

# The Only Fully-Automated Cyclosporine Assays for Enhanced Productivity

## The need: To monitor cyclosporine levels in transplant patients

Cyclosporine A (CSA) is one of the primary immunosuppressive agents used with patients who have undergone cardiac, renal, and liver transplants. Toxic side effects, a narrow window of therapeutic efficacy, and the need to maintain consistent drug levels to prevent organ rejection all require frequent CSA monitoring.<sup>1,2</sup> Although there is no universally established therapeutic range for CSA in whole blood, specific therapeutic ranges have been developed for each organ type and by each transplant institution.

## Siemens Healthcare Diagnostics Dimension® CSA and CSAE Assays Meet the Need

The two Dimension cyclosporine assays are the only automated cyclosporine assays on the market, requiring no manual pretreatment steps. This feature will increase your productivity and turn-around time and reduce the potential for errors caused by manual sample splitting.

## Add Cyclosporine testing to your routine

With Dimension CSA and CSAE, results are available around the clock, thanks to immediate testing made possible by the direct use of whole blood. Results can be reported rapidly with continuous bar code identification and online result transmission.



## Dimension Cyclosporine (CSA) and Cyclosporine Extended Range (CSAE) Assays

Answers for life.

**SIEMENS**

# Dimension Cyclosporine (CSA) and Cyclosporine Extended Range (CSAE) Assays

## Cyclosporine Flex® Reagent Cartridge

<b>Mnemonic</b>	CSA				
<b>Product Code</b>	DF89				
<b>Packaging</b>	80 Tests/Kit, 20 Tests/Flex				
<b>Calibration</b>	Dimension CSA Calibrator, Cat. No. DC89 Calibrator levels: 0, 80, 180, 330, 500 ng/mL Calibration frequency: 30 days or new reagent lot				
<b>Pretreatment</b>	No manual sample pretreatment – the sample is mixed on board by ultrasound, an aliquot taken, pretreated and analyzed fully automated.				
<b>Quality Control</b>	BioRad or MORE				
<b>Stability</b>	Closed on board (at 2-8° C): 30 days Open well stability: 3 days				
<b>Assay Principle</b>	Magnetic particle immunoassay (ACMIA)				
<b>Type of Measurement</b>	Photometric				
<b>Sample Type</b>	EDTA Whole Blood (200 µL/cup, 5 µL/test)				
<b>Reportable Range</b>	25-500 ng/mL				
<b>Sensitivity Limit</b>	Analytical: 25 ng/mL Functional: Not supplied				
<b>Precision</b>	<b>Control Level (ng/mL)</b>	<b>Within-run</b>		<b>Total Precision</b>	
		<b>SD</b>	<b>%CV</b>	<b>SD</b>	<b>%CV</b>
	108	5.3	4.9	12.2	11.3
	228	11.1	4.9	15.9	7.0
	328	17.8	5.4	25.6	7.8
<b>Method Comparison</b>	<b>HPLC</b>	<b>Slope</b>	<b>Int</b>	<b>R</b>	<b>n</b>
	All	1.19	-13.7	0.935	661
	Heart	1.28	-16.0	0.893	111
	Liver	1.18	-13.3	0.961	201
	Kidney	1.13	-8.9	0.920	273
	<b>Abbott TDx®</b>				
	All	0.83	-20.7	0.957	667
	Heart	0.83	-20.9	0.927	111
	Liver	0.82	-26.3	0.952	201
	Kidney	0.83	-18.8	0.966	279
<b>Specificity</b>	For specific cross-reactivity information, see Instructions for Use.				

## Cyclosporine (CSAE) Flex® Reagent Cartridge

<b>Mnemonic</b>	CSAE				
<b>Product Code</b>	DF108				
<b>Packaging</b>	80 Tests/Kit, 20 Tests/Flex				
<b>Calibration</b>	Dimension CSAE Calibrator, Cat. No. DC108A Calibrator levels: 200, 400, 800, 1400, 2000 ng/mL Calibration frequency: 30 days or new reagent lot				
<b>Pretreatment</b>	No manual sample pretreatment – the sample is mixed on board by ultrasound, an aliquot taken, pretreated and analyzed fully automated.				
<b>Quality Control</b>	BioRad or MORE				
<b>Stability</b>	Closed on board (at 2-8° C): 30 days Open well stability: 3 days				
<b>Assay Principle</b>	Magnetic particle immunoassay (ACMIA)				
<b>Type of Measurement</b>	Photometric				
<b>Sample Type</b>	EDTA Whole Blood (200 µL/cup, 3 µL/test)				
<b>Reportable Range</b>	350-2000 ng/mL				
<b>Sensitivity Limit</b>	Analytical: Not supplied Functional: <350 ng/mL				
<b>Precision</b>	<b>Control Level (ng/mL)</b>	<b>Within-run</b>		<b>Total Precision</b>	
		<b>SD</b>	<b>%CV</b>	<b>SD</b>	<b>%CV</b>
	488.7	13.99	2.86	28.77	5.89
	866.1	18.61	2.15	47.71	5.51
	1301.9	34.41	2.64	68.89	5.29
<b>Method Comparison</b>	<b>HPLC</b>	<b>Slope</b>	<b>Int</b>	<b>R</b>	<b>n</b>
	All	1.09	17.1	0.986	140
	Heart	0.93	93.7	0.983	35
	Liver	1.00	59.9	0.980	40
	Kidney	1.10	15.2	0.990	60
	<b>Abbott TDx®</b>				
	All	1.13	-67.2	0.980	140
	Heart	0.996	2.52	0.982	35
	Liver	1.11	-61.7	0.970	40
	Kidney	1.09	-32.3	0.973	60
<b>Specificity</b>	For specific cross-reactivity information, see Instructions for Use.				

For more information about Cyclosporine Assays, contact your local sales representative or call 1-800-242-3233, option 3.

### References:

1. Hardman, JG, Limbird LE, Malinoff PB, Ruddon RW. The Pharmacological Basis of Therapeutics. 9th ed. New York, NY: McGraw Hill; 1996.
2. Kaplan LA, Pesce AJ. Clinical Chemistry-Theory, Analysis, Correlation. 3rd ed. St. Louis, MO: Mosby; 1996.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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