

CEDIA[®] COCAINE OFT ASSAY APPLICATION
BECKMAN COULTER AU680[®]

Catalog No. 10014737, 10014743

The CEDIA Cocaine OFT Assay is intended for use in the qualitative determination of cocaine and cocaine metabolites at a cutoff of 5.0 ng/mL with human oral fluid samples that have been collected with the Thermo Scientific Oral Fluid Device.

For Criminal Justice and Forensic Use- Domestic Market.

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 storage, quality control, and additional performance data.

Ordering Information

Materials available:

Item	Catalog Number
CEDIA Cocaine OFT Assay	10014737, 10014743
CEDIA Multi-Drug OFT Negative Calibrator	10011942
CEDIA Multi-Drug OFT Cutoff Calibrator	10011943
CEDIA Multi-Drug OFT High Calibrator	10011944
CEDIA Multi-Drug OFT Controls Kit	10011945

To place an order or for technical service contact (North America):

**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***Continued on next page*

**Reagent
Storage**

Refer to package insert for information on reagent storage.

**Procedure for
Analyzer**

Refer to operator's manuals for information on analyzer operation.

Dispense adequate amounts of EA Reagent (first reagent) and ED Reagent (second reagent) into appropriate containers. **Make sure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting 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.

Continued on next page

CEDIA Cocaine OFT Assay 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 #			
						Correlation Factor A 1		B †	
Wavelength: Pri.		570 nm		Sec. 660 nm		Factor for Maker A 1 B 0			
Method:		RATE* ▾							
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					
		Sex		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 FIXED

† 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 – continued

Beckman Coulter System Parameters, AU680

(Option 1)

Parameters		Calibration Parameters	
Calibrators	Calibration Specific	STAT Table Calibration	
Test Name	# ▾	< ▾	> ▾
Type	Urine ▾	☐ Use Serum Cal.	
Calibration Type	MB ▾	Formula	Y=AX+B ▾
		Counts	2 ▾
< Calibrator Parameters >		Range	Slope Check
	Calibrator	OD	Conc
		Low	High
Point-1	▾		
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
		Low	High
Point-1	▾		
Point-2	▾		
MB Type Factor		1000	1-Point Calibration Point
			▾
		☐ with Conc-0	
		Slope Check	
		▾	
		Allowable Range Check	
		☐ Reagent Blank	
		☐ Calibration	
		Advanced Calibration	
		Operation	
		Interval (RB/ACAL)	
		No ▾	
		▾	
		☐ Lot Calibration	
		Stability	
		Reagent Blank	
		Calibration	
		# Day # Hour	
		# Day # Hour	

(Option 2 or 3)

Parameters		Calibration Parameters	
Calibrators	Calibration Specific	STAT Table Calibration	
Test Name	# ▾	< ▾	> ▾
Type	Urine ▾	☐ Use Serum Cal.	
Calibration Type	AB ▾	Formula	Y=AX+B ▾
		Counts	2 ▾
< Calibrator Parameters >		Factor Range	Slope Check
	Calibrator	OD	Conc
		Low	High
Point-1	# ▾		100
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
		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)	
		No ▾	
		▾	
		☐ Lot Calibration	
		Stability	
		Reagent Blank	
		Calibration	
		# Day # Hour	
		# Day # Hour	

User defined

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