

**CEDIA® AMPHETAMINES/ECSTASY  
(1000 NG/ML CUTOFF) ASSAY APPLICATION  
BECKMAN COULTER AU5800®**



Catalog No. 100104, 100103, 100040

Intended for the qualitative and semiquantitative determination of amphetamines and ecstasy 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 Amphetamines/Ecstasy Assay Reagents	3 x17 mL	100104
	1 x 65 mL	100103
	1 x 495 mL	100040
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 Secondary Calibrator	1 x 5 mL	1730428
	1 x 15 mL	1730517
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 Primary DAU Control Set	3 x 5 mL	100200

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

B-R-A-H-M-S GmbH, Neuendorfstrasse 25, 16761, Hennigsdorf, Germany  
Tel: +49 (0)851-88 6890/ Fax: +49 (0)851-88 68910

---

**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 Amphetamines/Ecstasy, Qualitative**

Parameters		Specific Test Parameters					
General	LIH	ISE	HbA1c		Calculated Test	Range	
Test Name: # ▾		< >		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> Last	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	†
Method	FIXED ▾			Factor for Maker	1	B	0
Reaction Slope	+ ▾			Onboard Stability Period	45 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	-9999999	High	‡			
Specific Ranges:								
	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 Amphetamines/Ecstasy, 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	▾					None ▾  Allowable Range Check <input type="checkbox"/> Reagent Blank <input type="text"/> <input type="checkbox"/> Calibration <input type="text"/>  Advanced Calibration Operation <input type="text" value="No"/> ▾ Interval (RB/ACAL) <input type="text"/> ▾  <input type="checkbox"/> Lot Calibration
Point-2	▾					
Point-3	▾					
Point-4	▾					
Point-5	▾					
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	OD Range		Stability
				Low	High	
Point-1	▾					Reagent Blank <input type="text"/> Day <input type="text"/> Hour Calibration <input type="text"/> Day <input type="text"/> Hour
Point-2	▾					

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	+ ▾  Allowable Range Check <input type="checkbox"/> Reagent Blank <input type="text"/> <input type="checkbox"/> Calibration <input type="text"/>  Advanced Calibration Operation <input type="text" value="No"/> ▾ Interval (RB/ACAL) <input type="text"/> ▾  <input type="checkbox"/> Lot Calibration
Point-2	▾					
Point-3	▾					
Point-4	▾					
Point-5	▾					
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	OD Range		Stability
				Low	High	
Point-1	▾					Reagent Blank <input type="text" value="#"/> Day <input type="text" value="#"/> Hour Calibration <input type="text" value="#"/> Day <input type="text" value="#"/> Hour
Point-2	▾					

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

# User defined

**Beckman Coulter AU5800 Parameters**  
**CEDIA Amphetamines/Ecstasy, Semiquantitative**

Parameters		Specific Test Parameters					
General	LIH	ISE	HbA1c		Calculated Test	Range	
Test Name:	# ▾	<	>	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	Dilution	μL	1 <sup>st</sup> .	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	†
Method	FIXED ▾	Factor for Maker A	1	B	0		
Reaction Slope	+ ▾	Onboard Stability Period	45 Day	#	Hour		
Measuring Point1 1 <sup>st</sup>	24	LIH Influence Check	# ▾				
Measuring Point2 1 <sup>st</sup>		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		Low	High		
<input type="checkbox"/> 1	Sex # ▾	Year #	Month #	Year #	Month #	Low #	High #
<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	#	

**Beckman Coulter AU5800 Parameters**  
**CEDIA Amphetamines/Ecstasy, Semiquantitative (continued)**

Parameters		Calibration Parameters			
Calibrators		Calibration Specific		STAT Table Calibration	
Test Name	# ▾	<	>	Type	Urine ▾ <input type="checkbox"/> Use Serum Cal.
Calibration Type	5AB ▾	Formula	POLYGONAL ▾	Counts	2 ▾
< Calibrator Parameters >			Range		Slope Check
	Calibrator	OD	Conc	Low	High
Point-1	# ▾		0	-2.000	3.000
Point-2	# ▾		500	-2.000	3.000
Point-3	# ▾		1000	-2.000	3.000
Point-4	# ▾		3000	-2.000	3.000
Point-5	# ▾		5000	-2.000	3.000
Point-6	▾				
Point-7	▾				
Point-8	▾				
Point-9	▾				
Point-10	▾				
			Slope Check		+ ▾
			Allowable Range Check		
			<input type="checkbox"/> Reagent Blank		
			<input type="checkbox"/> Calibration		
			Advanced Calibration		
			Operation		No ▾
			Interval (RB/ACAL)		▾
			<input type="checkbox"/> Lot Calibration		
< Point Cal. For Master Curve >			No. of Correction Points	Use Master Curve	
			▾	▾	
			OD Range		
	Calibrator	OD	Conc	Low	High
Point-1	▾				
Point-2	▾				
			Stability		
			Reagent Blank		# Day # Hour
			Calibration		# Day # Hour
MB Type Factor		1-Point Calibration Point		None ▾ <input type="checkbox"/> with Conc-0	

© 2017 Thermo Fisher Scientific Inc. All rights reserved.  
All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified.  
CEDIA is a trademark of Roche Diagnostics.  
AU Series Systems are trademarks of Beckman Coulter.

End