

## CEDIA<sup>®</sup> MYCOPHENOLIC ACID APPLICATION BECKMAN COULTER AU480<sup>®</sup>/AU680<sup>®</sup>/AU5800<sup>®</sup>

Beckman Coulter Reagent REF B01460

The CEDIA Mycophenolic Acid (MPA) Assay is an in vitro diagnostic medical device intended for the quantitative measurement of mycophenolic acid in human plasma using automated clinical chemistry analyzers as an aid in the management of mycophenolic acid therapy in renal and cardiac transplant patients.

For In Vitro Diagnostic Use Only

### Purpose

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 preparation, specimen storage, quality control, and additional performance data.

### Ordering Information

Item	Size	Beckman Coulter Reorder Number
CEDIA Mycophenolic Acid Assay	R1 26 mL, R2 11 mL	B01460
CEDIA Mycophenolic Acid Calibrator Set	2 levels, 5.0 mL - 2 bottle ea	B37609
MAS <sup>®</sup> Mycophenolic Acid Control 1 Kit	1 level, 5.0 mL 4 bottle ea	B37611
MAS Mycophenolic Acid Control 2 Kit	1 level, 5.0 mL 4 bottle ea	B01543
MAS Mycophenolic Acid Control 3 Kit	1 level, 5.0 mL 4 bottle ea	B01544
AU Bottle	15 mL	63165
AU Bottle	30 mL	63094

### Technical Support

For Technical Support, please contact your local Beckman Coulter Representative.

### Reagent Storage

Refer to the package insert for information on reagent storage.

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## Instructions For Use

### Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation. Refer to the package insert for complete reagent preparation.

Prior to pouring into AU bottles, allow the reagent to equilibrate for 15 minutes at refrigerated temperature (2 to 8°C). Dispense R1 reagent and R2 reagent into appropriate AU bottles as shown in the table below:

CEDIA MPA Assay Kit	AU Reagent Bottle	
	R1 Compartment	R2 Compartment
Antibody/Substrate Reagent [R1]	One Bottle (30 mL)	
Enzyme Conjugate Reagent [R2]		One Bottle (15 mL)

Warning: These reagents have to be programmed to fixed positions. Do not use the Thermo reagent bottles directly on the AU analyzer.

### Results and Data Interpretation

Results for samples will be printed in µg/mL.

### Specimen Preparation

There is no specimen preparation for the CEDIA Mycophenolic Acid assay.

### Calibration

Use the CEDIA Mycophenolic Acid Calibrator Kit. The value on the bottle is the value to use in the parameters below. These are lot number specific and should be updated when calibrator lot numbers change.

## Application Parameters

### Parameters

The following tables outline the CEDIA Mycophenolic Acid Assay chemistry parameters on the Beckman AU480, AU680, and AU5800 analyzers.

### CEDIA MYCOPHENOLIC ACID, AU480

Specific Test Parameters											
General		LIH		ISE		Range					
Test Name:		MPA		<		>		Type:		Serum	
								Operation:		Yes	
Sample Volume		7.5		μL		Dilution		0		μL	
Pre-Dilution Rate		1						Min. OD		-2.00	
								Max. OD		3.00	
Reagents Volume: R1(R1-1)		150		μL		Dilution		0		μL	
								Reagent OD limit:			
								First Low		-2.00	
								High		3.00	
								Last Low		-2.00	
								High		3.00	
R2 (R2-1)		60		μL		Dilution		0		μL	
								Dynamic Range Low		0.3	
								High		10.0	
Wavelength: Pri.		570		nm		Sec.		660		nm	
Method:		FIXED1						Correlation Factor A		1	
								B		0	
Reaction slope:		+						Factor for Maker A		1	
								B		0	
Measuring Point 1: First		24				Last		27			
Measuring Point 2: First						Last					
Linearity:				%				Onboard Stability		#	
No Lag Time:		No						Days		#	
								Hour			
								LIH Influence Check		#	
								Lipemia		∇	
								Icterus		∇	
								Hemolysis		∇	

Specific Test Parameters											
General		ISE		Range							
Test Name:		MPA		<		>		Type:		Serum	
Value/Flag:		#		∇		Level L:		#		Level H:	
Specific Ranges:		From		To		Low		High		Panic Value	
		Sex		Year		Month		Year		Month	
□ 1.		#		#		#		#		#	
□ 2.		#		#		#		#		#	
□ 3.		#		#		#		#		#	
□ 4.		#		#		#		#		#	
□ 5.		#		#		#		#		#	
□ 6.		#		#		#		#		#	
7. No demographics						#		#			
8. Not within expected values						#		#			
Unit		μg/mL		Decimal Places		#					

