



CEDIA® VALPROIC ACID II APPLICATION

**BECKMAN COULTER AU400® , AU640® , AU480® , AU680® ,
AU2700® , AU5400® , AU5800®**

Catalog No. 100013

Homogeneous Enzyme Immunoassay for Valproic Acid II



For In Vitro Diagnostic Use Only
Rx 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 preparation, specimen storage, quality control, and additional performance data. For package inserts, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field.

Ordering Information

For ordering information, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field. Not all intended uses and applications mentioned here are available in every country. Please contact your local sales representative or distributor for more information.

For Technical Service, contact:

USA	In Europe
Tel: (800) 232-3342 Fax: (510) 979-5420	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

Continued on next page

**Reagent
Storage**

Refer to the package insert for information on reagent storage.

**Analyzer
Procedure**

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

**Results and
Data
Interpretation**

Results for samples will be printed in µg/mL.

CEDIA Valproic Acid
Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

Specific Test Parameters									
General		LIH		ISE		Range			
Test Name:		VPA ▾		< ▾ > ▾		Type:		SERUM ▾	
Operation:		Yes ▾							
Sample Volume		2.0 μL		Dilution		0 μL		OD Limit	
Pre-Dilution Rate		1.0						Min. OD -2.00 Max. OD 3.00	
Reagents Volume:		R1(R1-1) 85 μL		Dilution		0 μL		Reagent OD limit:	
								First Low -2.00 High 3.00	
								Last Low -2.00 High 3.00	
		R2 (R2-1) 64 μL		Dilution		0 μL		Dynamic Range Low 3 High 150	
								Correlation Factor A 1 B 0	
								Factor for Maker A 1 B 0	
Wavelength:		Pri. 570 nm		Sec. 660 nm					
Method:		RATE1* ▾							
Reaction slope:		+ ▾							
Measuring Point 1:		First 24		Last 27		Onboard Stability # Days # Hour			
Measuring Point 2:		First		Last		LIH Influence Check # ▾			
Linearity:		% ▾							
No Lag Time:		NO ▾							
						Lipemia ▾			
						Icterus ▾			
						Hemolysis ▾			

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User defined.

* Can be ran as FIXED1

CEDIA Valproic Acid
Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400, (continued)

Calibration Specific									
General		ISE							
Test Name:		VPA ▾		< ▢ > ▢		Type		SERUM ▾ ☐ Use Serum Cal.	
Calibration Type:		AA ▾		Formula:		Y=AX+B ▾		Counts: 2	
<Calibrator Parameters>									
	Calibrator ↑	OD	Conc	Factor Range		Slope Check			
				Low	High				
Point 1:	# ▾		**	-999999	999999	Allowable Range Check			
Point 2:	# ▾		**	999999	999999	☐ Reagent Blank			
Point 3:	▾					☐ Calibration			
Point 4:	▾					Advanced Calibration			
Point 5:	▾					Operation		▾	
Point 6:	▾					Interval (RB/ACAL)		▾	
Point 7:	▾								
Point 8:	▾								
Point 9:	▾								
Point10:	▾								
<Point Cal. For Master Curve>		No. of Correction Points		▾ ▾		Use Master Curve		▾ ☐ Lot Calibration	
	Calibrator	OD	Conc	OD Range		Stability			
				Low	High	Reagent Blanks		# Day # Hour	
Point 1:						Calibration		# Day # Hour	
Point 2:									
MB Type Factor:				1-Point Calibration Point		▾ ☐ With CONC-0			

User Defined

** Lot Specific Calibrator value

CEDIA Valproic Acid

Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters													
General		LIH	ISE	Range									
Test Name:		VPA	<	>	Type:	SERUM	Operation:		Yes				
Sample Volume	2.0	μL	Dilution	0	μL	OD Limit							
Pre-Dilution Rate	1.0					Min. OD	-2.00	Max. OD	3.00				
Reagents Volume:	R1(R1-1)	85	μL	Dilution	0	μL	Reagent OD limit:						
						First Low	-2.00	High	3.00				
						Last Low	-2.00	High	3.00				
	R2 (R2-1)	64	μL	Dilution	0	μL	Dynamic Range Low		3				
							High	150					
Wavelength:	Pri.	570	nm	Sec.	660	nm	Correlation Factor A	1	B	0			
Method:	FIXED1*												
Reaction slope:	+												
Measuring Point 1:	First	24	Last	27	Onboard Stability					#	Days	#	Hour
Measuring Point 2:	First		Last		LIH Influence Check					#			
Linearity:										%			
No Lag Time:	NO												
							Lipemia						
							Icterus						
							Hemolysis						

