level 1) Agreement: • 100% are clear • 0% are light turbid • 0% are turbid
	Control 2: (Bio-Rad Liquichek Level 2) • Mean: 1.022 • Standard deviation = 0.000	Control 2: (Bio-Rad Liquichek Level 2) Agreement: • 100% are clear • 0% are light turbid • 0% are turbid
	Intermediate: Control 1: (Bio-Rad Liquichek Level 1) • Mean: 1.013 • Standard deviation = 0.000	**Intermediate**: Control 1: (Bio-Rad Liquichek Level 1) Agreement: • 100% are clear • 0% are light turbid • 0% are turbid
	Control 2: (Bio-Rad Liquichek Level 2) • Mean: 1.022 • Standard deviation = 0.000	Control 2: (Bio-Rad Liquichek Level 2) Agreement: • 100% are clear • 0% are light turbid • 0% are turbid

Performance data for SG and Clarity for the **cobas u** 601 urine analyzer

(a) Clarity is determined by the relation of scattered light and direct light measured with two separate detectors.