CEDIA® Negative Calibrator

thermo scientific

IVD **For In Vitro Diagnostic Use**

Rx Only

REF 1661388 Negative Calibrator (1 x 15 mL)
1557416 Negative Calibrator (1 x 5 mL)

Intended Use
The CEDIA® Negative Calibrator is for use as a calibrator in the CEDIA semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.

The calibrator is sold separately and may be used with any reagent lot. The ready-to-use calibrators contain human urine and preservative.

⚠ 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 calibrator contains ≤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 Stability[3]
Store calibrators at 2-8°C. **DO NOT FREEZE.**

Stability **prior** to opening the bottle: up to the printed expiration date.

Stability **after** opening the bottle: 60 days or until the printed expiration date, whichever comes first. Store calibrators tightly capped when not in use.

Procedure
Materials provided:
CEDIA Negative Calibrator

Additional materials required:
CEDIA Reagent Kits
CEDIA Calibrator Kits

Instructions for use:
The calibrators are liquid and do not require reconstitution. Mix the contents of the vial before each use by gently inverting the vial 2-3 times.

Record on the vial label the date on which the calibrator was opened.

Remove the cap and dispense the required quantity of the calibrator into a sample cup as specified in the appropriate CEDIA assay application sheet.

Assay
Use the calibrator 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 Corporation, a part of Thermo Fisher Scientific.

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

Microgenics Corporation,
part of Thermo Fisher Scientific
46500 Kato Road
Fremont, CA 94538 USA
US Customer and
Technical Support:
1-800-232-3342

CE

EC REP
B·R·A·H·M·S GmbH
Neuendorfstrasse 25
16761 Hennigsdorf, Germany
Tel: +49 (0) 800 404 077 12
Fax: +49 (0) 800 404 077 13

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www.thermofisher.com/diagnostics

Other countries:
Please contact your local representative.

98-700-12-EN
2018 04