05541760001V9.0

Preciset TDM II

cobas®

REF **03375781** 190

6 x 5 mL Calibrator (Bottles A-F)

1 x 10 mL Diluent

English

System information

For use on Roche/Hitachi analyzers, Roche/Hitachi MODULAR analyzers and **cobas c** analyzers the calibrator codes are 743-748 (A-F).

For use on COBAS INTEGRA analyzers the system ID is 07 6829 4.

Intended use

The Preciset TDM II calibrators are designed for the calibration of the Roche assays for the quantitative determination of digitoxin, amikacin, lidocaine, N-acetylprocainamide, procainamide and quinidine in human serum and plasma on Roche clinical chemistry analyzers.

The Diluent is negative human serum and may be used for dilution of high samples or as a blank sample.

Summary

Preciset TDM II consists of 6 ready-for-use calibrators prepared by the quantitative addition of drugs to human serum. The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

Reactive components:

Human serum with chemical additives (therapeutic drugs).

Non-reactive components:

Preservative and stabilizer.

The exact calibrator values are given in the electronically available or enclosed value sheets. The calibrator values are also encoded in the enclosed calibrator barcode sheets for Roche/Hitachi MODULAR and COBAS INTEGRA analyzers.

For the **cobas c** analyzers (except for the **cobas c** 111 analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

Traceability

Preciset TDM II calibrators are prepared by the quantitative addition of drugs to human serum and are traceable to Alltech (NAPA) or USP drugs.

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.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.
The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.
However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[1,2]

Handling

The product is ready-for-use. Mix carefully before use. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for Roche/Hitachi MODULAR automated analyzers and **cobas c** systems to identify the calibrator. Attach the barcoded labels to the tubes carrying the sample cups containing the calibrator material.

Storage and stability

Store at 2-8 °C. **Do not freeze**.

Stability:

Unopened: up to the stated expiration date at 2-8 °C.

After opening: 10 months at 2-8 °C or until the printed expiration date, whichever comes first.

Materials provided

- See “Reagents – working solutions” section
- Barcoded labels

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Use Preciset TDM II as specified in the relevant Method Sheet for the system reagents.

References

1 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

2 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

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.

Symbols

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

CONTENT	Contents of kit
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing

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

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