Specific Test Parameters										
General		ISE	Range							
Test Name:		VPA	<	>	Type:	SERUM				
Value/Flag:	#	Level L:	#	Level H:	#					
Specific Ranges:										
	Sex	Year	Month	Year	Month	Low	High			
☐ 1.	#	#	#	#	#	#	#			
☐ 2.	#	#	#	#	#	#	#			
☐ 3.	#	#	#	#	#	#	#			
☐ 4.	#	#	#	#	#	#	#			
☐ 5.	#	#	#	#	#	#	#			
☐ 6.	#	#	#	#	#	#	#			
7. No demographics						#	#			
8. Not within expected values						#	#			
Unit		ug/mL		Decimal Places		#				
Panic Value										
Low					High					
#					#					

User defined.

* Can be ran as RATE1

CEDIA Valproic Acid **Beckman Coulter System Parameters, AU480/AU680, (continued)**

Calibration Specific										
General		ISE								
Test Name:		VPA		<		>		Type	SERUM	☐ Use Serum Cal.
Calibration Type:		AA		Formula:		Y=AX+B		Counts:	2	
<Calibrator Parameters>										
	Calibrator ↑	OD	Conc	Factor Range				Slope Check	+	
				Low	High			Allowable Range Check		
Point 1:	#		**	-999999	999999			☐ Reagent Blank		
Point 2:	#		**	999999	999999			☐ Calibration		
Point 3:								Advanced Calibration		
Point 4:								Operation		
Point 5:								Interval (RB/ACAL)		
Point 6:										
Point 7:										
Point 8:										
Point 9:										
Point10:										
<Point Cal. For Master Curve>		No. of Correction Points				Use Master Curve				☐ Lot Calibration
	Calibrator	OD	Conc	OD Range				Stability		
				Low	High			Reagent Blanks	#	Day
Point 1:								Calibration	#	Day
Point 2:									#	Hour
MB Type Factor:				1-Point Calibration Point				☐ With CONC-0		

User Defined

** Lot Specific Calibrator value

CEDIA Valproic Acid Beckman Coulter System Parameters, AU5800

Parameters		Specific Test Parameters					
General	LIH	ISE	HbA1c		Calculated Test	Range	
Test Name: VPA < > Type: SERUM Operation Yes							
Sample Volume		2.0 μ L	Dilution		0 μ L	OD Limit	
Pre-Dilution Rate		1 ∇	Diluent Bottle		#	Min.OD -2.00 Max.OD 3.00	
Rgt. Volume		R1(R1-1) 85 μ L	Dilution		0 μ L	Reagent OD Limit	
		R1-2	Dilution			1 st . Low -2.00 High 3.00	
						Last Low -2.00 High 3.00	
		R2(R2-1) 64 μ L	Dilution		0 μ L		
Common Rgt. Type		None	Name		None	Dynamic Range Low 3 High 150	
Wavelength		Pri 570 ∇ nm	Sec.		660 ∇ nm	Correlation Factor A 1 B 0	
Method		FIXED1* ∇				Factor for Maker A 1 B 0	
Reaction Slope		+ ∇				Onboard Stability Period # Day # Hour	
Measuring Point1 1 st		24	Last		27	LIH Influence Check # ∇	
Measuring Point2 1 st			Last			Lipemia ∇	
Linearity Limit		%				Icterus ∇	
Lag Time Check		No ∇				Hemolysis ∇	

Parameters		Specific Test Parameters					
General	LIH	ISE	HbA1c		Calculated Test	Range	
Test Name: VPA < > Type: SERUM							
Value/Flag: # ∇							
Level To Low # High #							
Specific Ranges: From Year Month Year Month Low High							
☐ 1.	Sex	#	#	#	#	#	#
☐ 2.		#	#	#	#	#	#
☐ 3.		#	#	#	#	#	#
☐ 4.		#	#	#	#	#	#
☐ 5.		#	#	#	#	#	#
☐ 6.		#	#	#	#	#	#
7. Standard demographics							
8. Not within expected values							
Panic Value		Low	#	High	#	Unit	ug/mL
						Decimal Places	#

* Can be ran as RATE1
User defined.

CEDIA Valproic Acid
Beckman Coulter System Parameters, AU5800, (continued)

Parameters		Calibration Parameters																																																																																																																																							
Calibrators		Calibration Specific																																																																																																																																							
General		ISE																																																																																																																																							
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