

## CEDIA<sup>®</sup> CYCLOSPORINE PLUS (HIGH RANGE) APPLICATION BECKMAN COULTER AU480<sup>®</sup>/AU680<sup>®</sup>/AU5800<sup>®</sup>

Beckman Coulter Reagent REF A31849

The CEDIA Cyclosporine PLUS assay is for the in vitro quantitative determination of cyclosporine in human whole blood using automated clinical chemistry analyzers as an aid in the management of cyclosporine therapy in kidney, liver, and heart transplants.

For In Vitro Diagnostic Use Only

### Purpose

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.

### Ordering Information

Item	Size	Beckman Coulter Reorder Number
CEDIA Cyclosporine PLUS Assay	R1 41 mL, R2 19 mL, Lysing Reagent 98 mL, Low Cal A 2.5 mL, Low Cal B 2.5 mL	A31849
CsA PLUS High Cal Set	2 x 4 mL each level, low & high	979511
CsA Control High Level 4	6x2 mL 2x8 mL diluent	979512
CsA Control High Level 5	6x2 mL 2x8 mL diluent	979513
AU Bottle	30 mL	63094
AU Bottle	60 mL	63093

### Technical Support

For Technical Support, please contact your local Beckman Coulter Representative.

### Reagent Storage

Refer to the package insert for information on reagent storage.

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## Instructions For Use

### Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation. Refer to the package insert for complete reagent preparation.

Prior to pouring into AU bottles, allow the reagent to equilibrate for 15 minutes at refrigerated temperature (2 to 8°C). Dispense R1 reagent and R2 reagent into appropriate AU bottles as shown in the table below:

CEDIA Cyclosporine Assay Kit	AU Reagent Bottle	
	R1 Compartment	R2 Compartment
Antibody/Substrate Reagent [R1]	One Bottle (60 mL)	
Enzyme Conjugate Reagent [R2]		One Bottle (30 mL)

Warning: These reagents have to be programmed to fixed positions. Do not use the Thermo reagent bottles directly on the AU analyzer.

If running both CsA Low Range & High Range, shared reagent can be set up as follows:

In the "Common Test Parameter" menu, select the "Test Name" tab. Enter the same Reagent ID for CSAL and CSAH in the Reagent ID column.

### Results and Data Interpretation

Results for samples will be printed in ng/mL.

### Specimen Preparation

Refer to the package insert for the complete specimen preparation. The product insert can be found at the Thermo Fisher website:

[www.thermoscientific.com/Diagnostics](http://www.thermoscientific.com/Diagnostics)

### Calibration

Use the CEDIA Cyclosporine PLUS High Range Calibrator Kit. The calibrators are prepared like patient samples. The value on the bottle is the value to use in the parameters below. These are lot number specific and should be updated when calibrator lot numbers change.

## Application Parameters

### Parameters

The following tables outline the CEDIA Cyclosporine PLUS High Range Assay chemistry parameters on the Beckman AU480, AU680, and AU5800 analyzers.

### CEDIA CYCLOSPORINE PLUS – HIGH RANGE, AU480

Specific Test Parameters											
General		LIH		ISE		Range					
Test Name:		CSAH		<		>		Type:		Serum	
								Operation:		Yes	
Sample Volume		3		μL		Dilution		0		μL	
Pre-Dilution Rate		1						Min. OD		-2.00	
								Max. OD		3.00	
Reagents Volume: R1(R1-1)		146		μL		Dilution		0		μL	
								Reagent OD limit:			
								First Low		-2.00	
								High		3.00	
								Last Low		-2.00	
								High		3.00	
R2 (R2-1)		75		μL		Dilution		0		μL	
								Dynamic Range Low		450	
								High		2000	
Wavelength: Pri.		570		nm		Sec.		660		nm	
Method:		FIXED1						Correlation Factor A		1	
								B		0	
Reaction slope:		+						Factor for Maker A		1	
								B		0	
Measuring Point 1: First		24				Last		27			
Measuring Point 2: First						Last					
Linearity:				%				Onboard Stability		#	
No Lag Time:		No						Days		#	
								Hour			
								LIH Influence Check		#	
								Lipemia			
								Icterus			
								Hemolysis			

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

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## CEDIA CYCLOSPORINE PLUS – HIGH RANGE, AU480, continued

Calibration Specific									
General		ISE							
Test Name:		CSAH		<	>	Type	Serum		<input type="checkbox"/> 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	99999			<input type="checkbox"/> Reagent Blank	
Point 2:	#		*					<input type="checkbox"/> Calibration	
Point 3:								Advanced Calibration	
Point 4:								Operation	
Point 5:								Interval (RB/ACAL)	
Point 6:									
Point 7:									
Point 8:									
Point 9:									
Point 10:									
<Point Cal. For Master Curve>				No. of Correction Points		Use Master Curve		<input type="checkbox"/> Lot Calibration	
	Calibrator	OD	Conc	OD Range		Stability		Reagent Blanks Calibration	
				Low	High			# Day # Hour	
Point 1:								# Day # Hour	
Point 2:								# Day # Hour	
MB Type Factor:				1-Point Calibration Point				<input type="checkbox"/> With CONC-0	

