CEDIA® Buprenorphine II Assay Calibrators and Controls

thermo scientific

IVD **For *In Vitro* Diagnostic Use Only**

Rx Only

REF

10021390	CEDIA Negative Calibrator II (1 x 7.5 mL)
10020799	CEDIA Buprenorphine II Calibrator 10 ng/mL (1 x 5 mL)
10020800	CEDIA Buprenorphine II Calibrator 20 ng/mL (1 x 5 mL)
10020801	CEDIA Buprenorphine II Calibrator 50 ng/mL (1 x 5 mL)
10020802	CEDIA Buprenorphine II Calibrator 100 ng/mL (1 x 5 mL)
10020804	CEDIA Buprenorphine II Low (7.5 ng/mL) and High (12.5 ng/mL) Controls (2 x 5 mL each)

Intended Use
The CEDIA® Buprenorphine II calibrators and CEDIA Negative Calibrator II are intended for the calibration of the CEDIA Buprenorphine II Assay in human urine. The CEDIA Buprenorphine II Controls are used to validate the CEDIA Buprenorphine II Assay calibration in human urine. For *In Vitro Diagnostic* Use Only.

Description of CEDIA Buprenorphine II Calibrators & Controls
The CEDIA Buprenorphine II Assay calibrators and controls are liquid, ready-to-use. They are prepared by spiking known quantities of Buprenorphine into negative human urine matrix. The CEDIA Buprenorphine II 10 ng/mL calibrator can be used as a qualitative cutoff reference for distinguishing "positive" from "negative" samples. An estimate of drug concentration in the samples can be obtained by running a standard curve using all five calibrators and by estimating sample concentrations off the standard curve.

Each Calibrator Kit and Controls Kit is sold separately and may be used with any reagent lot.

Each laboratory should establish its own acceptable control ranges.

Tables 1 & 2: Buprenorphine concentrations in CEDIA Buprenorphine II Calibrators and Controls.

Table 1

Calibrator	Concentration (ng/mL)
CEDIA Negative Calibrator II	0
10	10
20	20
50	50
100	100

Table 2

Control	Concentration (ng/mL)
Low	7.5
High	12.5

⚠ Warnings and Precautions
The CEDIA Buprenorphine II Calibrators and Controls are harmful if swallowed.

H317 - May cause allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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

The calibrators and controls contain ≤0.2% bovine serum albumin (BSA) and ≤0.09% sodium azide. Avoid contact with skin and mucous membranes. Avoid inhalation. May cause skin or inhaled allergic reaction. Refer to Safety Data Sheet (SDS) for additional precautions, handling instructions, and accidental exposure treatment.

In the case of accidental spill, clean and dispose of material according to your laboratory's Standard Operating Procedure (SOP), local, and state regulations.

Do not use the calibrators or controls beyond the expiration dates printed on the respective labels. If packaging is damaged on arrival, contact the technical support representative (refer to back page of this Package Insert).

Calibrators and Controls Preparation and Storage
The CEDIA Buprenorphine II Calibrators and Controls are liquid, ready-to-use. The calibrators and controls should be stored refrigerated at 2-8°C when not in use. The calibrators and controls are stable until the expiration date indicated on the bottle label. Once opened the calibrators and controls are stable for 60 days when stored at 2-8°C. Do not use calibrators and controls beyond the expiration date.

Assay Procedure
For instructions, refer to the instrument specific application sheets for the CEDIA Buprenorphine II Assay.

Results and Expected Values
Qualitative Results
The 10 ng/mL calibrator can be used as a cutoff reference for distinguishing "positive" from "negative" samples. A sample that exhibits a change in absorbance value (Δ) equal to or greater than that obtained with the cutoff calibrator is considered as positive. A sample that exhibits a change in absorbance value (Δ) lower than that obtained with the cutoff calibrator is considered as 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
An estimate of drug concentrations in the samples can be obtained by running a standard curve with all five calibrators and estimating sample concentrations off the standard curve. Sample results above the high calibrator should be diluted with negative urine calibrator and retested.

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

Limitations
The CEDIA Buprenorphine II Calibrators and Controls are designed for use with the CEDIA Buprenorphine II Assay for the detection of Buprenorphine and its metabolites in human urine.

References
CEDIA Buprenorphine II Assay Package Insert.

Glossary:
http://www.thermofisher.com/symbols-glossary

Microgenics Corporation
46500 Kato Road
Fremont, CA 94538 USA
US Toll Free:
1-800-232-3342

EC REP
B·R·A·H·M·S GmbH
Neuendorfstrasse 25
16761 Hennigsdorf, Germany

CE

For insert updates go to:
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