

CEDIA CYCLOSPORINE (LOW RANGE) APPLICATION BECKMAN COULTER DxC 700 AU[®]



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
Rx 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. For package inserts, visit www.thermoscientific.com/diagnostics 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
More Diagnostics Control Level 1	4 x 4 mL	B51007
More Diagnostics Control Level 2	4 x 4 mL	A53712
More Diagnostics Control Level 3	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. For package inserts, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field.

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.

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. 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.

CEDIA Cyclosporine (Low Range) Assay Beckman Coulter System Parameters, DxC 700 AU

General		LIH		ISE		Calculated Test		Range		
Test Name:		#		Type: Serum		Operation Yes		▼		
Sample Volume	<input type="text" value="19.0"/> μL	Dilution	<input type="text" value="0"/> ▼ μL	OD Limit		Min. OD <input type="text" value="-2.0000"/> Max OD <input type="text" value="3.0000"/>				
Pre-Dilution Rate	<input type="text" value="1"/> ▼			Reagent OD Limit		1 st Low <input type="text" value="-2.0000"/> High <input type="text" value="3.0000"/>				
Reagent Volume	R1 (R1-1) <input type="text" value="146"/> μL	Dilution	<input type="text" value="0"/> μL	Last		Low <input type="text" value="-2.0000"/> High <input type="text" value="3.0000"/>				
	R1-2 <input type="text"/> μL	Dilution	<input type="text"/> μL							
	R2 (R2-1) <input type="text" value="75"/> μL	Dilution	<input type="text" value="0"/> μL	Analytical Measuring Range		Low <input type="text" value="25.0"/> High <input type="text" value="450.00"/>				
Common Reagent	Type <input type="text" value="None"/>	Name	<input type="text" value="None"/>	Correlation Factor		A <input type="text" value="1"/> B <input type="text" value="0"/>				
Wavelength	Pri <input type="text" value="570"/> ▼ nm	Sec	<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="FIXED1"/> ▼				Onboard Stability Period		<input type="text" value="28"/> Day <input type="text" value="0"/> Hour			
Reaction Slope	<input type="text" value="+"/> ▼				LIH Influence Check		<input type="text" value="No"/> ▼			
Measuring Point-1	1 st <input type="text" value="24"/>	Last	<input type="text" value="27"/>	Lipemia		<input type="text" value="+"/> ▼				
Measuring Point-2	1 st <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="text" value="No"/> ▼									

General		LIH		ISE		Calculated Test		Range	
Test Name:		#		Type: Serum		▼			
Value/Flag	<input type="text" value="#"/>	Level	Low	<input type="text" value="#"/>	High	<input type="text" value="#"/>			
Specific Ranges									
	Sex	Year	Month	Year	Month	Other Type	Low	High	
<input type="checkbox"/> 1:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	
<input type="checkbox"/> 2:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	
<input type="checkbox"/> 3:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	
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<input type="checkbox"/> 6:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	
7:	Standard demographics						<input type="text" value="#"/>	<input type="text" value="#"/>	
8:	Not within expected values						<input type="text" value="#"/>	<input type="text" value="#"/>	
Critical Limits	Low	<input type="text" value="#"/>	High	<input type="text" value="#"/>	Unit	<input type="text" value="ng/mL"/>	<input type="text" value="Select"/>	Decimal Places	<input type="text" value="2"/>

User defined

**CEDIA Cyclosporine (Low Range) Assay
Beckman Coulter System Parameters, DxC 700 AU (continued)**

Calibrators	General	ISE																																																			
Test Name: # Type: Serum																																																					
<input type="checkbox"/> Use Serum Cal.																																																					
Calibration Type: AA Formula: Y=AX+B Counts: 2																																																					
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<table border="1"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Calibrator</th> <th rowspan="2">OD</th> <th rowspan="2">Conc</th> <th colspan="2">Range</th> </tr> <tr> <th>Low</th> <th>High</th> </tr> </thead> <tbody> <tr> <td>Point-1</td> <td>#</td> <td></td> <td>*</td> <td>-99999</td> <td>99999</td> </tr> <tr> <td>Point-2</td> <td>#</td> <td></td> <td>*</td> <td></td> <td></td> </tr> <tr> <td>Point-3</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point-4</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point-5</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point-6</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Point-7</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>					Calibrator	OD	Conc	Range		Low	High	Point-1	#		*	-99999	99999	Point-2	#		*			Point-3						Point-4						Point-5						Point-6						Point-7					
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Allowable Range Check																																																					
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Interval (ACAL)																																																					
Stability																																																					
Reagent Blank: # Day 0 Hour																																																					
Calibration: # Day 0 Hour																																																					

User defined
* Lot specific calibrator values

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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