05178347005V5.0

Methadone Metabolite Calibrators

cobas®

REF **05393663**	190	1 x 10 mL DRI® Methadone Metabolite Calibrator 0
REF **05178584**	190	1 x 10 mL DRI Methadone Metabolite Calibrator 100
REF **05178592**	190	1 x 10 mL DRI Methadone Metabolite Calibrator 300
REF **05178606**	190	1 x 10 mL DRI Methadone Metabolite Calibrator 500
REF **05178614**	190	1 x 10 mL DRI Methadone Metabolite Calibrator 1000

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers, the calibrator codes are 940, 936, 937, 938, 939.

For use on COBAS INTEGRA analyzers, the system-IDs are:

- 07 7441 3 for qualitative assay, 100 ng/mL cutoff
- 07 7442 1 for qualitative assay, 300 ng/mL cutoff
- 07 7444 8 for semiquantitative assays, 100 and 300 ng/mL cutoffs

Intended use

DRI Methadone Metabolite calibrators are intended for use in calibration of the DRI Methadone Metabolite assay.

Summary

DRI Methadone Metabolite calibrators are liquid and ready-to-use for the qualitative and semiquantitative determination of methadone metabolite. They are prepared by spiking negative human urine with respective quantities of 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP).

Reagents – working solutions

Calibrator	Concentration (ng/mL)
DRI Methadone Metabolite Calibrator 0	0
DRI Methadone Metabolite Calibrator 100	100
DRI Methadone Metabolite Calibrator 300	300
DRI Methadone Metabolite Calibrator 500	500
DRI Methadone Metabolite Calibrator 1000	1000

DRI Methadone Metabolite calibrators are traceable to a primary reference method (GC/MS - gas chromatography/mass spectrometry).[1]

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.

The calibrators are prepared from non-sterile human urine.

The calibrators are harmful if swallowed.

Specimens containing human-sourced materials should be handled as if potentially infectious using safe laboratory procedures such as those outlined in *Biosafety in Microbiological and Biomedical Laboratories* (HHS Publication Number [CDC] 93-8395). In the event of exposure the directives of the responsible health authorities should be followed.[2,3]

Do not use the calibrators beyond the expiration dates printed on their label.

Disposal of all waste material should be in accordance with local guidelines.

The calibrators contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azide. When disposing of such reagents, always flush with a large volume of water to prevent azide build-up.

Safety data sheet available for professional user on request.

For USA: For prescription use only.

Handling

The calibrators are ready for use. No preparation is required. Mix the contents of the bottle before each use by gently inverting the bottle 2 to 3 times. Remove the cap and dispense. Record the date the calibrator was opened on each calibrator bottle label. After each use, tightly close each cap and return to refrigerated storage (2-8 °C).

Storage and stability

Store at 2-8 °C. **Do not freeze**.

Stability:
opened or unopened: until the printed expiration date at 2-8 °C

Materials provided

- See “Reagents – working solutions” section

Materials required (but not provided)

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

Assay

Use Methadone Metabolite Calibrators as specified in the relevant Method Sheet for the system reagents.

References

1 Data on traceability are on file at Microgenics Corporation.

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

3 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
GTIN	Global Trade Item Number

10012871-4

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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