CEDIA® AMPHETAMINE OFT ASSAY APPLICATION (ANZ) CE
BECKMAN COULTER AU680®

Catalog No. 10011931, 10011932

The Thermo Scientific CEDIA Amphetamine OFT Assay is intended for use in the semiquantitative determination of amphetamine 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
For International Use Only – Not for sale in US
(For Use with Oral-Eze Oral Fluid Collection System)

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 Amphetamine OFT Assay	3 x 18 mL 1 x 65 mL	10011931 10011932
CEDIA Multi-Drug OFT Negative Calibrator	1 x 20 mL	10016864
CEDIA Multi-Drug OFT Calibrator 1	1 x 10 mL	10016882
CEDIA Multi-Drug OFT Calibrator 2	1 x 10 mL	10016883
CEDIA Multi-Drug OFT Calibrator 3	1 x 10 mL	10016884
CEDIA Multi-Drug OFT Control 1	1 x 15 mL	10017711
CEDIA Multi-Drug OFT Control 2	1 x 15 mL	10017712
CEDIA Multi-Drug OFT Control 3	1 x 15 mL	10017713

To place an order or for technical service, contact:

In Europe
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

EC REP B·R·A·H·M·S GmbH, Neuendorfstrasse 25, 16761, Hennigsdorf, Germany

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510-979-5000
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Toll Free: 800-232-3342

Reagent Storage

Refer to 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. <u>**EA Reagent is used as R1; ED Reagent is used as R2.**</u> **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.
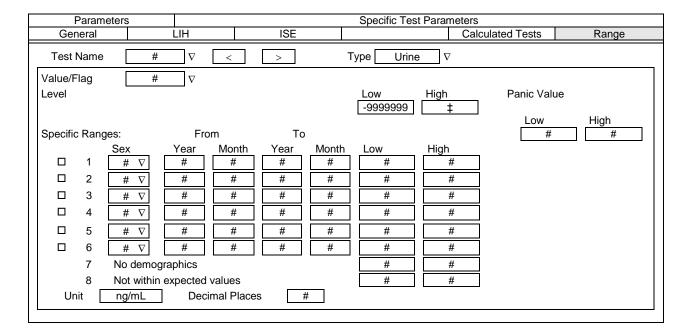
CEDIA Amphetamine OFT Assay (ANZ), Semiquantitative
Beckman Coulter System Parameters, AU680

Specific Test Parameters			
General	LIH	ISE	Range

Test Name: [AmpOFT ∇] [<] [>]   Type: [Urine ∇]   Operation: [Yes ∇]

Sample Volume	[25] μL	Dilution [0] μL	OD Limit
Pre-Dilution Rate	[1]		Min. OD [-2.00] Max. OD [3.00]
Reagents	R1(R1- [75] μL	Dilution [0] μL	Reagent OD
			First Low [-2.00] High [3.00]
			Last Low [-2.00] High [3.00]
	R2 (R2-1) [75] μL	Dilution [0] μL	
			Dynamic Range [-9999.9] High [9999.9]
			Correlation Factor A [*] B [0]
Wavelength:	Pri. [570] nm	Sec. [660] nm	Factor for Maker A [1] B [0]
Method:	[FIXED1 ∇]		
Reaction slope:	[+ ∇]		Onboard Stability [#] Days [#] Hour
Measuring Point 1:	First [24]	Last [27]	LIH Influence Check [# ∇]
Measuring Point 2:	First [ ]	Last [ ]	Lipemia [∇]
Linearity:	[ ] %		Icterus [∇]
No Lag Time:	[No ∇]		Hemolysis [∇]

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.

Parameters		Specific Test Parameters			
General	LIH	ISE		Calculated Tests	Range

Test Name [# ∇] [<] [>]   Type [Urine ∇]

Value/Flag [# ∇]

Level		Low High	Panic Value
		[-9999999] [‡]	
			Low High
			[#] [#]

Specific Ranges:

		Sex	Year	Month	Year	Month	Low	High
☐	1	[# ∇]	[#]	[#]	[#]	[#]	[#]	[#]
☐	2	[# ∇]	[#]	[#]	[#]	[#]	[#]	[#]
☐	3	[# ∇]	[#]	[#]	[#]	[#]	[#]	[#]
☐	4	[# ∇]	[#]	[#]	[#]	[#]	[#]	[#]
☐	5	[# ∇]	[#]	[#]	[#]	[#]	[#]	[#]
☐	6	[# ∇]	[#]	[#]	[#]	[#]	[#]	[#]
	7	No demographics					[#]	[#]
	8	Not within expected values					[#]	[#]

Unit [ng/mL]   Decimal Places [#]

CEDIA Amphetamine OFT Assay (ANZ), Semiquantitative
Beckman Coulter System Parameters, AU680, *continued*

Parameters		Calibration Parameters	
Calibrators	Calibration Specific	STAT Table Calibration	

Test Name [AmpOFT] ▽ [<] [>]   Type [Serum] ▽   □ 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	□ Reagent Blank [ ]
Point-3	3. ▽		17.0	-2.0000	3.0000	□ Calibration [ ]
Point-4	4. ▽		40.0	-2.0000	3.0000	
Point-5	▽					Advanced Calibration
Point-6	▽					Operation [No ▽]
Point-7	▽					Interval (RB/ACAL) [▽]
Point-8	▽					
Point-9	▽					□ Lot Calibration
Point-10	▽					

< Point Cal. For Master Curve > No. of Correction Points [▽] Use Master Curve [▽]

                                         OD Range

	Calibrator	OD	Conc	Low	High	Stability
Point-1	▽					Reagent Blank [ ] Day [ ] Hour
Point-2	▽					Calibration [ ] Day [ ] Hour

MB Type Factor [ ]   1-Point Calibration Point [None ▽]   □ with Conc-0

End