

# DRI® Oxycodone Calibrators and Controls

**IVD** For In Vitro Diagnostic Use

## Rx Only

- REF** 1664 DRI Negative Calibrator (10 mL)  
1388 DRI Negative Calibrator (25 mL)  
100250 DRI Oxycodone Calibrator 100 (10 mL)  
100251 DRI Oxycodone Calibrator 300 (10 mL)  
100252 DRI Oxycodone Calibrator 500 (10 mL)  
100253 DRI Oxycodone Calibrator 1000 (10 mL)  
100254 DRI Oxycodone 100 Control Kit (2 x 10 mL)  
100255 DRI Oxycodone 300 Control Kit (2 x 10 mL)

## Intended Use

The DRI® Oxycodone Calibrators are intended for the calibration of the DRI Oxycodone Assay. The DRI Oxycodone Controls are intended for validating the DRI Oxycodone Assay calibration. These calibrators and controls are for in vitro diagnostic use only for the detection of oxycodone and its metabolite, oxycodone, in human urine.

## Description of the DRI Oxycodone Urine Calibrators and Controls

The DRI Oxycodone Calibrators and Controls are liquid and ready-to-use. They are prepared by spiking negative human urine matrix with known quantities of Oxycodone. The DRI Oxycodone 100 ng/mL and 300 ng/mL Calibrators 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.

Tables 1, 2, 3. Oxycodone Concentrations in the DRI Oxycodone Calibrators and Controls

Table 1

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

Table 2

DRI Oxycodone 100 Controls	
Negative Control	75 ng/mL
Positive Control	125 ng/mL

Table 3

DRI Oxycodone 300 Controls	
Negative Control	225 ng/mL
Positive Control	375 ng/mL

## ⚠ Precautions and Warning

The DRI Oxycodone Calibrators and Controls are for in vitro diagnostic use only. They are harmful if swallowed.

**DANGER:** DRI Oxycodone Calibrator contains ≤0.3% bovine serum albumin (BSA).  
H317 - May cause allergic skin reaction.  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/ international regulations.

The calibrators and controls contain ≤0.09% sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.

The calibrators and controls are prepared from non-sterile human urine. **Handle the calibrators and controls as if they were potentially infectious.**

Do not use the calibrators or controls beyond their expiration dates printed on their respective labels.

## Storage

The calibrators and controls should be stored refrigerated at 2° to 8°C when not in use. They are stable until the expiration date indicated on the box label.

## Calibrators and Controls Preparation

The DRI Oxycodone Calibrators and Controls are ready-to-use.

## Assay Procedure

For instructions, refer to the instrument specific application sheet for the DRI Oxycodone Assay.

## Results and Expected Values

### Qualitative Results

The 100 ng/mL and 300 ng/mL Calibrators can be used as a cutoff reference for distinguishing "positive" from "negative" samples. A sample that exhibits a change in absorbance value ( $\Delta A$ ) equal to or greater than that obtained with cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value ( $\Delta A$ ) lower than that obtained with the cutoff calibrator is considered negative. The controls should be used in parallel to validate the assay. The results of the controls should be within the range established by each laboratory.

### Semi-quantitative Results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve with 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 Negative Calibrator and retested.

## Limitations

The DRI Oxycodone Calibrators and Controls are designed for use with the DRI Oxycodone Assay.

## Quality Control

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

## Glossary:

<http://www.thermofisher.com/symbols-glossary>

  
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46500 Kato Road  
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 For insert updates go to:  
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## Other countries:

Please contact your local Thermo Fisher Scientific representative.