

cobas u cuvette

REF

CONTENT

SYSTEM

06390552001

▽ 400

cobas u 701 microscopy analyzer

English**Intended use**

The **cobas u** cuvette is a cassette containing cuvettes for the in vitro quantitative determination of erythrocytes and leukocytes, the semi-quantitative determination of squamous and non-squamous epithelial cells, bacteria, hyaline casts and the qualitative determination of pathological casts, crystals, yeasts, mucus, and sperm in urine with the **cobas u 701** microscopy analyzer. These measurements are useful in the evaluation of kidney disease and urinary tract infections.

For professional use only.

Summary

Cuvettes are used to provide means for urine sediment examination with the **cobas u 701** microscopy analyzer.

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.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Storage and stability

Store the **cobas u** cuvette at 2-40 °C.

Materials provided

- [REF] 06390552001, **cobas u** cuvette with 400 cuvettes

Materials required (but not provided)

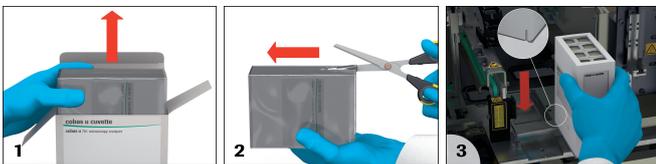
- [REF] 06390501001, **cobas u 701** microscopy analyzer
- General laboratory equipment

Handling

Ready for use.

1. Open the paper box and remove the **cobas u** cuvette.
2. Remove plastic foil from the cuvette container with help of scissors.
3. Place the **cobas u** cuvette immediately into the **cobas u 701** microscopy analyzer.

Follow the instructions of the on-screen wizard of the instrument for correct insertion and positioning.



Note: Do not open the **cobas u** cuvette.

Do not touch the cuvettes. The cuvettes must not be re-loaded into the cuvette container, if they are re-loaded into the container the measurement performance of the system cannot be guaranteed.

Do not remove the partially used cuvette container while the analyzer is in operation.

Always keep the partially used cuvette container upright once removed from the **cobas u 701** microscopy analyzer.

Inverting the cuvette container upside down may limit the usability of the remaining cuvettes.

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

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Performance data

Refer to the appropriate operator's manual for performance data information.

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.

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):

[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

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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