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## CEDIA MYCOPHENOLIC ACID, AU480, continued

Calibration Specific									
General		ISE							
Test Name:		MPA		<	>	Type	Serum		<input type="checkbox"/> Use Serum Cal.
Calibration Type:		AA		Formula:		Y = AX+B		Counts: 2	
<Calibrator Parameters>									
	Calibrator †	OD	Conc	Factor Range		Slope Check		+ ▾	
				Low	High			Allowable Range Check	
Point 1:	# ▾		*	-99999	99999			<input type="checkbox"/> Reagent Blank	
Point 2:	# ▾		*					<input type="checkbox"/> Calibration	
Point 3:	▾							Advanced Calibration	
Point 4:	▾							Operation	
Point 5:	▾							Interval (RB/ACAL) ▾	
Point 6:	▾								
Point 7:	▾								
Point 8:	▾								
Point 9:	▾								
Point 10:	▾								
<Point Cal. For Master Curve>		No. of Correction Points		Use Master Curve		<input type="checkbox"/> Lot Calibration			
	Calibrator	OD	Conc	OD Range		Stability		Reagent Blanks Calibration	
				Low	High			# Day # Hour	
Point 1:								# Day # Hour	
Point 2:								# Day # Hour	
MB Type Factor:		1-Point Calibration Point		<input type="checkbox"/> With CONC-0					

# User defined

\* Lot specific calibrator values

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## CEDIA MYCOPHENOLIC ACID, AU680

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:	MPA	<	>	Type: Serum	Operation: Yes					
Sample Volume	7.5	µL	Dilution	0	µL	OD Limit				
Pre-Dilution Rate	1					Min. OD	-2.00	Max. OD	3.00	
Reagents Volume:	R1(R1-1)	150	µL	Dilution	0	µL	Reagent OD limit:			
						First Low	-2.00	High	3.00	
						Last Low	-2.00	High	3.00	
R2 Volume	60	µL	Dilution	0	µL	Dynamic Range Low	0.3	High	10.0	
Common Reagent	Type	None	Name		Correlation Factor A	1	B	0		
Wavelength:	Pri.	570	nm	Sec.	660	nm	Factor for Maker A	1	B	0
Method:		FIXED1								
Reaction slope:		+				Onboard Stability	#	Days	#	Hour
Measuring Point 1:	First	24	Last	27		LIH Influence Check	#			
Measuring Point 2:	First		Last			Lipemia				
Linearity:			%			Icterus				
No Lag Time:		No				Hemolysis				

Specific Test Parameters										
General		ISE	Range							
Test Name:	MPA	<	>	Type: Serum						
Value/Flag:	#	Level L:	#	Level H:	#					
Specific Ranges:										
	Sex	Year	Month	Year	Month	Low	High	Panic Value		
<input type="checkbox"/>	1.	#	#	#	#	#	#	#	Low	High
<input type="checkbox"/>	2.	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	3.	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	4.	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	5.	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	6.	#	#	#	#	#	#	#	#	#
	7. No demographics						#	#		
	8. Not within expected values						#	#		
Unit	µg/mL				Decimal Places	#				

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## CEDIA MYCOPHENOLIC ACID, AU680, continued

Calibration Specific									
General		ISE							
Test Name:		MPA		<	>	Type	Serum		<input type="checkbox"/> Use Serum Cal.
Calibration Type:		AA		Formula:		Y = AX+B		Counts:	2
<Calibrator Parameters>									
	Calibrator †	OD	Conc	Factor Range				Slope Check	+
				Low	High			Allowable Range Check	
Point 1:	#		*	-99999	99999			<input type="checkbox"/> Reagent Blank	
Point 2:	#		*					<input type="checkbox"/> Calibration	
Point 3:								Advanced Calibration	
Point 4:								Operation	
Point 5:								Interval (RB/ACAL)	
Point 6:									
Point 7:									
Point 8:									
Point 9:									
Point 10:									
<Point Cal. For Master Curve>		No. of Correction Points			Use Master Curve		<input type="checkbox"/> Lot Calibration		
	Calibrator	OD	Conc	OD Range				Stability	
				Low	High			Reagent Blanks	# Day # Hour
Point 1:								Calibration	# Day # Hour
Point 2:									
MB Type Factor:				1-Point Calibration Point			<input type="checkbox"/> With CONC-0		

# User defined

\* Lot specific calibrator values

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## CEDIA MYCOPHENOLIC ACID, AU5800

