

CEDIA[®] OPIATE OFT ASSAY APPLICATION (UK) - CE

Beckman Coulter AU680

Catalog No. 10010612, 10010659

The Thermo Scientific CEDIA Opiate OFT Assay is intended for use in the qualitative determination of opiates in human oral fluid at a cutoff concentration of 10 ng/mL (diluted oral fluid) or 30 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 storage, quality control, and additional performance data.

Ordering Information

Materials available from Microgenics, a part of Thermo Fisher Scientific:

Item	Catalog Number
CEDIA Opiate OFT Assay	10010612, 10010659
CEDIA Multi-Drug OFT Negative Calibrator	10016864
CEDIA Multi-Drug OFT Cutoff Calibrator	10016894
CEDIA Multi-Drug OFT Control Set	10016895

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

B.R.A.H.M.S GmbH, Neuendorfstrasse 25, 16761, Hennigsdorf, Germany
Tel: +49 (0)851-88 6890/ Fax: +49 (0)851-88 68910

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Reagent Storage

Refer to package insert for information on reagent storage.

Procedure for Analyzer

1. Set up the Olympus 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.

Continued on next page

Olympus System Parameters, AU680 CEDIA® Opiate OFT Assay – Qualitative (UK)

Specific Test Parameters											
General		LIH		ISE		Range					
Test Name:	OpiOFT ▾		<	>	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:	FIXED ▾										
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	High		Panic Value				
			-9999999	‡						
Specific Ranges:	From		To		Low		High			
	Sex	Year	Month	Year	Month	Low	High			
<input type="checkbox"/>	1	# ▾	#	#	#	#	#			
<input type="checkbox"/>	2	# ▾	#	#	#	#	#			
<input type="checkbox"/>	3	# ▾	#	#	#	#	#			
<input type="checkbox"/>	4	# ▾	#	#	#	#	#			
<input type="checkbox"/>	5	# ▾	#	#	#	#	#			
<input type="checkbox"/>	6	# ▾	#	#	#	#	#			
	7	No demographics				#	#			
	8	Not within expected values				#	#			
Unit	#		Decimal Places	#						

User defined

For Specific Test Parameters → Range Tab, enter “mA/min” for Unit and “0” for Decimal Places.

† 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.

Olympus System Parameters, AU680
CEDIA® Opiate OFT Assay – Qualitative (UK), continued
(Option 1)

Parameters		Calibration Parameters				
Calibrators		Calibration Specific		STAT Table Calibration		
Test Name	<input type="text" value="OpiOFT"/> ▾	<input type="text" value="<"/>	<input type="text" value=">"/>	Type	<input type="text" value="Urine"/> ▾	<input type="checkbox"/> Use Serum Cal.
Calibration Type	<input type="text" value="MB"/> ▾	Formula	<input type="text" value="Y=AX+B"/> ▾	Counts	<input type="text" value="2"/> ▾	
< Calibrator Parameters >				Range	Slope Check	<input type="text" value=""/>
	Calibrator	OD	Conc	Low	High	
Point-1	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Allowable Range Check
Point-2	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Reagent Blank
Point-3	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Calibration
Point-4	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	
Point-5	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Advanced Calibration
Point-6	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Operation
Point-7	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Interval (RB/ACAL)
Point-8	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value="No"/> ▾
Point-9	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Lot Calibration
Point-10	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	
< Point Cal. For Master Curve >				No. of Correction Points	<input type="text" value=""/>	Use Master Curve
	Calibrator	OD	Conc	Low	High	Stability
Point-1	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Reagent Blank
Point-2	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Calibration
						<input type="text" value=""/> Day <input type="text" value=""/> Hour
						<input type="text" value=""/> Day <input type="text" value=""/> Hour
MB Type Factor	<input type="text" value="1000"/>	1-Point Calibration Point	<input type="text" value=""/>	<input type="checkbox"/> with Conc-0		

(Option 2 or 3)

Parameters		Calibration Parameters				
Calibrators		Calibration Specific		STAT Table Calibration		
Test Name	<input type="text" value="#"/> ▾	<input type="text" value="<"/>	<input type="text" value=">"/>	Type	<input type="text" value="Urine"/> ▾	<input type="checkbox"/> Use Serum Cal.
Calibration Type	<input type="text" value="AB"/> ▾	Formula	<input type="text" value="Y=AX+B"/> ▾	Counts	<input type="text" value="2"/> ▾	
< Calibrator Parameters >				Factor Range	Slope Check	<input type="text" value="+"/> ▾
	Calibrator	OD	Conc	Low	High	
Point-1	<input type="text" value="#"/> ▾	<input type="text" value=""/>	<input type="text" value="100"/>	<input type="text" value="-9999999"/>	<input type="text" value="9999999"/>	Allowable Range Check
Point-2	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Reagent Blank
Point-3	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Calibration
Point-4	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	
Point-5	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Advanced Calibration
Point-6	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Operation
Point-7	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Interval (RB/ACAL)
Point-8	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value="No"/> ▾
Point-9	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Lot Calibration
Point-10	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	
< Point Cal. For Master Curve >				No. of Correction Points	<input type="text" value=""/>	Use Master Curve
	Calibrator	OD	Conc	Low	High	Stability
Point-1	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Reagent Blank
Point-2	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Calibration
						<input type="text" value="#"/> Day <input type="text" value="#"/> Hour
						<input type="text" value="#"/> Day <input type="text" value="#"/> Hour
MB Type Factor	<input type="text" value=""/>	1-Point Calibration Point	<input type="text" value=""/>	<input type="checkbox"/> with Conc-0		

User defined

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