

CEDIA[®] METHADONE METABOLITE (EDDP)



ASSAY APPLICATION

BECKMAN COULTER AU5800[®]

Catalog No. 100087, 100096, 1868217

Intended for the qualitative and semiquantitative determination of methadone metabolite (EDDP (2-ethylidine-1, 5-dimethyl-3, 3-diphenylpyrrolidine)) in human urine

For In Vitro Diagnostic and Rx Use

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

Item	Size	Catalog No.
CEDIA Methadone Metabolite Assay	3 x17 mL	100087
	65 mL	100096
	495 mL	1868217
CEDIA Negative Calibrator	1 x 5 mL	1557416
	1 x 15 mL	1661388
CEDIA Primary Calibrator	1 x 5 mL	1815326
	1 x 15 mL	1815334
CEDIA Intermediate Calibrator	1 x 5 mL	1730380
	1 x 15 mL	1732218
CEDIA High Calibrator	1 x 5 mL	1730398
	1 x 15 mL	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 Fax: (510) 829-8115	Tel: +49 (0)851-88 6890 Fax: +49 (0)851-88 68910



Microgenics Corporation, part of Thermo Fisher Scientific
46500 Kato Road, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5001
U.S. Toll free fax: (888) 829-8115 / Fax: (510) 979-5420

EC REP Thermo Fisher Scientific Oy Ratastie 2, P.O. Box 100, 01621 Vantaa, Finland
Tel: +358-9-329100 / Fax: +358-9-32910300

Continued on next page

**Reagent
Storage**

Refer to the package insert for information on reagent storage.

**Procedure for
Analyzer**

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

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

**Results and
Data
Interpretation**

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

Beckman Coulter AU5800 Parameters
CEDIA Methadone Metabolite (EDDP) Assay, Qualitative

Parameters		Specific Test Parameters																																																																																							
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User defined

† 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.

Beckman Coulter AU5800 Parameters
CEDIA Methadone Metabolite (EDDP) Assay, Qualitative (continued)
(Option 1)

Parameters		Calibration Parameters			
Calibrators		Calibration Specific		STAT Table Calibration	

Test Name ▾ Type ▾ ☐ Use Serum Cal.

Calibration Type ▾ Formula ▾ Counts ▾

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

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

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

MB Type Factor 1-Point Calibration Point ▾ ☐ with Conc-0

(Option 2 or 3)

Parameters		Calibration Parameters			
Calibrators		Calibration Specific		STAT Table Calibration	

Test Name ▾ Type ▾ ☐ Use Serum Cal.

Calibration Type ▾ Formula ▾ Counts ▾

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

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

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

MB Type Factor 1-Point Calibration Point ▾ ☐ with Conc-0

User defined

Beckman Coulter AU5800 Parameters

CEDIA Methadone Metabolite (EDDP) Assay, Semiquantitative

Parameters		Specific Test Parameters					
General	LIH	ISE	HbA1c		Calculated Test	Range	
Test Name: # ▾		< >		Type: Urine ▾	Operation: Yes ▾		
Sample Volume: 8 μL		Dilution: 0 μL		OD Limit			
Pre-Dilution Rate: 1 ▾		Diluent Bottle: # ▾		Min.OD: -2.00		Max.OD: 3.00	
Rgt. Volume: R1(R1-1): 87 μL		Dilution: 0 μL		Reagent OD Limit			
R1-2: μL		Dilution: μL		1 st . Low: -2.00		High: 3.00	
R2(R2-1): 87 μL		Dilution: 0 μL		Last Low: -2.00		High: 3.00	
Common Rgt. Type: None		Name: None		Dynamic Range Low: #		High: #	
Wavelength: Pri 570 ▾nm		Sec. 660 ▾nm		Correlation Factor A: 1		B: 0	
Method: FIXED1 ▾				Factor for Maker A: 1		B: 0	
Reaction Slope: + ▾				Onboard Stability Period: 60 Day		# Hour	
Measuring Point1 1 st : 24		Last: 27		LIH Influence Check: # ▾			
Measuring Point2 1 st : %		Last: %		Lipemia: ▾			
Linearity Limit: No ▾				Icterus: ▾			
Lag Time Check: No ▾				Hemolysis: ▾			

Parameters		Specific Test Parameters					
General	LIH	ISE	HbA1c		Calculated Tests	Range	
Test Name: # ▾		< >		Type: Urine ▾			
Value/Flag: # ▾							
Level		Low: #		High: #			
Specific Ranges:							
	Sex	Year	Month	Year	Month	Low	High
☐	1 # ▾	#	#	#	#	#	#
☐	2 # ▾	#	#	#	#	#	#
☐	3 # ▾	#	#	#	#	#	#
☐	4 # ▾	#	#	#	#	#	#
☐	5 # ▾	#	#	#	#	#	#
☐	6 # ▾	#	#	#	#	#	#
	7 Standard Demographics					#	#
	8 Not within expected values					#	#
Panic Value		Low: #	High: #	Unit: ng/mL	Decimal Places: #		

User defined

Beckman Coulter AU5800 Parameters
CEDIA Methadone Metabolite (EDDP) Assay, Semiquantitative (continued)

Parameters		Calibration Parameters																																																																											
Calibrators		Calibration Specific		STAT Table Calibration																																																																									
Test Name # ▾		< >		Type Urine ▾	☐ Use Serum Cal.																																																																								
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AU Series Systems are trademarks of Beckman Coulter.

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