CEDIA® Specialty Control Set

thermo scientific

IVD **For In Vitro Dignostic Use**

REF 1815440

Quantity: Low 3 x 5 mL
High 3 x 5 mL

Intended use
The Specialty Controls are for use as unassayed control material with drugs of abuse assays in human urine on automated clinical chemistry analyzers.

Summary
This product is a set of two ready-to-use solutions of human urine containing drugs of abuse in two concentration ranges.

Reagents - contents and concentrations
Human urine, stabilizers, preservative and drugs in the following targeted concentrations:

	Low (ng/mL)	High (ng/mL)
Benzoylecgonine	112.5	187.5
EDDP	75	125
d-Methamphetamine	375	625
Morphine	225	375
Nitrazepam	150	250
Secobarbital	150	250

⚠ Precautions and warnings
For in vitro diagnostic use. Exercise the normal precautions required for handling all laboratory reagents.

DANGER: The controls contain ≤0.1% sodium azide and ≤0.3% bovine serum albumin (BSA). Avoid contact with skin and mucous membranes.
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.

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.

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]

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

Control handling
The controls are ready for use. No preparation is required. Before use, gently invert two to three times.

Storage and stability [3]
The CEDIA® Specialty Control Set should be stored refrigerated at 2-8°C and is stable until the expiration date indicated on the label.

Procedure
Materials provided
• Specialty Control Set 1
Additional materials required
• Drugs of Abuse Reagent Kits

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

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 Europe. Communities. No. L374 from Dec. 31, 1990.
3. Data on file at Microgenics Corporation, a part of Thermo Fisher Scientific.

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