

# cobas u 601 urine analyzer

Performance Data (International)

1.2



## Document information

### Revision history

Publication version	Revision date	Change description
1.0	May 2019	First publication as separate publication item.
1.1	March 2020	New layout.
1.2	February 2021	IVDR compliance.

☰ Revision history

### Edition notice

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

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

#### General attention

To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- ▶ Pay particular attention to all safety precautions.
- ▶ Always follow the instructions in this publication.
- ▶ Do not use the instrument in a way that is not described in this publication.
- ▶ Store all publications in a safe and easily retrievable place.

#### Incident reporting

- ▶ Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

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**Feedback**

Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

**Approvals**

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

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
- 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

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 regulations.



Eurasian Conformity. Demonstrates that the product meets the Eurasian Economic Union (EAEU)'s regulations and standards for customs clearance and trading.



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'Laboratory Equipment' is the product identifier as shown on the type plate.

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## Intended use

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



## Symbols and abbreviations

Visual cues are used to help locate and interpret information quickly. This section explains the conventions used for this purpose.

### Symbols used in this publication













The following symbols are used:


Symbol	Explanation
•	List item.
	Tip. Extra information on correct use or useful hints.
	Table. Used in table titles and cross-references to tables.
	Symbols used in this publication



Symbol	Comment
	Safety alert.
	Symbols used for easy recognition of information


### Symbols used on product

The following symbols are used:

Symbol	Explanation
	Catalogue number.
	Global Trade Item Number.
	Serial number.
	Date of manufacture.
	Manufacturer.
	Indicates that the equipment is suitable for alternating current only; to identify relevant terminals.
	For <i>in vitro</i> diagnostic use.
	Unique device identifier.
	Complies with the provisions of the applicable EU regulations.
	Please consult instructions for use.
	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.
	Eurasian Conformity.

 Symbols used on product

Symbol	Explanation
Equipment de Laboratoire / Laboratory Equipment	'Laboratory Equipment' is the product identifier as shown on the type plate.
	Temperature limit.
	Humidity limit.

 Symbols used on product

### Abbreviations

The following abbreviations are used:

Abbreviation	Explanation
CLA	Clarity
EC	European Community
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation
RD	Roche Diagnostics
SG	Specific gravity
UL	Underwriters Laboratories Inc.


 Abbreviations

# 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 (International).

## 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 <sup>(a)</sup>
<b>Method comparison</b> Versus Urisys 2400 with human urine samples	Deming regression: <ul style="list-style-type: none"> <li><math>y = 1.04 \cdot x - 0.0417</math></li> <li>Pearson's <math>r = 0.995</math></li> </ul> Measurement range: <ul style="list-style-type: none"> <li>1.002 - 1.050</li> </ul> Number of samples measured: <ul style="list-style-type: none"> <li><math>n = 1334</math></li> </ul>	Concordance rates: <ul style="list-style-type: none"> <li>clear: 89%</li> <li>light turbid: 80%</li> <li>turbid: 84%</li> </ul> Number of samples measured: <ul style="list-style-type: none"> <li><math>n = 1364</math></li> </ul>
<b>Precision</b> Measured over 21 days with 2 aliquots per control with 2 replicates each, total $n = 84$	<b>Repeatability:</b> Control 1: (Bio-Rad Liquichek Level 1) <ul style="list-style-type: none"> <li>Mean: 1.013</li> <li>Standard deviation = 0.000</li> </ul>	<b>Repeatability:</b> Control 1: (Bio-Rad Liquichek Level 1) Agreement: <ul style="list-style-type: none"> <li>100% are clear</li> <li>0% are light turbid</li> <li>0% are turbid</li> </ul>
	Control 2: (Bio-Rad Liquichek Level 2) <ul style="list-style-type: none"> <li>Mean: 1.022</li> <li>Standard deviation = 0.000</li> </ul>	Control 2: (Bio-Rad Liquichek Level 2) Agreement: <ul style="list-style-type: none"> <li>100% are clear</li> <li>0% are light turbid</li> <li>0% are turbid</li> </ul>
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 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.