

CEDIA® COCAINE OFT ASSAY APPLICATION (UK)

BECKMAN COULTER AU680®



Catalog No. 10014734, 10014740

The Thermo Scientific CEDIA Cocaine OFT Assay is intended for use in the qualitative determination of benzoylecgonine in human oral fluid at a cutoff concentration of 5 ng/mL (diluted oral fluid) or 15 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 Cocaine OFT Assay	3 x 18 mL	10014734
	1 x 65 mL	10014740
CEDIA Multi-Drug OFT Negative Calibrator	1 x 20 mL	10016864
CEDIA Multi-Drug OFT Cutoff Calibrator	1 x 10 mL	10016894
CEDIA Multi-Drug OFT Control Set	2 x 15 mL	10016895

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

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 Cocaine OFT Assay (UK), Qualitative Beckman Coulter System Parameters, AU680

Specific Test Parameters									
General		LIH		ISE		Range			
Test Name:		# ▾		< >		Type: Urine ▾		Operation: Yes ▾	
Sample Volume		25 µL		Dilution 0 µL		OD Limit			
Pre-Dilution Rate		1				Min. OD -2.00		Max. 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 #		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 # 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		▾	

Parameters		Specific Test Parameters							
General		LIH		ISE		Calculated Tests		Range	
Test Name		# ▾		< >		Type Urine ▾			
Value/Flag		# ▾							
Level				Low -9999999		High ‡		Panic Value	
								Low # High #	
Specific Ranges:		From		To		Low		High	
Sex		Year		Month		Year		Month	
☐	1	# ▾	#	#	#	#	#	#	#
☐	2	# ▾	#	#	#	#	#	#	#
☐	3	# ▾	#	#	#	#	#	#	#
☐	4	# ▾	#	#	#	#	#	#	#
☐	5	# ▾	#	#	#	#	#	#	#
☐	6	# ▾	#	#	#	#	#	#	#
7		No demographics				#	#	#	#
8		Not within expected values				#	#	#	#
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.

CEDIA Cocaine OFT Assay (UK), Qualitative Beckman Coulter System Parameters, AU680, *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 Low	High
Point-1					
Point-2					
Point-3					
Point-4					
Point-5					
Point-6					
Point-7					
Point-8					
Point-9					
Point-10					

Slope Check

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 Low	High
Point-1					
Point-2					

Stability
 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 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					

Slope Check

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 Low	High
Point-1					
Point-2					

Stability
 Reagent Blank Day Hour
 Calibration Day Hour

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

User defined

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