CEDIA® CYCLOSPORINE PLUS (LOW RANGE) APPLICATION BECKMAN COULTER AU480®/AU680®/AU5800®

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
More Diagnostics Rap/Tac/CsA Control Level 1	4 x 4 mL	B51007
More Diagnostics Rap/Tac/CsA Control Level 2	4 x 4 mL	A53712
More Diagnostics Rap/Tac/CsA Control Level 3	4 x 4 mL	A53713
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.

Continued on next page

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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 8ºC). Dispense R1 reagent and R2 reagent into appropriate AU bottles as shown in the table below:

	AU Reagent Bottle	
CEDIA Cyclosporine Assay Kit	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

Calibration

Use the CEDIA Cyclosporine PLUS Low 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 Assay chemistry parameters on the Beckman AU480, AU680, and AU5800 analyzers.

CEDIA CYCLOSPORINE PLUS – LOW RANGE, AU480

Specific Test Parameters

General | LIH | ISE | Range

Test Name: CSAL ∇ < > Type: Serum ∇ Operation: Yes ∇

Sample Volume	19.0	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 (R2-1)	75	µL	Dilution	0	µL			
						Dynamic Range Low	25	High 450
						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: CSAL ∇ < > Type: Serum ∇

Value/Flag: # ∇ Level L: # Level H: #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ∇	#	#	#	#	#	#
☐ 2.	# ∇	#	#	#	#	#	#
☐ 3.	# ∇	#	#	#	#	#	#
☐ 4.	# ∇	#	#	#	#	#	#
☐ 5.	# ∇	#	#	#	#	#	#
☐ 6.	# ∇	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Panic Value

Low	High
#	#

Unit ng/mL Decimal Places #

Continued on next page

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CEDIA CYCLOSPORINE PLUS – LOW RANGE, AU480, continued

Calibration Specific

General | ISE

Test Name: CSAL ∇ | < | > | Type Serum ∇ | ☐ Use Serum Cal.

Calibration Type: AA ∇ | Formula: Y = AX+B ∇ | Counts: 2

<Calibrator Parameters> | Slope Check: + ∇

	Calibrator †	OD	Conc	Factor Range Low	Factor Range High
Point 1:	# ∇		*	-99999	99999
Point 2:	# ∇		*		
Point 3:	∇				
Point 4:	∇				
Point 5:	∇				
Point 6:	∇				
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point10:	∇				

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration
Operation: No ∇
Interval (RB/ACAL): ∇

<Point Cal. For Master Curve> | No. of Correction Points ∇ | Use Master Curve ∇ | ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:					
Point 2:					

Stability
Reagent Blanks: # Day # Hour
Calibration: # Day # Hour

MB Type Factor: | 1-Point Calibration Point ∇ | ☐ With CONC-0

User defined
* Lot specific calibrator values

Continued on next page

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CEDIA CYCLOSPORINE PLUS – LOW RANGE, AU680

Specific Test Parameters

General | LIH | ISE | Range

Test Name: CSAL ∇ < > Type: Serum ∇ Operation: Yes ∇

Sample Volume		19.0 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	40 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	25	High	450
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: CSAL ∇ < > Type: Serum ∇

Value/Flag: # ∇ Level L: # Level H: #

Specific Ranges:

		Sex	From Year	From Month	To Year	To Month	Low	High
☐	1.	# ∇	#	#	#	#	#	#
☐	2.	# ∇	#	#	#	#	#	#
☐	3.	# ∇	#	#	#	#	#	#
☐	4.	# ∇	#	#	#	#	#	#
☐	5.	# ∇	#	#	#	#	#	#
☐	6.	# ∇	#	#	#	#	#	#
	7. No demographics						#	#
	8. Not within expected values						#	#

Panic Value

Low	High
#	#

Unit ng/mL Decimal Places #

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CEDIA CYCLOSPORINE PLUS – LOW RANGE, AU680, continued

Calibration Specific

General | ISE

Test Name: CSAL ∇ | < | > | Type Serum ∇ | ☐ Use Serum Cal.

