

CEDIA[®] CANNABINOIDS OFT ASSAY APPLICATION (EU) BECKMAN COULTER AU680[®], AU2700[®]

Catalog No. 10010883 and 10010888

The Thermo Scientific CEDIA Cannabinoids OFT Assay is intended for use in the qualitative and semi-quantitative determination of cannabinoids in human oral fluid at a cutoff concentration of 3.3 ng/mL (diluted oral fluid) or 10 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 Cannabinoids OFT Assay	10010883, 10010888
CEDIA THC OFT Negative Calibrator	10016643
CEDIA THC OFT Calibrator 1	10016644
CEDIA THC OFT Calibrator 2	10016646
CEDIA THC OFT Calibrator 3	10016647
CEDIA THC OFT Calibrator 4	10016648
CEDIA THC OFT Control Set	10016649

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

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Reagent Storage

Refer to package insert for information on reagent storage.

Analyzer Procedure

1. Set up the Beckman Coulter AU680/AU2700 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 Cannabinoids OFT Assay – Qualitative (EU) Beckman Coulter System Parameters, AU680

Parameters		Specific Test Parameters								
General	LIH	ISE		Calculated Tests	Range					
Test Name	THCOFT ▾	<	>	Type	Urine ▾	Operation	Yes ▾			
Sample Volume	8 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	#	High	#	
Wavelength Pri.	540 ▾ nm	Sec.	660 ▾ nm	Correlation Factor		A	1	B	†	
Method	RATE ▾			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		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	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.

CEDIA Cannabinoids OFT Assay – Qualitative (EU) Beckman Coulter System Parameters, AU680, *continued*

(Option 1)

Parameters	Calibration Parameters						
Calibrators	Calibration Specific	STAT Table Calibration					
Test Name	# ▾	<	>	Type	Urine ▾	<input type="checkbox"/> 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	Stability	
Point-1	▾					Reagent Blank	▾ Day ▾ Hour
Point-2	▾					Calibration	▾ Day ▾ Hour
MB Type Factor				1000	1-Point Calibration Point	▾	<input type="checkbox"/> with Conc-0

(Option 2 or 3)

Parameters	Calibration Parameters						
Calibrators	Calibration Specific	STAT Table Calibration					
Test Name	# ▾	<	>	Type	Urine ▾	<input type="checkbox"/> 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	-9999999	9999999		
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	Stability	
Point-1	▾					Reagent Blank	# Day # Hour
Point-2	▾					Calibration	# Day # Hour
MB Type Factor				▾	1-Point Calibration Point	▾	<input type="checkbox"/> with Conc-0

User defined

CEDIA Cannabinoids OFT Assay – Qualitative (EU) Beckman Coulter System Parameters, AU2700

Specific Test Parameters											
General		LIH		ISE		Range					
Test Name:	THCOFT	<	>	Type:	Urine	Operation:	Yes				
Sample:	Volume	8	μL	Dilution	0	μL	Pre-Dilution Rate:	1			
Reagents:	R1 Volume	75	μL	Dilution	0	μL	Min OD	Max OD			
	R2 Volume	75	μL	Dilution	0	μL	L	-2.00	H	3.00	
Wavelength:	Pri.	540	▼	Sec.	660	▼	Reagent OD limit:				
Method:	RATE						First L	-2.00	First H	3.00	
Reaction slope:	+						Last L	-2.00	Last H	3.00	
Measuring Point 1:	First	24		Last	27		Dynamic Range:	L	#	H	#
Measuring Point 2:	First			Last			Correlation Factor:				
Linearity:							A	1	B	†	
No Lag Time:							On-board stability period:	#			

Specific Test Parameters									
General		LIH		ISE		Range			
Test Name:	#	<	>	Type:	Urine				
Value/Flag:	#	Level L:	-999999	Level H:	#				
Normal Ranges:									
	Sex	Year	Month	Year	Month	L	H		
<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. None Selected						#	#		
8. Out of Range						#	#		
Panic Value:	#	L	#	H	#	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.

