

# CEDIA® Heroin Metabolite (6-AM) Calibrator and Control Kit

**Thermo**  
SCIENTIFIC

**IVD** For In Vitro Diagnostic Use

Rx Only

**REF** 100031 Cutoff Calibrator (5.0 mL)  
100034 High Calibrator (5.0 mL)  
100202 MGC Select DAU Control Set

## Intended use

The CEDIA® Heroin Metabolite (6-AM) calibrator is used to calibrate the CEDIA Heroin Metabolite Assay for detection of 6-Acetyl Morphine in urine. The CEDIA 6-Acetyl Morphine controls are used as unassay control material to validate the calibration of the CEDIA Heroin Metabolite Assay.

**CEDIA Heroin Metabolite calibrators and controls are sold separately and may be used with any CEDIA Heroin Metabolite reagent lot. The calibrators and controls contain < 0.09% sodium azide and the following targeted concentration of 6-Acetyl Morphine in human urine.**

Cutoff Calibrator: 10 ng/mL  
Negative Control: 7.5 ng/mL  
Positive Control: 12.5 ng/mL  
High Calibrator: 20 ng/mL

## Precautions and warnings

**WARNING:** The CEDIA Heroin Metabolite calibrators and controls are prepared from nonsterile human urine. These calibrators and controls should be handled at Biosafety Level 2, as recommended for any potentially infectious human serum, blood specimen, or urine in the *Centers for Disease Control/National Institutes of Health manual Biosafety in Microbiological and Biomedical Laboratories, 1993*.

### DANGER/CAUTION:

The calibrators contain less than 0.09% sodium azide. The calibrators contain ≤0.2% bovine serum albumin (BSA). Avoid contact with skin and mucous membranes. 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 calibrators, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.

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. Specific treatment (see First Aid information on product label and/or Section 4 of the SDS). 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.

## Storage and Stability

Store calibrators and controls at 2-8 °C. Once opened the calibrator and controls are stable until the expiration date on the bottle.

## Procedure

Refer to Heroin Metabolite Reagent Kit package insert.

### Materials provided:

CEDIA Heroin Metabolite calibrators and controls.

### Additional materials required (but not provided):

REF	Description
1557416	Negative Calibrator
100107 (SC Kit) or 100108 (MC Kit)	Heroin Metabolite Reagent Kit

## Instructions for use:

The calibrators and controls are ready to use.

## Results

The CEDIA Heroin Metabolite Calibrators and Controls are used as a reference in distinguishing between positive and negative 6-Acetyl Morphine samples. Refer to the appropriate CEDIA Heroin Metabolite application sheet for specific information.

## Limitations

The CEDIA Heroin Metabolite Calibrators and Controls set are intended for use solely as specified. Further information is given in the appropriate CEDIA Heroin Metabolite application sheet.

## Quality Control

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

## Glossary:

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



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For insert updates go to:  
[www.thermoscientific.com/diagnostics](http://www.thermoscientific.com/diagnostics)

### Other countries:

Please contact your local representative.

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