



CEDIA® CYCLOSPORINE PLUS [LOW RANGE]

BECKMAN SYNCHRON DxC600 ANALYZER

Catalog No. 100147

Homogeneous Enzyme Immunoassay for the Quantitative
Determination of Cyclosporine Levels in Whole Blood

For In Vitro Diagnostic Use 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.

Ordering Information Materials available from Microgenics:

Item	Catalog Number
CEDIA Cyclosporine PLUS Assay Reagents and Calibrators	100047

To place an order or for technical service, contact (North America):

Microgenics Corporation
46360 Fremont Boulevard, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5001
U.S. Toll free fax: (800) 829-8115 / Fax: (510) 979-5002

Materials Required, Not Available from Microgenics

- UDR Cartridges (PN 442835)
 - Microtubes (PN 448774–1000 pk; PN 756776–100 pk)
- To order these materials, contact Beckman-Coulter at 1-800-526-3821.
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**Reagent
Storage**

Refer to package insert for information on reagent storage.

**Procedure for
analyzer**

Refer to operator's manuals for information on analyzer operation.

**Calibration
Frequency**

Refer to package insert for information on calibration frequency.

**Results and
data
interpretation**

Refer to package insert for information on results and data interpretation.

BECKMAN SYNCHRON DxC600 CEDIA CYCLOSPORINE PLUS [LOW RANGE]

Number **Chem**
- ******
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Chemistry Parameters

Reaction Type: <input type="text" value="Rate 1"/>	Calculation Factor: <input type="text" value="1.000"/>		
Units: <input type="text" value="ng/mL"/>	No. of Calibrators: <input type="text" value="2"/>		
Precision: <input type="text" value="X.X"/>	Setpoints:	1: <input type="text" value="*"/>	4: <input type="text" value="NA"/>
Reaction Direction: <input type="text" value="Positive"/>		2: <input type="text" value="*"/>	5: <input type="text" value="NA"/>
Math Mode: <input type="text" value="Linear"/>		3: <input type="text" value="NA"/>	6: <input type="text" value="NA"/>
Primary Wavelength: <input type="text" value="560"/>	Cal Time Limit: <input type="text" value="**"/>		
Secondary Wavelength: <input type="text" value="650"/>			

* Refer to the appropriate Calibrator Assigned Value Card in the Calibrator or to the appropriate calibrator vial
 ** User Defined

Processing Parameters
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Component: <input type="text" value="A"/>	Second Inject: <input type="text" value="None"/>	Third Inject: <input type="text" value="B"/>	
Dispense Volume: <input type="text" value="210"/> <small>uL</small>	<input type="text" value="NA"/> <small>uL</small>	<input type="text" value="75"/> <small>uL</small>	
Inject Time: <input type="text" value="NA"/> <small>sec</small>	<input type="text" value="NA"/> <small>sec</small>	<input type="text" value="304"/> <small>sec</small>	
Sample Volume: <input type="text" value="23"/> <small>uL</small>			
Reagent: <input type="text" value="Blank"/>	Reaction 1	Reaction 2	Usable Result Range
Start Read: <input type="text" value="-80"/> <small>sec</small>	<input type="text" value="540"/> <small>sec</small>	<input type="text" value="NA"/> <small>sec</small>	Lower Limit: <input type="text" value="25"/>
End Read: <input type="text" value="-32"/> <small>sec</small>	<input type="text" value="600"/> <small>sec</small>	<input type="text" value="NA"/> <small>sec</small>	Upper Limit: <input type="text" value="450"/>

** User Defined

**BECKMAN SYNCHRON DxC600
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	Blank	Reaction 1	Reaction 2
ABS Low Limit	-1.500	-1.500	-1.500
ABS High Limit	2.200	2.200	2.200
Rate Low Limit	-1.500	-1.500	-1.500
Rate High Limit	2.200	2.200	2.200
Mean Derivation	2.200	2.200	2.200

Substrate Depletion		Multipoint Span			
Initial Rate	99.999	1-2	0.000	NA	NA
Delta ABS	2.200		NA	NA	NA

DxC Precision Low Assay Range Evaluations for within-run and total precision using packaged reagents, controls and calibrators yielded the following results (n=60):

	<u>Control I</u>	<u>Control II</u>	<u>Control III</u>
Mean (ng/mL)	64.46	189.94	331.13
Within-run			
SD (ng/mL)	8.13	13.40	20.27
%CV	12.66	7.06	6.12
Total			
SD (ng/mL)	9.6	15.45	21.64
%CV	14.88	8.14	6.54

Method Comparison Low Assay Range A total of fifty (50) patient samples were evaluated using the CEDIA Cyclosporine PLUS Low Range Assay on the Beckman LX and DxC analyzer systems. The following regression analysis equation was observed:
 DxC Analyzer=1.024(LX Analyzer) + 9.18, with a correlation coefficient [r]= 0.98.

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