CEDIA Cannabinoids OFT Assay – Qualitative (EU) Beckman Coulter System Parameters, AU2700, *continued*

(Option 1)

Calibration Specific					
General		ISE			
Test Name:		<input type="text"/>	<	>	Type <input type="text" value="Urine"/>
Calibration Type:		<input type="text" value="MB"/>	Formula:	<input type="text" value="Y=AX+B"/>	Counts: <input type="text" value="2"/> Process: <input type="text" value="CONC"/>
	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	<input type="text"/>	<input type="text"/>	*	*	*
Point 2:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 3:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 4:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 5:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 6:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 7:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1-Point Cal. Point:	<input type="text"/>	<input type="checkbox"/>	With CONC-0	Slope Check <input type="text"/>	Advanced Calibration: <input type="text"/>
MB Type Factor:	<input type="text" value="1000"/>		Calibration Stability Period: <input type="text"/>		

(Option 2 or 3)

Calibration Specific					
General		ISE			
Test Name:		<input type="text"/>	<	>	Type <input type="text" value="Urine"/>
Calibration Type:		<input type="text" value="AB"/>	Formula:	<input type="text" value="Y=AX+B"/>	Counts: <input type="text" value="2"/> Process: <input type="text" value="CONC"/>
	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	<input type="text"/>	<input type="text"/>	100	-999999	999999
Point 2:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 3:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 4:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 5:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 6:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Point 7:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1-Point Cal. Point:	<input type="text"/>	<input type="checkbox"/>	With CONC-0	Slope Check <input type="text"/>	Advanced Calibration: <input type="text"/>
MB Type Factor:	<input type="text"/>		Calibration Stability Period: <input type="text"/>		

* User Defined

CEDIA Cannabinoids OFT Assay – Semi-quantitative (EU) Beckman Coulter System Parameters, AU680

Parameters		Specific Test Parameters			
General		LIH	ISE	Calculated Tests	Range
Test Name	THCOFT ▾	<	>	Type	Urine ▾
				Operation	Yes ▾
Sample Volume	8 μL	Dilution	0 ▾ μL	OD Limit	
Pre-Dilution Rate	1 ▾			Min.OD	-2.0000
				Max.OD	3.0000
Reagent Volume R1(R1-1)	75 μL	Dilution	0 μL	Reagent OD Limit	
				First	Low -2.0000 High 3.0000
R2(R2-1)	75 μL	Dilution	0 μL	Last	Low -2.0000 High 3.0000
Common Reagent Type	None	Name		Dynamic Range	Low -9999.9 High 9999.9
Wavelength Pri.	540 ▾ nm	Sec.	660 ▾ nm	Correlation Factor	A * B 0
Method	RATE1 ▾			Factor for Maker	A 1 B 0
Reaction slope	+ ▾			Onboard Stability Period	Day Hour
Measuring Point-1	First 24	Last	27		
Measuring Point-2	First	Last			
Linearity Limit	%				
Lag Time Check	No ▾				

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		Calibration Parameters			
Calibrators		Calibration Specific	STAT Table Calibration		
Test Name	THCOFT ▾	<	>	Type	Urine ▾
				<input type="checkbox"/> Use Serum Cal.	
Calibration Type	5AB ▾	Formula	Spline ▾	Counts	2 ▾
< Calibrator Parameters >		Range		Slope Check	+ ▾
	Calibrator	OD	Conc	Low	High
Point-1	1. ▾		0.0	-2.0000	3.0000
Point-2	2. ▾		1.7	-2.0000	3.0000
Point-3	3. ▾		3.3	-2.0000	3.0000
Point-4	4. ▾		10.0	-2.0000	3.0000
Point-5	5. ▾		20.0	-2.0000	3.0000
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	None ▾	<input type="checkbox"/> with Conc-0	
Allowable Range Check				<input type="checkbox"/> Reagent Blank	
				<input type="checkbox"/> Calibration	
Advanced Calibration				Operation	No ▾
				Interval (RB/ACAL)	▾
				<input type="checkbox"/> Lot Calibration	
Stability				Reagent Blank	Day Hour
				Calibration	Day Hour