Calibration Type: AA ∇ | Formula: Y = AX+B ∇ | Counts: 2

<Calibrator Parameters> | Slope Check: + ∇

	Calibrator †	OD	Conc	Factor Range Low	Factor Range High
Point 1:	# ∇		*	-99999	99999
Point 2:	# ∇		*		
Point 3:	∇				
Point 4:	∇				
Point 5:	∇				
Point 6:	∇				
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point10:	∇				

Allowable Range Check
☐ Reagent Blank
☐ Calibration
Advanced Calibration
Operation: No ∇
Interval (RB/ACAL): ∇

<Point Cal. For Master Curve> | No. of Correction Points ∇ | Use Master Curve ∇ | ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:					
Point 2:					

Stability
Reagent Blanks: # Day # Hour
Calibration: # Day # Hour

MB Type Factor: | 1-Point Calibration Point ∇ | ☐ With CONC-0

User defined
* Lot specific calibrator values

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CEDIA CYCLOSPORINE PLUS – LOW RANGE, AU5800

Parameters	Specific Test Parameters				
General	LIH	ISE	HbA1c	Calculated Test	Range

Test Name: CSAL ∇ < > Type: Serum ∇ Operation Yes ∇

Sample Volume		17 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					
					Dynamic Range	Low 25	High	450	
Common Rgt. 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 Period	# Day	# Hour		
Measuring Point1 1st		24	Last	27	LIH Influence Check	# ∇			
Measuring Point2 1st			Last		Lipemia	∇			
Linearity Limit		%			Icterus	∇			
Lag Time Check		No ∇			Hemolysis	∇			

Parameters	Specific Test Parameters				
General	LIH	ISE	HbA1c	Calculated Test	Range

Test Name: CSAL ∇ < > Type: Serum ∇

Value/Flag: # ∇

Level Low # High #

Specific Ranges:

	Sex	From Year	From Month	To Year	To 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 – LOW RANGE, AU5800, continued

Parameters | Calibration Parameters
Calibrators | Calibration Specific
General | ISE

Test Name: CSAL ∇ | < | > Type Serum ∇ Cuvette . ∇
□ Use Serum Cal.

Calibration Type: AA ∇ Formula: Y=AX+B ∇ Counts: 2 ∇

<Calibrator Parameters>

	Calibrator	OD	Conc	Range Low	Range High
Point 1:	# ∇		*	-99999	99999
Point 2:	# ∇		*		
Point 3:	∇				
Point 4:	∇				
Point 5:	∇				
Point 6:	∇				
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point 10:	∇				

Slope Check + ∇

Allowance Range Check
□ Reagent Blank
□ Calibration

Advanced Calibration Operation No ∇

Interval (RB/ACAL) ∇

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇ □ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point-1	∇				
Point-2	∇				

