

CEDIA® CARBAMAZEPINE II APPLICATION – BECKMAN COULTER AU680



Catalog No. 100006

Homogeneous Enzyme Immunoassay for the Quantitative Determination of Carbamazepine Levels in Serum and Plasma



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 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.

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Reagent Storage

Refer to package insert for information on reagent storage.

Procedure for Olympus AU680 Analyzer

1. Set up the Olympus AU680 as instructed in the operator's manual.
 2. Place 100 μ L each of the Low and High Calibrators into sample cups in appropriate yellow calibrator racks.
 3. Dispense 100 μ L of control and serum sample(s) into sample cups in the appropriate green or white racks.
 4. Dispense adequate amounts of EA and ED reagents into appropriate containers.
 5. 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.**
 6. Perform a reagent volume check as instructed in the operator's manual.
 7. Select "All" to calibrator the test. It is not necessary to test the blank rack during calibration.
 8. Define a worklist as instructed in the operator's manual. Press Start to be
 9. Results for calibrators will be printed in OD. Results for samples will be printed in μ g/mL.
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Results and Data Interpretation

Results for samples will be printed in μ g/mL.

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CEDIA Carbamazepine II Assay

Beckman Coulter System Parameters, AU680

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:		#	<	>	Type:	Serum	Operation:		Yes	
Sample Volume	2.0	μL	Dilution	0	μL	OD Limit				
Pre-Dilution Rate	1					Min. OD	-2.00	Max. OD	3.00	
Reagents Volume:	R1(R1-1)	87	μL	Dilution	0	μL	Reagent OD limit:			
						First Low	-2.00	High	3.00	
						Last Low	-2.00	High	3.00	
	R2 (R2-1)	87	μL	Dilution	0	μL	Dynamic Range Low	0.5	High	20
						Correlation Factor A	1	B	0	
						Factor for Maker A		B		
Wavelength:	Pri.	570	nm	Sec.	660	nm	Onboard Stability	#	Days	0
Method:	FIXED1						LIH Influence Check	#		
Reaction slope:	+						Lipemia			
Measuring Point 1:	First	24	Last	27			Icterus			
Measuring Point 2:	First		Last				Hemolysis			
Linearity:										
No Lag Time:	No									

Specific Test Parameters										
General		ISE	Range							
Test Name:		#	<	>	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	#	Decimal Places	#							
Panic Value										
Low					High					
#					#					

CEDIA Carbamazepine II Assay, *continued* Beckman Coulter System Parameters, AU680

Calibration Specific										
General		ISE								
Test Name:				<		>		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:	#		**	-99999	999999			☐ Reagent Blank		
Point 2:	#		**	-99999	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		
Point 1:								Calibration		
Point 2:									Day	Hour
MB Type Factor:				1-Point Calibration Point				☐ With CONC-0		

User Defined

** Lot-specific calibrator values

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