CEDIA Cannabinoids OFT Assay – Semi-quantitative (EU) Beckman Coulter System Parameters, AU2700

Specific Test Parameters										
General		LIH		ISE		Range				
Test Name:	THCOFT		<	>	Type:	Urine		Operation:	Yes	
Sample:	Volume	8	μL	Dilution	0	μL	Pre-Dilution Rate:	1		
Reagents:	R1 Volume	75	μL	Dilution	0	μL	Min OD	Max OD		
	R2 Volume	75	μL	Dilution	0	μL	L	-2.00	H	3.00
Wavelength:	Pri.	540	▼	Sec.	660	▼	Reagent OD limit:			
Method:	RATE		▼				First L	-2.00	First H	3.00
Reaction slope:	+		▼				Last L	-2.00	Last H	3.00
Measuring Point 1:	First	24		Last	27		Dynamic Range:			
Measuring Point 2:	First			Last			L	-9999.9	H	9999.9
Linearity:			%				Correlation Factor:			
No Lag Time:			▼				A	*	B	0
						On-board stability period:				

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.

Calibration Specific										
General		ISE								
Test Name:	THCOFT		<	>	Type:	Urine				
Calibration Type:	5AB		▼	Formula:	Spline		▼	Counts:	2	
							Process:	CONC		
Point 1:	Cal. No.			OD			Factor/OD-L	*	Factor/OD-H	*
Point 2:										
Point 3:										
Point 4:										
Point 5:										
Point 6:										
Point 7:										
1-Point Cal. Point:	None	<input type="checkbox"/>	With CONC-0	Slope Check	+		▼	Advanced Calibration:		▼
MB Type Factor:							Calibration Stability Period:			

* User Defined

Precision The within-run and total precision, evaluated with approved lot reagents and production lot controls and calibrators, yielded the following results (n=48):

Qualitative

Cals / Ctrls	n = 48	Within-Run Precision		Total Run Precision	
		Mean Rate	SD	CV%	SD
1.7 ng/mL	359	4.0	1.1	6.5	1.8
3.3 ng/mL	414	4.7	1.1	7.8	1.8
5.0 ng/mL	484	6.2	1.3	9.2	1.9

Semi-quantitative

Cals / Ctrls	n = 48	Within-Run Precision		Total Run Precision	
		Mean Recovery	SD	CV%	SD
1.7 ng/mL	2.0	0.1	6.7	0.3	14.7
3.3 ng/mL	3.5	0.1	3.2	0.2	6.8
5.0 ng/mL	5.6	0.1	2.6	0.3	5.0

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 Cannabinoid OFT Assay in qualitative and semi-quantitative modes and compared to an LC-MS/MS method.

Qualitative: The overall concordance between CEDIA Cannabinoids OFT Assay and LC-MS/MS using a cutoff of 3.3 ng/mL is 98%. The comparison of sample results by the CEDIA Cannabinoids OFT Assay to LC-MS/MS showed 100% sensitivity and 95% specificity.

Semi-quantitative: The overall concordance between CEDIA Cannabinoids OFT Assay and LC-MS/MS using a cutoff of 3.3 ng/mL is 100%. The comparison of sample results by the CEDIA Cannabinoids OFT Assay to LC-MS/MS showed 100% sensitivity and 100% specificity.

Qualitative				Semi-quantitative			
LC-MS/MS (ng/mL)				LC-MS/MS (ng/mL)			
		+	-			+	-
AU680	+	20	1*	AU680	+	20	0
	-	0	20		-	0	21

***Discrepant Sample**

Sample ID	AU680 (ΔRate, mA/min)	LC-MS/MS (ng/mL)
17	9	2.56

*Discrepant sample was borderline negative by LC-MS/MS

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