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		MPA	<	>	Type:	Serum	Operation	Yes			
Sample Volume	7.5	μL	Dilution	0	μL	OD Limit					
Pre-Dilution Rate	1	∇	Diluent Bottle	#	∇	Min.OD	-2.00	Max.OD	3.00		
Rgt. Volume	R1(R1-1)	150	μL	Dilution	0	μL	Reagent OD Limit				
	R1-2		μL	Dilution		μL	First	Low	-2.00	High	3.00
							Last	Low	-2.00	High	3.00
	R2(R2-1)	60	μL	Dilution	0	μL					
Common Rgt. Type	None		Name			Dynamic Range Low	0.3	High	10.0		
Wavelength	Pri	570	∇nm	Sec.	660	∇nm	Correlation Factor A	1	B	0	
Method	FIXED1					Factor for Maker A	1	B	0		
Reaction Slope	+					Onboard Stability Period	#	Day	#	Hour	
Measuring Point1 1 <sup>st</sup>	24		Last	27		LIH Influence Check	#	∇			
Measuring Point2 1 <sup>st</sup>			Last			Lipemia		∇			
Linearity Limit						Icterus		∇			
Lag Time Check	No					Hemolysis		∇			

Parameters		Specific Test Parameters						
General	LIH	ISE	HbA1c		Calculated Test	Range		
Test Name:		MPA	<	>	Type:	Serum		
Value/Flag:	#							
Specific Ranges:	From	Level	To	Low	#	High	#	
	Sex	Year	Month	Year	Month	Low	High	
o 1.	#	∇	#	#	#	#	#	
o 2.	#	∇	#	#	#	#	#	
o 3.	#	∇	#	#	#	#	#	
o 4.	#	∇	#	#	#	#	#	
o 5.	#	∇	#	#	#	#	#	
o 6.	#	∇	#	#	#	#	#	
7.	Standard demographics						#	#
8.	Not within expected values						#	#
Panic Value	Low	#	High	#	Unit	μg/mL	Decimal Places	#

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## CEDIA MYCOPHENOLIC ACID, AU5800, continued

Parameters		Calibration Parameters			
Calibrators		Calibration Specific			
General		ISE			
Test Name: MPA ▾		< >		Type: Serum ▾	Cuvette: ▾
<input type="checkbox"/> Use Serum Cal.					
Calibration Type: AA ▾		Formula: Y=AX+B ▾		Counts: 2 ▾	
<Calibrator Parameters>					
Calibrator		OD	Conc	Range	
Point 1:	# ▾		*	Low	High
Point 2:	# ▾		*	-99999	99999
Point 3:	▾				
Point 4:	▾				
Point 5:	▾				
Point 6:	▾				
Point 7:	▾				
Point 8:	▾				
Point 9:	▾				
Point 10:	▾				
<Point Cal. For Master Curve>		No. of Correction Points	Use Master Curve		Interval (RB/ACAL)
		▾	▾		▾
		OD Range		Stability	
Calibrator		OD	Conc	Low	High
Point-1	▾				
Point-2	▾				
MB Type Factor: ▾		1-Point Calibration Point		None ▾	
				<input type="checkbox"/> with Conc-0	
				Slope Check: + ▾	
				Allowance Range Check	
				<input type="checkbox"/> Reagent Blank	
				<input type="checkbox"/> Calibration	
				Advanced Calibration Operation: No ▾	
				Reagent Blank: # Day # Hour	
				Calibration: # Day # Hour	

