

BECKMAN SYNCHRON DxC600 CEDIA CYCLOSPORINE PLUS [HIGH RANGE]

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Number	Chem		
.	**		

Chemistry Parameters

Reaction Type	Rate 1	Calculation Factor	1.000						
Units	ng/mL	No. of Calibrators	2						
Precision	XX	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	**						
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

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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

**DxC 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 IV</u>	<u>Control V</u>
Mean (ng/mL)	670.36	1563.49
Within-run		
SD (ng/mL)	55.09	63.78
%CV	8.22	4.08
Total		
SD (ng/mL)	68.65	130.60
%CV	10.24	8.35

**Method
Comparison High
Assay Range**

A total of nineteen (19) patient samples were evaluated using the CEDIA Cyclosporine PLUS High Range Assay on the Beckman LX and DxC analyzer systems. The following regression analysis equation was observed:
DxC Analyzer=1.111(LX Analyzer) + 35.61, with a correlation coefficient [r]= 0.99.

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10010623APPS-0
2006
Printed in USA

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