

CEDIA® AMPHETAMINES/ECSTASY APPLICATION



BECKMAN COULTER AU480®, AU680®

Catalog No. 100104, 100103, 100040, 10016417

Intended for the Qualitative and Semiquantitative Determination of Amphetamines and Ecstasy 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 Amphetamines/Ecstasy Assay Reagents	3 x 17 mL	10016417
	3 x 17 mL	100104
	65 mL	100103
	495 mL	100040
CEDIA Negative Calibrator	5 mL	1557416
	15 mL	1661388
CEDIA Primary Calibrator	5 mL	1815326
	15 mL	1815334
CEDIA Secondary Calibrator	5 mL	1730428
	15 mL	1730517
CEDIA Intermediate Calibrator	5 mL	1730380
	15 mL	1732218
CEDIA High Calibrator	5 mL	1730398
	15 mL	1732226
MGC Primary DAU Control Set	3 x 5 mL	100200
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) 979-5420	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) 979-5000
U.S. Toll free fax: (888) 527-8001 / Fax: (510) 979-5420

B.R.A.H.M.S GmbH, Neuendorfstrasse 25, 16761, Hennigsdorf, Germany

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**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 the temperature of the analyzer reagent compartment before starting analysis.**

**Results and
Data
Interpretation**

Results for samples will be printed in ng/mL.

CEDIA Amphetamines/Ecstasy Assay – Qualitative (500 ng/mL Cutoff)
Beckman Coulter AU480 & AU680 Parameters
CEDIA Amphetamines/Ecstasy Assay – Qualitative (500 ng/mL Cutoff)
Beckman Coulter AU480 & AU680 Parameters

Specific Test Parameters									
General		LIH		ISE		Range			
Test Name:		#	<	>	Type:	Urine	Operation:		Yes
Sample Volume		4.0	μL	Dilution		0	μL	OD Limit	
Pre-Dilution Rate		1						Min. OD	-2.00
Reagents Volume: R1(R1-1)		87	μL	Dilution		0	μL	Reagent OD limit:	
								First Low	-2.00
								High	3.00
R2 (R2-1)		87	μL	Dilution		0	μL	Last Low	-2.00
								High	3.00
								Dynamic Range Low	#
								High	#
Wavelength: Pri.		570	nm	Sec.		660	nm	Correlation Factor A	1
Method:		FIXED*						B	†
Reaction slope:		+						Factor for Maker A	1
Measuring Point 1: First		24		Last		27		B	0
Measuring Point 2: First				Last					
Linearity:								Onboard Stability	#
No Lag Time:		No						Days	#
								Hour	#
								LIH Influence Check	#
								Lipemia	
								Icterus	
								Hemolysis	

Parameters		Specific Test Parameters				
General	LIH	ISE	HbA1c	Calculated Tests	Range	
Test Name		#	<	>	Type	Urine
Value/Flag		#				
Level		Low		High		Panic Value
		-9999999		‡		
Specific Ranges:		From		To		
	Sex	Year	Month	Year	Month	
☐	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.

CEDIA Amphetamines/Ecstasy Assay – Qualitative (1000 ng/mL Cutoff) Beckman Coulter AU480 & AU680 Parameters, *continued*

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

Parameters		Specific Test Parameters					
General	LIH	ISE	HbA1c	Calculated Tests	Range		
Test Name		#	<	>	Type	Urine	
Value/Flag		#					
Level			Low	-9999999	High	‡	Panic Value
Specific Ranges:		From	To				
	Sex	Year	Month	Year	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.

