CEDIA® CYCLOSPORINE PLUS

HIGH RANGE APPLICATION

BECKMAN SYNCHRON CX®

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
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 cartridge (PN 442835) ordered from Beckman Diagnostic Systems Group (1-800-526-3821)

Procedure for Beckman Synchron CX Analyzer

1. Set up the Beckman Synchron CX as instructed in the operator's manual.
2. See package insert for reagent preparation.
3. Transfer the reconstituted EA Reagent to the "A" compartment, and the reconstituted ED Reagent to the "B" compartment of a UDR cartridge.
4. Place the filled cartridge on the reagent tray in the position defined by the user. **Make sure the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis.**
5. See package insert for specimen preparation.
6. Results for patient samples will be printed in ng/mL.

CX PARAMETERS:

Test Name:	CSAH	Calculation Factor:	0
Reaction Type:	[RATE 1]	Math Model:	[Linear]
Reaction Direction:	[Increasing]	Cal Time Limit:	168 Hrs
Units:	[ng/mL]	No. of Calibrators:	2
Decimal Precision:	[X.X]		
Primary Wavelength:	[560] nm	Secondary Wavelength:	[650] nm
Calculation:	0 (qualitative)		

		CALIBRATORS		**MULTIPOINT SPAN**	
Sample Volume:	4 µL				
Primary Inject Rgt:	[A] Vol: 210 µL	#1:	Lot-specific	1-2:	0.000
Secondary Inject Rgt:	[B] Vol: 75 µL	#2:	Lot-specific		
Add Time:	624 sec				

REAGENT BLANK

Start Read:	240 sec
End Read:	288 sec
Low ABS Limit:	-1.500
High ABS Limit:	1.500

REACTION

Start Read:	540 sec
End Read:	600 sec
Low ABS Limit:	-1.500
High ABS Limit:	1.500

USABLE RANGE

Lower Limit:	400
Upper Limit:	2000

SUBSTRATE DEPLETION

Initial Rate:	99.999
Delta ABS:	1.5

Beckman Synchron CX Performance

Precision: The Total and Within-Run precision, evaluated with packaged reagents, controls and calibrators, yielded the following results:

Controls	Level Three	Level Four	Level Five
Mean (ng/mL)	469.5	615.1	1025.3
Within-Run SD (ng/mL)	22.5	30.2	36.7
Within-Run CV (%)	4.8	4.9	3.6
Total SD (ng/mL)	23.9	30.0	40.9
Total CV (%)	5.1	4.9	4.0

Within-Run & Total n = 60

Assay Accuracy and Correlation:

A total of 51 samples were evaluated, using the Hitachi 911 as the reference instrument. Least Squares Regression analysis yielded the following results:

CX vs. H911 $y = 0.97x + 19.1$; $r = 0.981$

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