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# CEDIA® OPIATE APPLICATION
# BECKMAN COULTER AU480®, AU680®

CE

Catalog No. 100089, 100098, 1661248, 10016429

**Intended for the Qualitative and Semiquantitative Determination of Opiate in Human Urine**

For In Vitro Diagnostic Use Only

## Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen preparation, specimen storage, quality control, and additional performance data.

## Ordering Information

Materials available from Microgenics, a part of Thermo Fisher Scientific:

| Item | Size | Catalog Number |
|---|---|---|
| CEDIA Opiate Assay Reagents | 3x17 mL<br>3x17 mL<br>65 mL<br>495 mL | 10016429<br>100089<br>100098<br>1661248 |
| CEDIA Negative Calibrator | 5 mL<br>15 mL | 1557416<br>1661388 |
| CEDIA Primary Calibrator | 5 mL<br>15 mL | 1815326<br>1815334 |
| CEDIA Secondary Calibrator | 5 mL<br>15 mL | 1730428<br>1730517 |
| CEDIA Intermediate Calibrator | 5 mL<br>15 mL | 1730380<br>1732218 |
| CEDIA High Calibrator | 5 mL<br>15 mL | 1730398<br>1732226 |
| MGC Clinical DAU Control Set | 3 x 5 mL | 100201 |

To place an order or for technical service, contact:

| USA | In Europe |
|---|---|
| **Tel: (800) 232-3342**<br>**Fax: (510) 979-5420** | **Tel: +49 (0)851-88 6890**<br>**Fax: +49 (0)851-88 68910** |


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EC REP Thermo Fisher Scientific Oy, Ratastie 2, P.O. Box 100, 01621 Vantaa, Finland


*Continued on next page*

## Reagent Storage

Refer to the package insert for information on reagent storage.

## Analyzer Procedure

Refer to the operator's manuals for information on analyzer operation.

Dispense adequate amounts of Reagent 1 (EA reagent) and Reagent 2 (ED Reagent) into appropriate containers. **Ensure that reagents have equilibrated to temperature of analyzer reagent compartment before starting analysis.**

## Results and Data Interpretation

Refer to package insert for information on results and data interpretation.



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# CEDIA Opiate Assay – Qualitative (300 ng/mL cutoff)
# Beckman Coulter AU480 & AU680 Parameters

Specific Test Parameters

General | LIH | ISE | Range

Test Name: # ∇ < > Type: Urine ∇ Operation: Yes ∇

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sample Volume | 2.0 µL | Dilution | 0 µL | OD Limit | | | |
| Pre-Dilution Rate | 1 | | | Min. OD | -2.00 | Max. | 3.00 |
| Reagents R1(R1- | 87 µL | Dilution | 0 µL | Reagent OD | | | |
| | | | | First Low | -2.00 | High | 3.00 |
| | | | | Last Low | -2.00 | High | 3.00 |
| R2 (R2-1) | 87 µL | Dilution | 0 µL | | | | |
| | | | | Dynamic Range | # | High | # |
| | | | | Correlation Factor A | 1 | B | † |
| Wavelength: Pri. | 570 nm | Sec. | 660 nm | Factor for Maker A | 1 | B | 0 |
| Method: | FIXED* ∇ | | | | | | |
| Reaction slope: | + ∇ | | | Onboard Stability | # Days | # | Hour |
| Measuring Point 1: First | 24 | Last | 27 | LIH Influence Check | # ∇ | | |
| Measuring Point 2: First | | Last | | Lipemia | ∇ | | |
| Linearity: | % | | | Icterus | ∇ | | |
| No Lag Time: | No ∇ | | | Hemolysis | ∇ | | |

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Tests | Range

Test Name # ∇ < > Type Urine ∇

Value/Flag # ∇

Level — Low: -9999999, High: ‡ — Panic Value: Low #, High #

Specific Ranges:

| | | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|---|
| ☐ | 1 | # ∇ | # | # | # | # | # | # |
| ☐ | 2 | # ∇ | # | # | # | # | # | # |
| ☐ | 3 | # ∇ | # | # | # | # | # | # |
| ☐ | 4 | # ∇ | # | # | # | # | # | # |
| ☐ | 5 | # ∇ | # | # | # | # | # | # |
| ☐ | 6 | # ∇ | # | # | # | # | # | # |
| | 7 | No demographics | | | | | # | # |
| | 8 | Not within expected values | | | | | # | # |

Unit # Decimal Places #

\# User defined
* Can also be run as RATE
† Option 1: Enter 0.0 Option 2: Enter 0.0 Option 3: Enter -100
‡ Option 1: Enter 9999999 Option 2: Enter 100 Option 3: Enter 0.0

- Option 1: Run a reagent blank (blue rack). Run the cutoff calibrator in a white rack. Compare the sample response to the cutoff calibrator response to determine if the sample is positive or negative. Positive samples will not be flagged.

