

For Criminal Justice and Forensic Use Only

REF	10022930	CEDIA Negative Calibrator III (1 x 10 mL)
	10022931	CEDIA AB-PINACA 5 ng/mL Calibrator (1 x 5 mL)
	10022932	CEDIA AB-PINACA 20 ng/mL Calibrator (1 x 5 mL)
	10022933	CEDIA AB-PINACA 50 ng/mL Calibrator (1 x 5 mL)
	10022934	CEDIA AB-PINACA 100 ng/mL Calibrator (1 x 5 mL)
	10022935	CEDIA AB-PINACA Control set (2 x 5 mL each)

Intended Use

The CEDIA® AB-PINACA calibrators and the CEDIA Negative Calibrator III are intended for the calibration of the CEDIA AB-PINACA Assay in human urine. The CEDIA AB-PINACA Controls are used to validate the CEDIA AB-PINACA Assay calibration in human urine. For Criminal Justice and Forensic Use Only.

Description of CEDIA AB-PINACA Calibrators & Controls

The CEDIA AB-PINACA Assay calibrators and controls are liquid, ready-to-use. They are prepared by spiking known quantities of the AB-PINACA calibrator analyte into negative human urine matrix. The CEDIA AB-PINACA 20 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.

Table 1 Analyte concentrations in CEDIA AB-PINACA Calibrators

Calibrator	Concentration (ng/mL)
CEDIA Negative Calibrator III	0
Calibrator 5	5
Calibrator 20	20
Calibrator 50	50
Calibrator 100	100

Table 2 Analyte concentrations in CEDIA AB-PINACA Controls

Calibrator	Concentration (ng/mL)
Low Control	10
High Control	30

Warnings and Precautions

The CEDIA AB-PINACA Calibrators and Controls are harmful if swallowed.

H317 - May cause allergic 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 & 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 AB-PINACA 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 Procedures

For instructions, refer to the instrument specific application sheets for the CEDIA AB-PINACA Assay.

Results and Expected Values

Qualitative Results

The 20 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 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 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 AB-PINACA Calibrators and Controls are designed for use with the CEDIA AB-PINACA Assay for the detection of the parent compound or the metabolites of AB-PINACA, AB-CHMINACA, AB-FUBINACA, and other structure-related synthetic cannabinoids in human urine.

References

CEDIA AB-PINACA Assay Package Insert.

Key to Symbols Used



Manufacturer



Caution



Lot Number/Batch Code



Use-by Date



Consult Instructions for Use



Catalog Number



Temperature Limit



Health Hazard



Biological Risks



Calibrator



Control



Contents



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