

**CEDIA® OPIATE APPLICATION**  
**BECKMAN COULTER AU5800®**



Catalog No. 100089, 100098, 1661248

Intended for the qualitative and semiquantitative determination of opiates 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 Opiate Assay	3 x17 mL	100089
	65 mL	100098
	495 mL	1661248
CEDIA Multi Drug Negative Calibrator	5 mL	1557416
	15 mL	1661388
CEDIA Multi Drug Secondary Calibrator	5 mL	1730428
	15 mL	1730517
CEDIA Multi Drug Intermediate Calibrator	5 mL	1730380
	15 mL	1732218
CEDIA Multi Drug High Calibrator	5 mL	1730398
	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

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

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**Reagent  
Storage**

Refer to the package insert for information on reagent storage.

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**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.**

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**Results and  
Data  
Interpretation**

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

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**Beckman Coulter AU5800 Parameters  
CEDIA Opiate, Qualitative**

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		PCP-Q	<	>	Type:	Urine	Operation	Yes			
Sample Volume	2	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 <sup>st</sup> .	Low	-2.00	High	3.00
							Last	Low	-2.00	High	3.00
	R2(R2-1)	87	μL	Dilution	0	μL					
Common Rgt. Type	None		Name	None		Correlation Factor A		High	#		
Wavelength	Pri	570	▽nm	Sec.	660	▽nm	Factor for Maker A		B	†	
Method	FIXED							B	0		
Reaction Slope	+		▽			Onboard Stability Period	60	Day	#	Hour	
Measuring Point1	1 <sup>st</sup>	24		Last	27	LIH Influence Check	#	▽			
Measuring Point2	1 <sup>st</sup>			Last		Lipemia		▽			
Linearity Limit			%			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			
			-9999999		‡			
Specific Ranges:								
		From	To					
	Sex	Year	Month	Year	Month	Low	High	
<input type="checkbox"/>	1	#	▽	#	#	#	#	
<input type="checkbox"/>	2	#	▽	#	#	#	#	
<input type="checkbox"/>	3	#	▽	#	#	#	#	
<input type="checkbox"/>	4	#	▽	#	#	#	#	
<input type="checkbox"/>	5	#	▽	#	#	#	#	
<input type="checkbox"/>	6	#	▽	#	#	#	#	
	7	Standard Demographics				#	#	
	8	Not within expected values				#	#	
Panic Value	Low	#	High	#	Unit	%	Decimal Places	#

# 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 Opiate, 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 >

	Calibrator	OD	Conc	Range		Slope Check
				Low	High	
Point-1	▾					
Point-2	▾					
Point-3	▾					
Point-4	▾					
Point-5	▾					
Point-6	▾					
Point-7	▾					
Point-8	▾					
Point-9	▾					
Point-10	▾					

Allowable Range Check  
 Reagent Blank   
 Calibration

Advanced Calibration  
 Operation  ▾  
 Interval (RB/ACAL)  ▾

Lot Calibration

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

	Calibrator	OD	Conc	OD Range		Stability
				Low	High	
Point-1	▾					
Point-2	▾					

Reagent Blank  Day  Hour  
 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 >

	Calibrator	OD	Conc	Factor Range		Slope Check
				Low	High	
Point-1	# ▾		100	-9999999	9999999	
Point-2	▾					
Point-3	▾					
Point-4	▾					
Point-5	▾					
Point-6	▾					
Point-7	▾					
Point-8	▾					
Point-9	▾					
Point-10	▾					

Allowable Range Check  
 Reagent Blank   
 Calibration

Advanced Calibration  
 Operation  ▾  
 Interval (RB/ACAL)  ▾

Lot Calibration

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

	Calibrator	OD	Conc	OD Range		Stability
				Low	High	
Point-1	▾					
Point-2	▾					

Reagent Blank  Day  Hour  
 Calibration  Day  Hour

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

# User defined

**Beckman Coulter AU5800 Parameters  
CEDIA Opiate, Semiquantitative**

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		PCP-Q ▾	<	>	Type: Urine ▾	Operation Yes ▾					
Sample Volume	2	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 <sup>st</sup> .	Low	-2.00	High	3.00
							Last	Low	-2.00	High	3.00
	R2(R2-1)	87	μL	Dilution	0	μL					
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 <sup>st</sup>	24		Last	27		LIH Influence Check	#	▽			
Measuring Point2 1 <sup>st</sup>			Last			Lipemia		▽			
Linearity Limit						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:		From		To				
	Sex	Year	Month	Year	Month	Low	High	
<input type="checkbox"/>	1	# ▾	#	#	#	#	#	
<input type="checkbox"/>	2	# ▾	#	#	#	#	#	
<input type="checkbox"/>	3	# ▾	#	#	#	#	#	
<input type="checkbox"/>	4	# ▾	#	#	#	#	#	
<input type="checkbox"/>	5	# ▾	#	#	#	#	#	
<input type="checkbox"/>	6	# ▾	#	#	#	#	#	
	7	Standard Demographics				#	#	
	8	Not within expected values				#	#	
Panic Value	Low	#	High	#	Unit	ng/mL	Decimal Places	#