# User defined

\* Lot specific calibrator values

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## CEDIA CYCLOSPORINE PLUS – HIGH RANGE, AU680

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:		CSAH ▾		< >		Type:	Serum ▾		Operation:	Yes ▾
Sample Volume	3 μL		Dilution	0 μL		OD Limit				
Pre-Dilution Rate	1				Min. OD	-2.00		Max. OD	3.00	
Reagents Volume:	R1(R1-1)	146 μL		Dilution	0 μL		Reagent OD limit:			
						First Low	-2.00		High	3.00
						Last Low	-2.00		High	3.00
R2 Volume	75 μL		Dilution	0 μL		Dynamic Range Low		450	High	2000
Common Reagent	Type	None		Name			Correlation Factor A	1	B	0
Wavelength:	Pri.	570 nm		Sec.	660 nm		Factor for Maker A	1	B	0
Method:	FIXED1 ▾									
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	▾					

Specific Test Parameters										
General		ISE	Range							
Test Name:		CSAH ▾		< >		Type:	Serum ▾			
Value/Flag:	# ▾		Level L:	#		Level H:	#			
Specific Ranges:										
		From	To		Low	High		Panic Value		
<input type="checkbox"/>	Sex	Year	Month	Year	Month	Low	High		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	ng/mL		Decimal Places	#						

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## CEDIA CYCLOSPORINE PLUS – HIGH RANGE, AU680, continued

Calibration Specific									
General		ISE							
Test Name:		CSAH		<	>	Type	Serum		<input type="checkbox"/> 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	99999			<input type="checkbox"/> Reagent Blank	
Point 2:	#		*					<input type="checkbox"/> Calibration	
Point 3:								Advanced Calibration	
Point 4:								Operation	
Point 5:								Interval (RB/ACAL)	
Point 6:									
Point 7:									
Point 8:									
Point 9:									
Point 10:									
<Point Cal. For Master Curve>		No. of Correction Points		Use Master Curve		<input type="checkbox"/> Lot Calibration			
	Calibrator	OD	Conc	OD Range		Stability		Reagent Blanks Calibration	
				Low	High			# Day # Hour	
Point 1:								# Day # Hour	
Point 2:								# Day # Hour	
MB Type Factor:		1-Point Calibration Point		<input type="checkbox"/> With CONC-0					

# User defined

\* Lot specific calibrator values

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## CEDIA CYCLOSPORINE PLUS – HIGH RANGE, AU5800

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		CSAH	<	>	Type:	Serum	Operation	Yes			
Sample Volume	2.7	μL	Dilution	0	μL	OD Limit					
Pre-Dilution Rate	1	∇	Diluent Bottle	#	∇	Min.OD	-2.00	Max.OD	3.00		
Rgt. Volume	R1(R1-1)	131	μL	Dilution	0	μL	Reagent OD Limit				
	R1-2		μL	Dilution		μL	First	Low	-2.00	High	3.00
							Last	Low	-2.00	High	3.00
	R2(R2-1)	67	μL	Dilution	0	μL					
Common Rgt. Type	None		Name			Dynamic Range Low	450	High	2000		
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 <sup>st</sup>	24		Last	27		LIH Influence Check	#	∇			
Measuring Point2 1 <sup>st</sup>			Last			Lipemia		∇			
Linearity Limit						Icterus		∇			
Lag Time Check	No					Hemolysis		∇			

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

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## CEDIA CYCLOSPORINE PLUS – HIGH RANGE, AU5800, continued

Parameters		Calibration Parameters					
Calibrators		Calibration Specific					
General		ISE					
Test Name:		CSAH	<	>	Type: Serum	Cuvette .	
		<input type="checkbox"/> Use Serum Cal.					
Calibration Type:		AA	Formula: Y=AX+B		Counts: 2		
<Calibrator Parameters>		Range					
	Calibrator	OD	Conc	Low	High	Slope Check	
Point 1:	#		*	-99999	99999	+	
Point 2:	#		*			Allowance Range Check	
Point 3:						<input type="checkbox"/> Reagent Blank	
Point 4:						<input type="checkbox"/> Calibration	
Point 5:						Advanced Calibration	
Point 6:						Operation	
Point 7:						No	
Point 8:						Interval (RB/ACAL)	
Point 9:							
Point 10:							
<Point Cal. For		No. of Correction Points		Use Master Curve		<input type="checkbox"/>	
Master Curve>		OD Range					
	Calibrator	OD	Conc	Low	High	Stability	
Point-1						Reagent Blank	
Point-2						Calibration	
MB Type Factor:		1-Point Calibration Point		None	<input type="checkbox"/> with Conc-0		