- Option 2: Run a reagent blank (blue rack). Calibrate by placing the appropriate cutoff calibrator in the assigned position in the calibration rack (yellow rack). Positive samples will be flagged (P) and will be greater than or equal to 100.

- Option 3: Run a reagent blank (blue rack). Calibrate by placing the appropriate cutoff calibrator in the assigned position in the calibration rack (yellow rack). Positive samples will be flagged (P) and will be greater than or equal to zero.



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## CEDIA Opiate Assay – Qualitative (300 ng/mL cutoff)
## Beckman Coulter AU480 & AU680 Parameters, *continued*

**(Option 1)**

Parameters | Calibration Parameters

Calibrators | Calibration Specific | STAT Table Calibration

Test Name: # ∇ | < | > Type: Urine ∇ □ Use Serum Cal.

Calibration Type: MB ∇ Formula: Y=AX+B ∇ Counts: 2 ∇

| < Calibrator Parameters> | | | Range | | Slope Check: ∇ |
|---|---|---|---|---|---|
| | Calibrator | OD | Conc | Low | High | |
| Point-1 | ∇ | | | | | Allowable Range Check |
| Point-2 | ∇ | | | | | □ Reagent Blank |
| Point-3 | ∇ | | | | | □ Calibration |
| Point-4 | ∇ | | | | | |
| Point-5 | ∇ | | | | | Advanced Calibration |
| Point-6 | ∇ | | | | | Operation: No ∇ |
| Point-7 | ∇ | | | | | Interval (RB/ACAL): ∇ |
| Point-8 | ∇ | | | | | |
| Point-9 | ∇ | | | | | □ Lot Calibration |
| Point-10 | ∇ | | | | | |

< Point Cal. For Master Curve > No. of Correction Points: ∇ Use Master Curve: ∇

| | | | OD Range | | Stability | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Calibrator | OD | Conc | Low | High | | | | |
| Point-1 | ∇ | | | | | Reagent Blank | | Day | Hour |
| Point-2 | ∇ | | | | | Calibration | | Day | Hour |

MB Type Factor: 1000 1-Point Calibration Point: ∇ □ with Conc-0

**(Option 2 or 3)**

Parameters | Calibration Parameters

Calibrators | Calibration Specific | STAT Table Calibration

Test Name: # ∇ | < | > Type: Urine ∇ □ Use Serum Cal.

Calibration Type: AB ∇ Formula: Y=AX+B ∇ Counts: 2 ∇

| < Calibrator Parameters> | | | | Factor Range | | Slope Check: + ∇ |
|---|---|---|---|---|---|---|
| | Calibrator | OD | Conc | Low | High | |
| Point-1 | # ∇ | | 100 | -9999999 | 9999999 | Allowable Range Check |
| Point-2 | ∇ | | | | | □ Reagent Blank |
| Point-3 | ∇ | | | | | □ Calibration |
| Point-4 | ∇ | | | | | |
| Point-5 | ∇ | | | | | Advanced Calibration |
| Point-6 | ∇ | | | | | Operation: No ∇ |
| Point-7 | ∇ | | | | | Interval (RB/ACAL): ∇ |
| Point-8 | ∇ | | | | | |
| Point-9 | ∇ | | | | | □ Lot Calibration |
| Point-10 | ∇ | | | | | |

< Point Cal. For Master Curve > No. of Correction Points: ∇ Use Master Curve: ∇

| | | | OD Range | | Stability | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Calibrator | OD | Conc | Low | High | | | | |
| Point-1 | ∇ | | | | | Reagent Blank | # | Day | # Hour |
| Point-2 | ∇ | | | | | Calibration | # | Day | # Hour |