Stability
Reagent Blank # Day # Hour
Calibration # Day # Hour

MB Type Factor: 1-Point Calibration Point None ∇ □ with Conc-0

User defined
* Lot specific calibrator values

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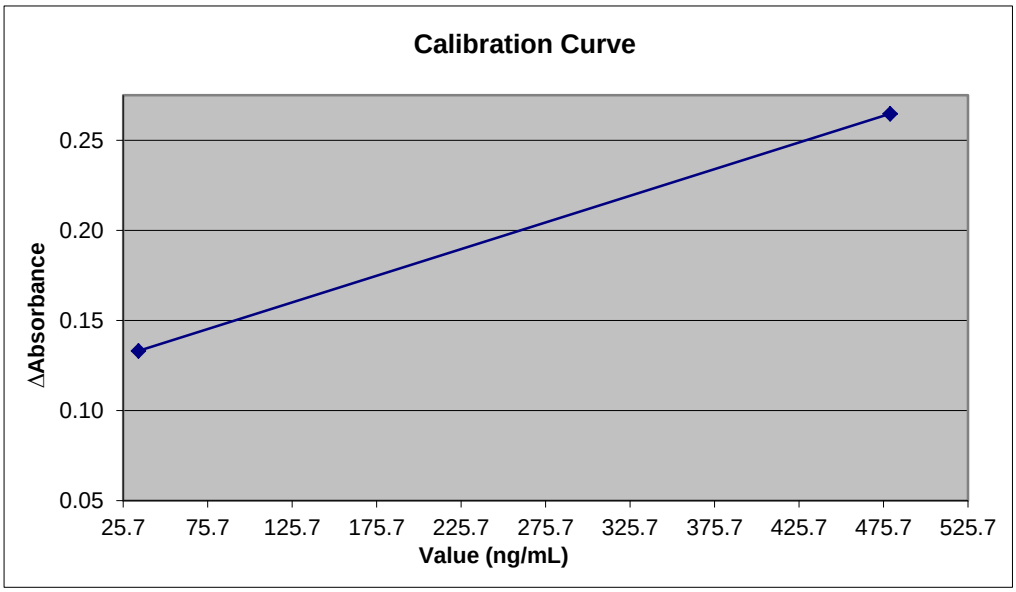
Results and Data Interpretation

Performance Data

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

Example Calibration Curve, CsA LR (AU480):



Continued on next page

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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:

Controls	Control 1	Control 2	Control 3
AU480			
Mean (ng/mL)	77.2	220.6	347.5
Within-Run SD (ng/mL)	2.41	3.02	3.27
Within-Run CV (%)	3.1	1.4	0.9
Total SD (ng/mL)	6.03	11.45	16.37
Total CV (%)	7.8	5.2	4.7
AU680			
Mean (ng/mL)	48.0	201.7	309.4
Within-Run SD (ng/mL)	3.40	4.54	5.36
Within-Run CV (%)	7.1	2.3	1.7
Total SD (ng/mL)	6.12	7.69	10.36
Total CV (%)	12.7	3.8	3.3
AU5800			
Mean (ng/mL)	79.1	222.8	349.7
Within-Run SD (ng/mL)	3.51	7.03	5.61
Within-Run CV (%)	4.4	3.2	1.6
Total SD (ng/mL)	6.10	12.79	18.57
Total CV (%)	7.7	5.7	5.3

Continued on next page

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Linearity

Ten levels of manufacturing calibrators were run against a single calibration curve and the linearity calculated for the AU480, AU680, and AU5800. The analytical range for this assay is 25 – 450 ng/mL. Error flags will appear for samples recovering above or below the assay range.

The Cyclosporine PLUS Low Range assay recovered between 102 – 105% of expected values on the AU480.

The Cyclosporine PLUS Low Range assay recovered between 95 – 100% of expected values on the AU680.

The Cyclosporine PLUS Low Range assay recovered between 91 – 98% of expected values on the AU5800.

LDD

A negative blood sample was run against the same calibration curve for 21 replicates. The LDD is calculated as 2*SD.

The observed LDD for the Cyclosporine PLUS Low Range Assay was 0.01 ng/mL on the AU480.

The observed LDD for the Cyclosporine PLUS Low Range Assay was 0.04 ng/mL on the AU680.

The observed LDD for the Cyclosporine PLUS Low Range Assay was 0.01 ng/mL on the AU5800.

Accuracy and Correlation

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

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

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

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

Beckman Coulter AU480 = 1.03*(Hitachi 911) - 0.40 with a correlation coefficient of 0.995.

Beckman Coulter AU680 = 0.97*(Hitachi 911) + 13.00 with a correlation coefficient of 0.995.

Beckman Coulter AU5800 = 1.00*(Hitachi 911) - 0.50 with a correlation coefficient of 0.994.

Continued on next page

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Additional Information

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.

Shipping Damage

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

CE

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