

CEDIA CYCLOSPORINE (LOW & HIGH RANGE) APPLICATION BECKMAN COULTER DxC 500 AU®



Beckman Coulter Reagent REF A31849

This Application is Intended for the Quantitative Determination of Cyclosporine in Human Whole Blood



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.thermofisher.com and enter the assay name in the *Search* field.

Ordering Information

Item	Size	Catalog Number
CEDIA Cyclosporine PLUS Assay	R1: 1 x 41 mL R2: 1 x 19 mL Lysing Reagent: 1 x 98 mL Low Cal A: 1 x 2.5 mL Low Cal B: 1 x 2.5 mL	A31849
CsA PLUS High Range Calibrator Kit	2 x 4 mL each Level, Low & High	979511
More Diagnostics Control Level 1 (Low Range)	4 x 4 mL	B51007
More Diagnostics Control Level 2 (Low Range)	4 x 4 mL	A53712
More Diagnostics Control Level 3 (Low Range)	4 x 4 mL	A53713
AU Bottle	20 X 30 mL	63094
AU Bottle	20 X 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

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 PLUS 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:

1. In the *Common Test Parameter* menu, select the *Test Name* tab.
2. 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.

Use the following conversion factor to convert ng/mL to µg/L

$$1 \text{ ng/mL} = 1 \text{ } \mu\text{g/L}$$

$$1 \text{ } \mu\text{g/L} = 1 \text{ ng/mL}$$

Specimen Preparation

Refer to the package insert for the complete specimen preparation. The product insert can be found at the Thermo Fisher Scientific website: For package inserts, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field.

Calibration

Use the CEDIA Cyclosporine PLUS Low Range calibrators provided in the assay kit for the Low Range Assay. Use the CEDIA Cyclosporine PLUS High Range calibrator kit or the High Range Assay. The calibrators are prepared like patient samples. Refer to the value assignment card for calibrator values to program in the parameters below. These are lot number-specific and should be updated when calibrator lot numbers change.

Reagent Name: CEDIA Cyclosporine PLUS (Low Range) Assay REF A31849 DxC 500 AU
Settings
Calibrator Name: CEDIA Cyclosporine Calibrator Kit REF A31849

Reagent ID 565

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	<input type="text" value="CSA-L"/>		Calculated Result	<input type="checkbox"/>
LIS Code	<input type="text" value="CSA-L"/>		Result Type	<input type="text" value="Quantitative"/>

UNITS AND RANGE SETTINGS

Use Settings from	<input type="text" value="None"/>	Units	<input type="text" value="ng/mL"/>	Decimal Places	<input type="text" value="x.xx"/>	<input type="text" value="Other"/>
Test Kind	<input type="text" value="General"/>	Revision	<input type="text" value="02"/>	<input checked="" type="checkbox"/> Multi Reagent Switch		
Reagent Name	<input type="text" value="CSA"/>	Reagent ID	<input type="text" value="565"/>	<input type="checkbox"/> FSE Test		
ABB Name	<input type="text" value="CYP1G"/>	Parameter Long Name	<input type="text" value="Cyclosporine A31849 CYP1G Serum"/>			

Region US OUS AP JP EU Other

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume <input type="text" value="19.0"/> μ L	Dilution <input type="text" value="0"/> μ L	REACTION OD LIMIT	Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
	Predilution Rate <input type="text" value="1"/>		REACTION BLANK OD LIMIT	First: Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
REAGENT VOLUME	R1-1 <input type="text" value="146"/> μ L	Dilution <input type="text" value="0"/> μ L		Last: Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
	R2-1 <input type="text" value="75"/> μ L	Dilution <input type="text" value="0"/> μ L	ANALYTICAL MEASURING RANGE	Low <input type="text" value="25.00"/>	High <input type="text" value="450.00"/>
WAVELENGTH	Primary <input type="text" value="570"/> nm	Secondary <input type="text" value="660"/> nm	MANUFACTURER FACTOR	A <input type="text" value="1"/>	B <input type="text" value="0"/>
METHOD	<input type="text" value="FIXED 1"/>		REAGENT ONBOARD STABILITY	<input type="text" value="31"/> Days <input type="text" value="0"/> Hours	
REACTION SLOPE	<input type="text" value="+"/>		LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check	
MEASURING POINT	Point 1: First <input type="text" value="24"/>	Last <input type="text" value="27"/>	Lipemia	<input type="text" value="+"/>	
	Point 2: First <input type="text"/>	Last <input type="text"/>	Icterus	<input type="text" value="+"/>	
Linearity Limit	<input type="text"/> %		Hemolysis	<input type="text" value="+"/>	
Lag Time Check	<input type="checkbox"/> Perform Lag Time Check				

