

IVD For In Vitro Diagnostic Use

Rx Only

- REF** 1815326 Multi-Drug Calibrator, Primary Cutoffs (1 x 5 mL)
 1815334 Multi-Drug Calibrator, Primary Cutoffs (1 x 15 mL)
 1730428 Multi-Drug Calibrator, Secondary Cutoffs (1 x 5 mL)
 1730517 Multi-Drug Calibrator, Secondary Cutoffs (1 x 15 mL)
 1730380 Multi-Drug Intermediate Calibrator (1 x 5 mL)
 1732218 Multi-Drug Intermediate Calibrator (1 x 15 mL)
 1730398 Multi-Drug High Calibrator (1 x 5 mL)
 1732226 Multi-Drug High Calibrator (1 x 15 mL)
 1730401 Multi-Drug Calibrator, Primary Clinical Cutoffs (1 x 5 mL)

Intended Use

The CEDIA® Multi-Drug Calibrators are for use as calibrators in the CEDIA qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.

Each calibrator is sold separately and may be used with any reagent lot. The ready-to-use calibrators contain human urine, preservative and drugs in the following targeted concentrations:

Compound	Primary Clinical Cutoff (ng/mL)	Primary Cutoff (ng/mL)	Secondary Cutoff (ng/mL)	Intermediate Cutoff (ng/mL)	High (ng/mL)
Benzoylcegonine	300	300	150	2000	5000
EDDP	100	100	100	500	2000
d-Methamphetamine	1000	1000	500	3000	5000
Morphine	300	2000	300	800	2000
Nitrazepam	300	300	200	800	5000
Phencyclidine	25	25	25	75	150
Secobarbital	300	300	200	800	3000

⚠ Precautions and Warnings

Exercise the normal precautions required for handling all laboratory reagents.

☠ Materials of human origin were tested for HIV 1 and 2, hepatitis B, and hepatitis C. The findings were negative. However, as no test method can rule out the potential risk of infection with absolute certainty, the material must be handled just as carefully as the patient sample. In the event of exposure the directives of the responsible health authorities should be followed.^{1,2}

WARNING: The calibrators contain ≤0.13% sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate 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.

EUH032 - Contact with acids liberates very toxic gas.

Storage and Stability³

Store at 2-8 °C. **Do not freeze.**

Stability:

Unopened at 2-8 °C: up to the expiration date.

After opening: 60 days, or until the printed expiration date, whichever comes first, at 2-8 °C. Store calibrators tightly capped when not in use. To avoid cross-contamination of calibrator levels, match color-coded caps to the appropriate calibrator bottle.

Procedure

Materials provided:

CEDIA Multi-Drug Calibrators

Additional materials required:

CEDIA Reagent Kits
 CEDIA Negative Calibrator

Instructions for use:

The calibrators are ready for use. No preparation is required. Before use, mix by gentle inversion to obtain a homogeneous solution. Record the date that the calibrator was opened on each calibrator bottle label.

Assay

Use the calibrators as specified in the appropriate assay package insert or application sheet.

Quality Control

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

References

1. Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens; Final Rule. Fed. Register. 1991;56:64175-64182.
2. Council Directive (90/679/EEC). Official J. of the Europ. Communities. No. L374 from Dec. 31, 1990.
3. Data on file at Microgenics, a part of Thermo Fisher Scientific.

Glossary:

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


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EC REP

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For insert updates go to:
www.thermoscientific.com/diagnostics

Other countries:

Please contact your local representative.

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