# User defined

\* Lot specific calibrator values

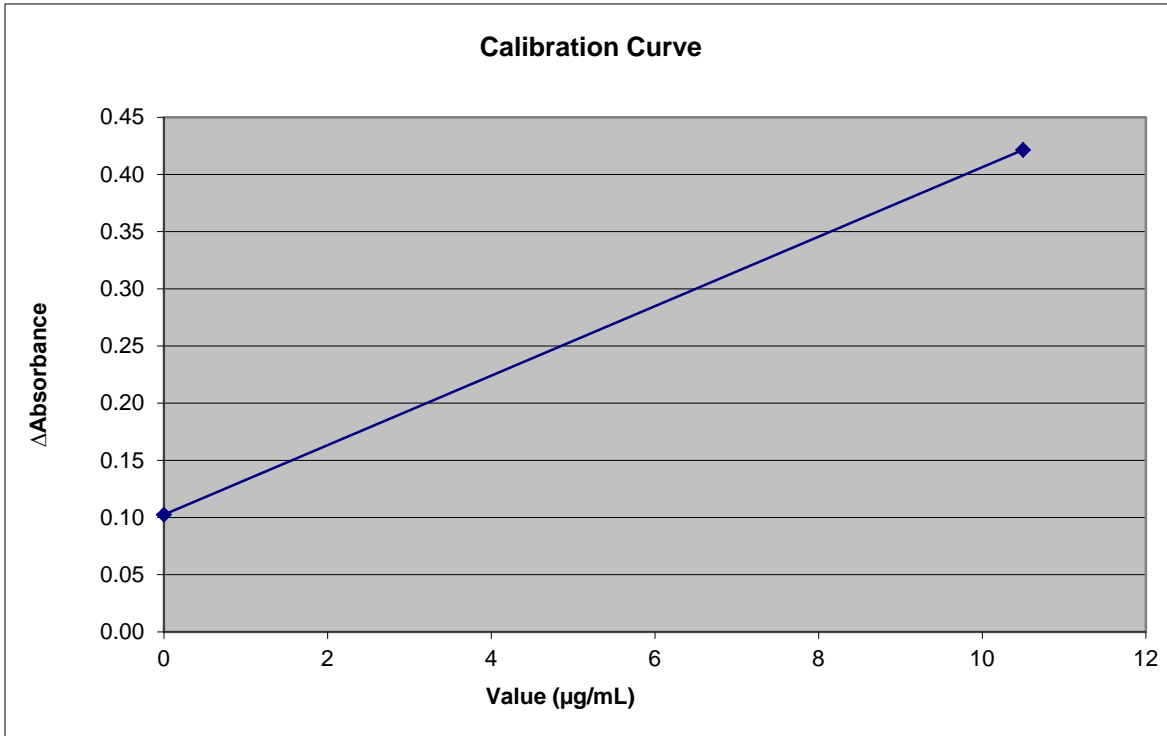


## Results and Data Interpretation

**Performance Data**

Refer to the CEDIA Mycophenolic Acid Assay kit package insert for additional information on results and data interpretation.

**Example Calibration Curve, MPA (AU480):**



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**Precision**

These degrees of precision and equivalency were obtained in typical testing procedures on an AU system and are not intended to represent the performance specifications for this reagent.

Control samples were tested in replicates of 2, twice per day for 20 days, total N = 80. The results are presented in the following table:

<b>Controls</b>	<b>Control 1</b>	<b>Control 2</b>	<b>Control 3</b>
<b>AU480</b>			
Mean (µg/mL)	0.9	2.8	6.4
Within-Run SD (µg/mL)	0.03	0.05	0.07
Within-Run CV (%)	3.0	1.8	1.1
Total SD (µg/mL)	0.05	0.07	0.11
Total CV (%)	5.2	2.4	1.7
<b>AU680</b>			
Mean (µg/mL)	0.9	3.0	6.6
Within-Run SD (µg/mL)	0.06	0.07	0.13
Within-Run CV (%)	6.1	2.2	1.9
Total SD (µg/mL)	0.07	0.10	0.16
Total CV (%)	7.7	3.2	2.5
<b>AU5800</b>			
Mean (µg/mL)	0.9	2.8	6.4
Within-Run SD (µg/mL)	0.05	0.07	0.14
Within-Run CV (%)	5.3	2.3	2.2
Total SD (µg/mL)	0.06	0.09	0.15
Total CV (%)	6.7	3.0	2.4

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**Linearity**

Seven levels of manufacturing calibrators were run against a single calibration curve and the linearity calculated. The analytical range for this assay is 0.3 to 10 µg/mL. Error flags will appear for samples recovering above or below the assay range.

The MPA assay recovered between 102 – 105% of expected values on the AU480.

The MPA assay recovered between 101 – 107% of expected values on the AU680.

The MPA assay recovered between 102 – 104% of expected values on the AU5800.

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**LDD**

The negative calibrator was run against the same calibration curve for 21 replicates. The LDD is calculated as 2\*SD.

The observed LDD for the MPA Assay was 0.06 µg/mL on the AU480.

The observed LDD for the MPA Assay was 0.07 µg/mL on the AU680.

The observed LDD for the MPA Assay was 0.05 µg/mL on the AU5800.

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**Accuracy and Correlation**

One hundred and seven plasma samples were assayed with the CEDIA Mycophenolic Acid Assay on the Beckman Coulter AU480, AU680, and AU5800, and tested with reference method Hitachi 917.

A Deming's Regression Analysis yielded the following:

AU480 = 0.992\*(Hitachi 917) – 0.10 with a correlation coefficient of 0.998

AU680 = 0.995\*(Hitachi 917) – 0.04 with a correlation coefficient of 0.998

AU5800 = 0.993\*(Hitachi 917) + 0.09 with a correlation coefficient of 0.998

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## Additional Information

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**Important**

Since Beckman Coulter does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the Manufacturer.

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**Shipping  
Damage**

Please notify your Beckman Coulter Clinical Support Center if this product is received damaged.

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 Thermo Fisher Scientific Oy, Ratastie 2, P.O. Box 100, 01621 Vantaa, Finland  
Tel: +358-9-329100/Fax: +358-9-32910300

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