**A major task in urine drug testing is to detect heroin intake. The most common way of doing this is by using morphine as the analytical target in opiate immunoassay screening. However, this strategy leads to false-positive results because morphine is not a metabolite unique to heroin and to false negative results due to a typical heroin metabolism pattern.**
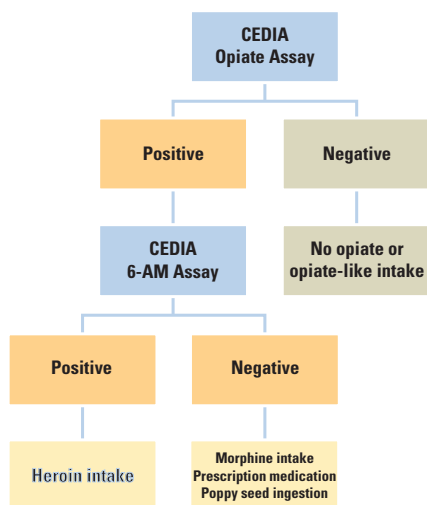
Thermo Scientific CEDIA Heroin Metabolite (6-AM) Assay
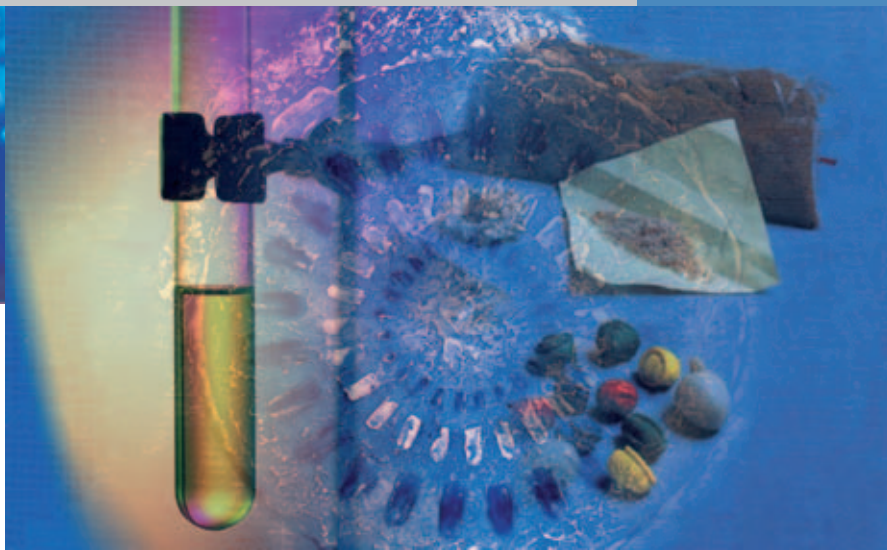
Introduction

The Thermo Scientific CEDIA Heroin Metabolite (6-Acetyl-morphine) is an innovative homogenous immunoassay that can be used in combination with the CEDIA Opiate assay to identify:

- Opiate positive samples that are positive because of Heroin intake
- Opiate positive samples that are positive due to morphine intake, prescription medication and/or poppy seed ingestion.

CEDIA Opiate Assay
- Positive
  - **CEDIA 6-AM Assay**
    - Positive → Heroin intake
    - Negative → Morphine intake / Prescription medication / Poppy seed ingestion
- Negative → No opiate or opiate-like intake

The CEDIA Heroin Metabolite (6-AM) Assay can also be used as a stand-alone assay when heroin intake is the reason for testing.

Recently, cases have been reported where individuals were indentified with an atypical heroin metabolism pattern. These individuals were negative for opiates in urine using a 300 ng/ml cut-off, although Heroin Metabolite (6-AM) was present in the urine using a 10 ng/ml cut-off. In these cases, heroin intake could only be detected by using the CEDIA 6-AM assay[*].

*Beck, Böttcher. Paradoxical Results in Urine Drug Testing for 6-Acetylmorphine and Total Opiates: Implications for Best Analytical Strategy. Journal of Analytical Toxicology. Vol.30. March 2006

Key Features

- Only immunoassay available for specifically detecting heroin abuse
- Excellent specificity → no interference from Morphine metabolites
- Excellent sensitivity → Cut-off 10 ng/mL; LDD ~ 0,6 ng/mL
- Fully automated semi-quantitative or qualitative results in minutes
- Improved efficiency in drug screening - eliminates the need for expensive and time consuming confirmation testing

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Specifications and Ordering Information

Cross Reactivity

The following compounds were tested with the CEDIA Heroin Metabolite (6-AM) Assay and yielded negative results against the cut-off calibrator (10 ng/mL):

Substance	Concentration tested (ng/mL)
Codeine	500 000
Dihydrocodeine	500 000
Hydrocodone	300 000
Hydromorphone	10 000
Morphine	9 000
Morphine-3-Glucuronide	600 000
Morphine-6-Glucuronide	600 000
Norcodeine	600 000
Normorphine	30 000

Accuracy: Specificity/Sensitivity Box

Sensitivity: 96.2 %

Specificity: 100.2 %

3 of the 4 samples contain 10.4, 10.5 and 11.2 ng/mL 6-Acetylmorphine by GC/MS.

Precision

Precision study following NCCLS replication validation

	Within-run Precision		
	Negative Control	Cut-off	Positive Control
n	120	120	120
Mean	437	467	494
SD	5.2	5.5	5.5
(%)CV	1.2	1.2	1.1

	Total Precision		
	Negative Control	Cut-off	Positive Control
n	120	120	120
Mean	437	467	494
SD	6.4	8.0	8.3
(%)CV	1.5	1.7	1.7

Ordering Information

Product		Size	Number
Heroin Metabolite (6-AM)	TSC	3 x 17 mL R1 & 3 x 17 mL R2	1 001 07
	MCC	65 mL R1 & 65 mL R2	1 001 08
Negative Calibrator	0 ng/mL	5 mL	1 557 416
Cut-off Calibrator	10 ng/mL	5 mL	1 000 31
High Calibrator	20 ng/mL	5 mL	1 000 34
MGC Select DAU Control Set	7.5 ng/mL / 12.5 ng/mL	3 x 5 mL each level	1 002 02