



Control Test M



REF	CONTENT	SYSTEM
11379194 263	 50	Miditron M Miditron Junior II Supertron Urilux S cobas u 411 Urisys 1800 Urisys 1100

English

Intended use

The Control-Test M calibration strip is used to perform the calibration of the Miditron M, Miditron Junior II, Supertron, Urilux S, **cobas u 411**, Urisys 1800 and Urisys 1100 reflectance photometers and to check the analyzers performance.

Summary

The ready-to-use calibration strip is made of inert gray plastic material of constant reflectance characteristics. The calibration values were determined with reference to a white standard and are stored in the software of the respective analyzer.

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents. Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

Do not immerse the calibration strip in urine. The strips are designed for single use only.

Reagent handling

Calibration strips are ready for use.

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.

Store the tube in a horizontal position.

Materials provided

-  11379194263, package with 50 strips

Materials required (but not provided)

- Miditron M, Miditron Junior II, Supertron, Urilux S, **cobas u 411**, Urisys 1800 or Urisys 1100 urinalysis analyzer.
- General laboratory equipment

Assay

Refer to the operator’s manual of the respective instrument for full details on calibration and performance checks.

- Take a calibration strip out of the vial. Do not touch the elevated areas of the strip to avoid contamination and falsification of results.
- Insert the strip into the instrument. Follow the instructions in the operator’s manual for correct positioning of the strip.
- Follow the operator’s manual to execute the calibration. Under routine conditions, a calibration interval of 2 weeks is recommended (1 week with Urilux S and Urisys 1100, 4 weeks with **cobas u 411** and Urisys 1800).

Calibration

The instrument measures the elevated areas of the strip by means of reflectance photometry. The results are automatically calculated and printed by the instrument as reflectance values. For interpretation of these values, please refer to the relevant section in the operator’s manual. If the values obtained deviate from the tolerances specified, the calibration has to be repeated with a new strip. This permits the user to check whether the instrument is malfunctioning or whether the strip used is dirty or damaged.

For further information, please refer to the appropriate operator’s manual for the instrument 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

Operator’s Manual of the respective analyzer.

Symbols



Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.


CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used

COBAS, COBAS U, MIDITRON, SUPERTRON, URILUX and URISYS are trademarks of Roche.

Significant additions or changes are indicated by a change bar in the margin.

© 2013, Roche Diagnostics



 Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

