

**CEDIA[®] METHAMPHETAMINE OFT ASSAY APPLICATION
(ANZ)
BECKMAN COULTER AU680[®]**



Catalog No. 10011934 and 10011936

Intended for the semi quantitative determination of methamphetamine in human oral fluid at a cutoff concentration of 17 ng/mL (diluted oral fluid) or 51 ng/mL (neat oral fluid). The specimen must be collected exclusively with the Oral-Eze[®] Oral Fluid Collection System.

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 Methamphetamine OFT Assay	3 x 18	10011934
	1 x 65	10011936
CEDIA Methamphetamine OFT Negative Calibrator	1 x 10	10016344
CEDIA Methamphetamine OFT Calibrator 1	1 x 5	10016362
CEDIA Methamphetamine OFT Calibrator 2	1 x 5	10016363
CEDIA Methamphetamine OFT Calibrator 3	1 x 5	10016364
CEDIA Methamphetamine OFT Control 1	1 x 10	10017686
CEDIA Methamphetamine OFT Control 2	1 x 10	10017687
CEDIA Methamphetamine OFT Control 3	1 x 10	10017688

To place an order or for technical service, contact:

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



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

1. Set up the Beckman Coulter AU680 as instructed in the operator's manual.
2. Dispense adequate amounts of calibrators/control and sample(s) into sample cups in the appropriate racks.
3. Dispense adequate amounts of EA and ED reagents into appropriate containers.
4. Place the filled reagent containers on the reagent trays in positions defined by the user. **EA Reagent is used as R1; ED Reagent is used as R2. Make sure the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.**
5. Perform a reagent volume check as instructed in the operator's manual.
6. Define a worklist as instructed in the operator's manual. Press START to begin analysis.

Note: Under Specific Test Parameters/General Tab, Linearity % should be left blank, as reflected in the following pages. **Do Not Enter 0.**

Results and Data Interpretation

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

CEDIA Methamphetamine OFT Assay – Semi quantitative (ANZ) Beckman Coulter System Parameters, AU680

Parameters		Specific Test Parameters							
General	LIH	ISE		Calculated Tests	Range				
Test Name	MethOFT ▾	<	>	Type	Serum ▾	Operation	Yes ▾		
Sample Volume	25 μL	Dilution	0 ▾ μL	OD Limit		Min.OD	-2.0000	Max.OD	3.0000
Pre-Dilution Rate	1 ▾								
Reagent Volume R1(R1-1)	75 μL	Dilution	0 μL	Reagent OD Limit		First	Low -2.0000	High	3.0000
						Last	Low -2.0000	High	3.0000
	R2(R2-1) 75 μL	Dilution	0 μL						
Common Reagent Type	None	Name		Dynamic Range		Low	-9999.9	High	9999.9
Wavelength Pri.	570 ▾ nm	Sec.	660 ▾ nm	Correlation Factor	A *	B	0		
Method	FIXED1 ▾			Factor for Maker	A 1	B	0		
Reaction slope	+ ▾								
Measuring Point-1	First 24	Last	27	Onboard Stability Period		Day		Hour	
Measuring Point-2	First	Last							
Linearity Limit									
Lag Time Check	No ▾								

Parameters		Calibration Parameters				
Calibrators	Calibration Specific	STAT Table Calibration				
Test Name	MethOFT ▾	<	>	Type	Serum ▾	<input type="checkbox"/> Use Serum Cal.
Calibration Type	4AB ▾	Formula	Polygonal ▾	Counts	2 ▾	
< Calibrator Parameters >		Range		Slope Check	+ ▾	
	Calibrator	OD	Conc	Low	High	
Point-1	1. ▾		0.0	-2.0000	3.0000	Allowable Range Check
Point-2	2. ▾		10.0	-2.0000	3.0000	<input type="checkbox"/> Reagent Blank
Point-3	3. ▾		17.0	-2.0000	3.0000	<input type="checkbox"/> Calibration
Point-4	4. ▾		40.0	-2.0000	3.0000	
Point-5	▾					Advanced Calibration
Point-6	▾					Operation
Point-7	▾					Interval (RB/ACAL)
Point-8	▾					
Point-9	▾					<input type="checkbox"/> Lot Calibration
Point-10	▾					
< Point Cal. For Master Curve >		No. of Correction Points	▾	Use Master Curve	▾	
	Calibrator	OD	Conc	Low	High	Stability
Point-1	▾					Reagent Blank
Point-2	▾					Calibration
						Day
						Hour
MB Type Factor		1-Point Calibration Point	None ▾	<input type="checkbox"/> with Conc-0		

For Specific Test Parameters → Range Tab, enter “ng/mL” for Unit and “1” for Decimal Places.

* Option 1: When the correlation factor “1” is used, the sample results represent diluted oral-fluid concentrations.

* Option 2: When the correlation factor “3” is used, the sample results are multiplied by 3 to represent undiluted (neat) oral-fluid concentrations.

Precision

Tests for within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (N=60/ level):

Controls	Control 1	Control 2	Control 3
Beckman Coulter AU680 Semi Quantitative			
Mean (ng/mL)	13.9	18.3	27.7
Within-Run SD (ng/mL)	0.8	0.9	1.1
Within-Run CV (%)	5.8	4.9	4.1
Total SD (ng/mL)	0.8	1.0	1.3
Total CV (%)	5.8	5.7	4.6

Accuracy and Correlation

Forty one oral fluid samples from a rehabilitation clinic were collected using the Oral-Eze Oral Fluid Collection Device. The oral fluid samples were tested using the CEDIA Methamphetamine OFT Assay and by an LC-MS/MS method.

Semi Quantitative Method Comparison			
	Positive Agreement (%)	Negative Agreement (%)	Total Agreement (%)
AU680	100.0	100.0	100.0

**Semi quantitative
LC-MS/MS**

		+	-
AU680	+	21	0
	-	0	20

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