05178339005V5.0

Oxycodone Controls

cobas®

REF **05178568** 190 — DRI® Oxycodone Control Set 100
1 x 10 mL Positive Control 125 ng/mL
1 x 10 mL Negative Control 75 ng/mL

REF **05178550** 190 — DRI Oxycodone Control Set 300
1 x 10 mL Positive Control 375 ng/mL
1 x 10 mL Negative Control 225 ng/mL

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers.

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

DRI Oxycodone Control Set 100		
Positive Control 125 ng/mL	OXY1P	System-ID 07 7445 6
Negative Control 75 ng/mL	OXY1N	System-ID 07 7446 4
DRI Oxycodone Control Set 300		
Positive Control 375 ng/mL	OXY3P	System-ID 07 7447 2
Negative Control 225 ng/mL	OXY3N	System-ID 07 7448 0

Intended use

The DRI Oxycodone Control Set 100 and 300 are intended for validating the DRI Oxycodone assay calibration. These controls are for in vitro diagnostic use only for the detection of oxycodone and its metabolite, oxymorphone, in human urine.

Summary

DRI Oxycodone controls are liquid ready-to-use. They are prepared by spiking negative human urine matrix with known quantities of oxycodone.

Reagents – working solutions

Control	Assay Cutoff	Concentration (ng/mL)	
		Negative Control	Positive Control
DRI Oxycodone Control Set 100	100	75	125
DRI Oxycodone Control Set 300	300	225	375

DRI Oxycodone controls are traceable to a primary reference method (GC/MS).

Precautions and warnings

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

The controls are prepared from non-sterile human urine.

The controls 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 controls beyond the expiration dates printed on their label.

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

The controls 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 controls are ready for use. No preparation is required. Record the date the control was opened on the 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 Controls as specified in the relevant Method Sheet for the system reagents. Control intervals must be adapted to individual laboratory requirements.

Follow the applicable government regulations and local guidelines for quality control.

Results

For qualitative assays on Roche/Hitachi analyzers and **cobas c** analyzers, the negative control should produce a negative value and the positive control should produce a positive or “0” value.

For qualitative assays on COBAS INTEGRA analyzers, the negative control should produce a value between 0 and 999 inclusive and the positive control should produce a value greater than or equal to 1000.

For semiquantitative assays, the negative control should recover less than the assay cutoff and the positive control should recover greater than or equal to the assay cutoff.

Laboratory values obtained should fall within these established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

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
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

10013017-4

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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