# User defined

\* Lot specific calibrator values

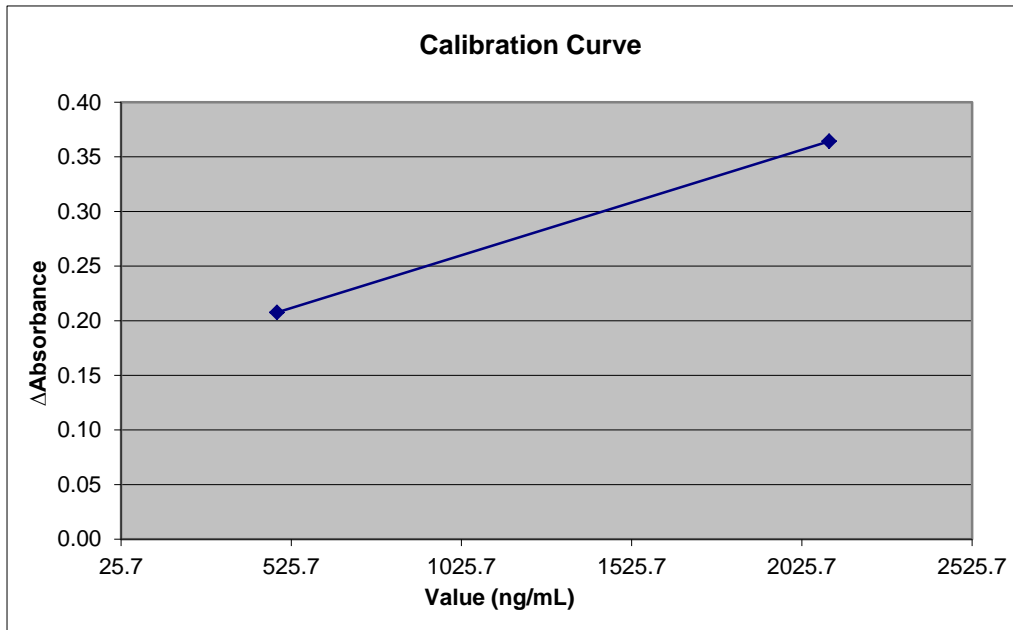


## Results and Data Interpretation

**Performance Data**

Refer to the CEDIA Cyclosporine PLUS assay kit package insert for additional information on results and data interpretation.

**Example Calibration Curve, CsA HR (AU480):**



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**Precision**

These degrees of precision and equivalency were obtained in typical testing procedures on an AU system and are not intended to represent the performance specifications for this reagent.

Control samples were tested in replicates of 2, twice per day for 20 days, total N = 80. The results are presented in the following table:

<b>Controls</b>	<b>Control 4</b>	<b>Control 5</b>
<b>AU480</b>		
Mean (ng/mL)	696	1594
Within-Run SD (ng/mL)	18.8	35.1
Within-Run CV (%)	2.7	2.2
Total SD (ng/mL)	55.9	139.4
Total CV (%)	8.0	8.7
<b>AU680</b>		
Mean (ng/mL)	709	1608
Within-Run SD (ng/mL)	31.5	49.6
Within-Run CV (%)	4.4	3.1
Total SD (ng/mL)	53.1	138.8
Total CV (%)	7.5	8.6
<b>AU5800</b>		
Mean (ng/mL)	677	1557
Within-Run SD (ng/mL)	21.8	36.5
Within-Run CV (%)	3.2	2.3
Total SD (ng/mL)	52.8	87.5
Total CV (%)	7.8	5.6

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**Linearity**

Ten levels of manufacturing calibrators were run against a single calibration curve and the linearity calculated. The analytical range for this assay is 450 to 2000 ng/mL. Error flags will appear for samples recovering above or below the assay range.

The Cyclosporine PLUS High Range assay recovered between 103 – 110% of expected values on the AU480.

The Cyclosporine PLUS High Range assay recovered between 99 – 110% of expected values on the AU680.

The Cyclosporine PLUS High Range assay recovered between 98 – 109% of expected values on the AU5800.

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**Accuracy and Correlation**

One hundred and fourteen blood samples were assayed with the CEDIA Cyclosporine PLUS High Range Assay on the Beckman Coulter AU480 and tested with reference method Hitachi 911.

One hundred and fifteen blood samples were assayed with the CEDIA Cyclosporine PLUS High Range Assay on the Beckman Coulter AU680 and tested with reference method Hitachi 911.

One hundred and fifteen blood samples were assayed with the CEDIA Cyclosporine PLUS High Range Assay on the Beckman Coulter AU5800 and tested with reference method Hitachi 911.

A Deming's Regression Analysis for CsA HR yielded the following:

Beckman Coulter AU480 =  $1.03 * (\text{Hitachi 911}) + 90.96$  with a correlation coefficient of 0.971.

Beckman Coulter AU680 =  $1.07 * (\text{Hitachi 911}) + 30.23$  with a correlation coefficient of 0.968.

Beckman Coulter AU5800 =  $1.05 * (\text{Hitachi 911}) + 9.00$  with a correlation coefficient of 0.975.

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## Additional Information

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**Important**

Since Beckman Coulter does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the Manufacturer.

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**Shipping  
Damage**

Please notify your Beckman Coulter Clinical Support Center if this product is received damaged.

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