MB Type Factor: 1-Point Calibration Point: ∇ □ with Conc-0



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# CEDIA Opiate Assay – Semiquantitative (300 ng/mL cutoff)
# Beckman Coulter AU480 & AU680 Parameters

Specific Test Parameters

General | LIH | ISE | Range

Test Name: # ∇ < > Type: Urine ∇ Operation: Yes ∇

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sample Volume | 2.0 µL | Dilution | 0 µL | OD Limit | | | |
| Pre-Dilution Rate | 1 | | | Min. OD | -2.00 | Max. | 3.00 |
| Reagents R1(R1- | 87 µL | Dilution | 0 µL | Reagent OD | | | |
| | | | | First Low | -2.00 | High | 3.00 |
| | | | | Last Low | -2.00 | High | 3.00 |
| R2 (R2-1) | 87 µL | Dilution | 0 µL | | | | |
| | | | | Dynamic Range | # | High | # |
| | | | | Correlation Factor A | 1 | B | 0 |
| Wavelength: Pri. | 570 nm | Sec. | 660 nm | Factor for Maker A | 1 | B | 0 |
| Method: | FIXED1* ∇ | | | | | | |
| Reaction slope: | + ∇ | | | Onboard Stability | # Days | # | Hour |
| Measuring Point 1: First | 24 | Last | 27 | LIH Influence Check | # ∇ | | |
| Measuring Point 2: First | | Last | | Lipemia | ∇ | | |
| Linearity: | % | | | Icterus | ∇ | | |
| No Lag Time: | No ∇ | | | Hemolysis | ∇ | | |

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Tests | Range

Test Name # ∇ < > Type Urine ∇

Value/Flag # ∇

Level — Low # — High # — Panic Value: Low # — High #

Specific Ranges:

| | | Sex | From Year | From Month | To Year | To Month | Low | High |
|---|---|---|---|---|---|---|---|---|
| ☐ | 1 | # ∇ | # | # | # | # | # | # |
| ☐ | 2 | # ∇ | # | # | # | # | # | # |
| ☐ | 3 | # ∇ | # | # | # | # | # | # |
| ☐ | 4 | # ∇ | # | # | # | # | # | # |
| ☐ | 5 | # ∇ | # | # | # | # | # | # |
| ☐ | 6 | # ∇ | # | # | # | # | # | # |
| | 7 | No demographics | | | | | # | # |
| | 8 | Not within expected values | | | | | # | # |

Unit # Decimal Places #

\# User defined
* Can also be run as RATE1



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## CEDIA Opiate Assay – Semiquantitative (300 ng/mL cutoff)
## Beckman Coulter AU480 & AU680 Parameters, *continued*

| Parameters | Calibration Parameters | | |
|---|---|---|---|
| Calibrators | Calibration Specific | STAT Table Calibration | |

Test Name: # ∇ | < | > | Type: Urine ∇ | □ Use Serum Cal.

Calibration Type: 4AB ∇ | Formula: EIA Type 1* ∇ | Counts: 2 ∇

< Calibrator Parameters>

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point-1 | # ∇ | | 0 | -2.0000 | 3.0000 |
| Point-2 | # ∇ | | 300 | -2.0000 | 3.0000 |
| Point-3 | # ∇ | | 800 | -2.0000 | 3.0000 |
| Point-4 | # ∇ | | 2000 | -2.0000 | 3.0000 |
| Point-5 | ∇ | | | | |
| Point-6 | ∇ | | | | |
| Point-7 | ∇ | | | | |
| Point-8 | ∇ | | | | |
| Point-9 | ∇ | | | | |
| Point-10 | ∇ | | | | |

Slope Check: + ∇

Allowable Range Check
□ Reagent Blank
□ Calibration

Advanced Calibration
Operation: No ∇
Interval (RB/ACAL): ∇

□ Lot Calibration

< Point Cal. For Master Curve > No. of Correction Points: ∇ | Use Master Curve: ∇

| | Calibrator | OD | Conc | OD Range Low | OD Range High |
|---|---|---|---|---|---|
| Point-1 | ∇ | | | | |
| Point-2 | ∇ | | | | |

Stability
Reagent Blank: Day | Hour
Calibration: Day | Hour

MB Type Factor | 1-Point Calibration Point: None ∇ | □ with Conc-0

# User defined
* Can also be run as Polygonal or Spline



*End*



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