



CEDIA® CYCLOSPORINE PLUS [HIGH RANGE]

BECKMAN SYNCHRON LX® 20, LX® 20 PRO, LX® i 725 ANALYZERS

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 Reagent and Low Range Calibrator Kit	100147
CEDIA Cyclosporine High Range Calibrator Kit	100012
Cyclosporine Control Level 1	100204
Cyclosporine Control Level 2	100205
Cyclosporine Control Level 3	100206
Cyclosporine Control Level 4	100207
Cyclosporine Control Level 5	100208
Rap/Tac/CsA Multi-drug ISD Control Level 1	280-1
Rap/Tac/CsA Multi-drug ISD Control Level 2	280-2
Rap/Tac/CsA Multi-drug ISD Control Level 3	280-3

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

Microgenics Corporation
46360 Fremont Boulevard, Fremont, CA 94538 USA
US Toll free: (800) 232-3342 / Tel: (510) 979-5001
US 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.

**Procedure
for the
Beckman
SYNCHRON
LX20,
LX20 PRO, and
LXi 725
Analyzers**

1. Set up the Beckman LX as instructed in the operator's manual or as instructed in *LX User-Defined Procedure for SYNCHRON CX and LX Systems*.
2. Refer to the CEDIA Cyclosporine PLUS Assay package insert for reagent preparation.
3. Transfer the reconstituted EA (R1) Reagent to the "A" compartment and the reconstituted ED (R2) Reagent to the "B" compartment of a user-defined reagent (UDR) cartridge.
4. Place the filled cartridge on the reagent tray in the position defined by the user. Ensure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analyses.
5. Refer to the CEDIA Cyclosporine PLUS Assay package insert for specimen preparation. When preparing calibrators, controls, and samples, use microtubes provided by Beckman-Coulter. Place all prepared calibrators, controls, and samples on 13x100 user-defined sample racks designed for the LX family of analyzers. Refer to Beckman-Coulter for further details.
6. Results will be printed-out in ng/mL.

**Calibration
Frequency**

Perform a calibration when changing a UDR cartridge, when changing calibrator or reagent lots, after performing monthly maintenance, and as required during the monitoring of control results. Calibration stability should be monitored in accordance with each laboratory's operating guidelines, reproducibility of control results, and changes in reagents.

**BECKMAN SYNCHRON LX20, LX20 PRO, LXi 725
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Number	Chem								
-	**								
Chemistry Parameters									
Reaction Type	Rate 1	Calculation Factor	1.000						
Units	ng/mL	No. of Calibrators	2						
Precision	X.X	Setpoints	<table border="1"> <tr><td>1</td><td>*</td></tr> <tr><td>2</td><td>*</td></tr> <tr><td>3</td><td>NA</td></tr> </table>	1	*	2	*	3	NA
1	*								
2	*								
3	NA								
Reaction Direction	Positive		<table border="1"> <tr><td>4</td><td>NA</td></tr> <tr><td>5</td><td>NA</td></tr> <tr><td>6</td><td>NA</td></tr> </table>	4	NA	5	NA	6	NA
4	NA								
5	NA								
6	NA								
Math Model	Linear	Cal Time Limit	168						
Primary Wavelength	560								
Secondary Wavelength	650								

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

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Processing Parameters			
Component	First Inject	Second Inject	Third Inject
	A	None	B
Dispense Volume	210 μ L	NA μ L	75 μ L
Inject Time	NA sec	NA sec	304 sec
Sample Volume	4 μ L		
Reagent	Blank	Reaction 1	Reaction 2
Start Read	-80 sec	540 sec	NA sec
End Read	-32 sec	600 sec	NA sec
			Usable Result Range
			Lower Limit
			Upper Limit
			450
			2000

** User Defined

----- Parameters continue on page 4 of 4.

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Error Detection Limits				Page 3 of 3			
	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

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

	<u>Control III</u>	<u>Control IV</u>	<u>Control V</u>
Mean (ng/mL)	539.5	764.5	1445.3
Within-run			
SD (ng/mL)	30.0	31.7	51.4
%CV	5.6	4.1	3.6
Total			
SD (ng/mL)	29.4	33.0	51.1
%CV	5.5	4.3	3.5

Method Comparison High Assay Range A total of eighty-two (82) patient samples were evaluated using the CEDIA Cyclosporine PLUS Low Range Assay on the Beckman CX and LX analyzer systems. The following regression analysis equation was observed:
LX Analyzer=1.09 (CX Analyzer)-40.7, with a correlation coefficient [r]= 0.97.

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