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Oxycodone Calibrators

cobas®

REF **05201284** 190	1 x 10 mL DRI® Oxycodone Calibrator 0
REF **05178517** 190	1 x 10 mL DRI Oxycodone Calibrator 100
REF **05178525** 190	1 x 10 mL DRI Oxycodone Calibrator 300
REF **05178533** 190	1 x 10 mL DRI Oxycodone Calibrator 500
REF **05178541** 190	1 x 10 mL DRI Oxycodone Calibrator 1000

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers, the calibrator codes are 570, 572, 573, 574, 575.

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

- 07 7434 0 for qualitative assay, 100 ng/mL cutoff
- 07 7435 9 for qualitative assay, 300 ng/mL cutoff
- 07 7436 7 for semiquantitative assays, 100 and 300 ng/mL cutoffs

Intended use

The DRI Oxycodone calibrators are intended for the calibration of the DRI Oxycodone assay. These calibrators are for in vitro diagnostic use only for the detection of oxycodone and its metabolite, oxymorphone, in human urine.

Summary

DRI Oxycodone calibrators are liquid ready-to-use. They are prepared by spiking negative human urine matrix with known quantities of oxycodone. The DRI Oxycodone Calibrator 100 and Calibrator 300 can be used as a qualitative cutoff reference for distinguishing “positive” from “negative” samples. A rough estimate of drug concentration in the samples can be obtained by running a standard curve using all calibrators and by quantitating samples off the standard curve.

Reagents – working solutions

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

DRI Oxycodone calibrators are traceable to a primary reference method (GC/MS - gas chromatography/mass spectrometry).

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.[1,2]

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

Handling

The calibrators are ready for use. No preparation is required. Record the date the calibrator was opened on each calibrator bottle label.

Storage and stability

Store at 2-8 °C. **Do not freeze.**

Stability:
up to 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 Oxycodone Calibrators as specified in the relevant Method Sheet for the system reagents.

Results and expected values

Qualitative results

The DRI Oxycodone Calibrator 100 and Calibrator 300 can be used as a cutoff reference for distinguishing “positive” from “negative” samples. A sample that exhibits a change in absorbance value (ΔAbs) equal to or greater than that obtained with the cutoff calibrator is considered preliminary positive. A sample that exhibits a change in absorbance value (ΔAbs) lower than that obtained with the cutoff calibrator is considered negative.

Semiquantitative results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve using all calibrators and by quantitating samples off the standard curve. When the sample concentration is greater than the highest calibrator, the sample can be diluted with DRI Oxycodone Calibrator 0 and retested.

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 (for USA: see https://usdiagnostics.roche.com for definition of symbols used):

CONTENT	Contents of kit
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

10012985-4

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cobas®

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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