Reagent Name: CEDIA Cyclosporine PLUS (Low Range) Assay REF A31849 DxC 500 AU Settings
Calibrator Name: CEDIA Cyclosporine Calibrator Kit REF A31849, Continued

Reagent ID 565

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
ng/mL ▼	2 ▼	ug/L ▼	1	None ▼	0	None ▼	0	None ▼	0

CALIBRATOR SPECIFIC

Calibration Type Counts ▼

Formula ▼ MB Factor

Calibrator Name Positive Cutoff

Add ▼ Number of Levels

SLOPE CHECK Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours Interval ▼
 Calibration Stability Days Hours Interval ▼

CALIBRATION OD AND CONCENTRATION PARAMETERS

Use highest calibrator for Upper AMR

	Calibrator Name	Conc	Factor Range Low	Factor Range High
Point 1	CSAL CAL-1		-9999999	9999999
Point 2	CSAL CAL-2			
Point 3				
Point 4				
Point 5				
Point 6				
Point 7				

OD DELTA CHECK

Reagent Blank
 Calibration

PROZONE CHECK PARAMETERS

Logic Check 1

Check Points: Point 1 Point 2 Point 3

Decision Values: Value 1 Value 2 Value 3

Limit Points: Limit 1 Limit 2

Check Pattern: Pattern ▼

Logic Check 2

Check Points: Point 1 Interval

Decision Values: Value 1 Value 2

Limit Points: Limit 1 Limit 2

Logic Check 3

Check Points: Point 1 Interval

Decision Values: Value 1 Value 2

Limit Points: Limit 1 Limit 2

Reagent Name: CEDIA Cyclosporine PLUS (High Range) Assay REF A31849 DxC 500 AU
Settings
Calibrator Name: CEDIA CsA High Range Calibrator Kit REF 979511

Reagent ID 565

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	CSA-H		Calculated Result	<input type="checkbox"/>
LIS Code	CSA-H		Result Type	Quantitative ▼
UNITS AND RANGE SETTINGS				
Use Settings from	None ▼	Units	ng/mL ▼	Decimal Places
				x.xx ▼
Test Kind	General ▼	Revision	02	<input checked="" type="checkbox"/> Multi Reagent Switch
Reagent Name	CSA	Reagent ID	565	<input type="checkbox"/> FSE Test
ABB Name	CYP2G	Parameter Long Name	Cyclosporine A31849 CYP2G Serum	
Region	<input checked="" type="checkbox"/> US	<input checked="" type="checkbox"/> OUS	<input checked="" type="checkbox"/> AP	<input type="checkbox"/> JP
			<input checked="" type="checkbox"/> EU	<input type="checkbox"/> Other

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume	3.0	µL	Dilution	0	µL	REACTION OD LIMIT	Low	-2.0000	High	3.0000
	Predilution Rate	1					REACTION BLANK OD LIMIT	First: Low	-2.0000	High	3.0000
REAGENT VOLUME	R1-1	146	µL	Dilution	0	µL		Last: Low	-2.0000	High	3.0000
	R2-1	75	µL	Dilution	0	µL	ANALYTICAL MEASURING RANGE	Low	450.00	High	2000.00
WAVELENGTH	Primary	570	nm	Secondary	660	nm	MANUFACTURER FACTOR	A	1	B	0
METHOD	FIXED 1 ▼						REAGENT ONBOARD STABILITY		31	Days	0
REACTION SLOPE	+										
MEASURING POINT	Point 1: First	24		Last	27		LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check			
	Point 2: First			Last			Lipemia	+	▼		
							Icterus	+	▼		
							Hemolysis	+	▼		
Linearity Limit			%								
Lag Time Check				<input type="checkbox"/> Perform Lag Time Check							

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
ng/mL	2	ug/L	1	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

Formula

MB Factor

Calibrator Name
Add

Positive Cutoff

SLOPE CHECK Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours

Interval

Calibration Stability Days Hours

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

Use highest calibrator for Upper AMR

Point	Calibrator Name	Conc	Factor Range Low	Factor Range High
Point 1	CSAH CAL-1		-9999999	9999999
Point 2	CSAH CAL-2			
Point 3				
Point 4				
Point 5				
Point 6				
Point 7				

OD DELTA CHECK

Reagent Blank
 Calibration

PROZONE CHECK PARAMETERS

Logic Check 1

Check Points
Point 1
Point 2
Point 3

Decision Values
Value 1
Value 2
Value 3

Logic Check 2

Check Points
Point 1
Interval

Limit Points
Limit 1
Limit 2

Logic Check 3

Check Points
Point 1
Interval

Limit Points
Limit 1
Limit 2

Decision Values
Value 1
Value 2

Check Pattern
Pattern

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 Technical Support Center if this product is received damaged.

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