(Option 1)

(Option 2 or 3)

User defined

CEDIA Amphetamines/Ecstasy Assay – Semiquantitative (500 ng/mL Cutoff) **Beckman Coulter AU480 & AU680 Parameters**

Specific Test Parameters									
General		LIH		ISE		Range			
Test Name:		#	▽	<	>	Type:	Urine	▽	Operation: Yes
Sample Volume	4.0	μL	Dilution	0	μL	OD Limit			
Pre-Dilution Rate	1					Min. OD	-2.00	Max. OD	3.00
Reagents Volume:	R1(R1-1)	87	μL	Dilution	0	μL	Reagent OD limit:		
						First Low	-2.00	High	3.00
						Last Low	-2.00	High	3.00
	R2 (R2-1)	87	μL	Dilution	0	μL	Dynamic Range Low	#	High
							Correlation Factor A	1	B
Wavelength:	Pri.	570	nm	Sec.	660	nm	Factor for Maker A	1	B
Method:	FIXED* ▽								
Reaction slope:	+		▽			Onboard Stability	#	Days	#
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:		From		To							
	Sex	Year	Month	Year	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

CEDIA Amphetamines/Ecstasy Assay – Semiquantitative (500 ng/mL Cutoff)
Beckman Coulter AU480 & AU680 Parameters, *continued*

Parameters		Calibration Parameters			
Calibrators		Calibration Specific		STAT Table Calibration	

Test Name ▾ Type ▾ ☐ Use Serum Cal.

Calibration Type ▾ Formula ▾ Counts ▾

< Calibrator Parameters>

	Calibrator	OD	Conc	OD Range	
				Low	High
Point-1	# ▾		0	-2.0000	3.0000
Point-2	# ▾		500	-2.0000	3.0000
Point-3	# ▾		1000	-2.0000	3.0000
Point-4	# ▾		3000	-2.0000	3.0000
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	
				Low	High
Point-1	▾				
Point-2	▾				

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

Slope Check ▾

Allowable Range Check

☐ Reagent Blank

☐ Calibration

Advanced Calibration Operation ▾

Interval (RB/ACAL) ▾

☐ Lot Calibration

Stability

Reagent Blank Day Hour

Calibration Day Hour

User defined

* Can also be run as Polygonal or Spline

CEDIA Amphetamines/Ecstasy Assay – Semiquantitative (1000 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. OD	3.00
Reagents Volume:	R1(R1-1)	87	μL	Dilution	0	μL	Reagent OD limit:		
						First Low	-2.00	High	3.00
						Last Low	-2.00	High	3.00
	R2 (R2-1)	87	μL	Dilution	0	μL	Dynamic Range Low	#	High #
							Correlation Factor A	1	B †
							Factor for Maker A	1	B 0
Wavelength:	Pri.	570	nm	Sec.	660	nm	Onboard Stability	#	Days # Hour
Method:	FIXED* ▾								
Reaction slope:	+ ▾								
Measuring Point 1:	First	24		Last	27		LIH Influence Check	#	▾
Measuring Point 2:	First			Last			Lipemia		▾
Linearity:									
No Lag Time:	No ▾								
							Icterus		▾
							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:		From		To		
	Sex	Year	Month	Year	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

Parameters		Calibration Parameters			
Calibrators	Calibration Specific	STAT Table Calibration			
Test Name # ▾ <input type="button" value("<")"=""/> <input type="button" value(">")"=""/> Type Urine ▾ ☐ Use Serum Cal.					
Calibration Type 5AB ▾ Formula EIA Type 1* ▾ Counts 2 ▾					
< Calibrator Parameters >		OD Range		Slope Check	
	Calibrator	OD	Conc	Low	High
Point-1	# ▾		0	-2.0000	3.0000
Point-2	# ▾		500	-2.0000	3.0000
Point-3	# ▾		1000	-2.0000	3.0000
Point-4	# ▾		3000	-2.0000	3.0000
Point-5	# ▾		5000	-2.0000	3.0000
Point-6	# ▾				
Point-7	# ▾				
Point-8	# ▾				
Point-9	# ▾				
Point-10	# ▾				
				Allowable Range Check ☐ Reagent Blank	
				☐ Calibration	
				Advanced Calibration Operation No ▾	
				Interval (RB/ACAL) ▾	
				☐ Lot Calibration	
< Point Cal. For Master Curve >		No. of Correction Points 1 ▾		Use Master Curve 1 ▾	
	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 ▾		☐ with Conc-0	

* Can also be run as Polygonal or Spline

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