

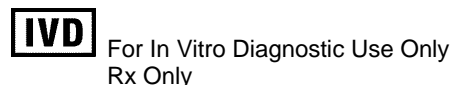
CEDIA™ Mycophenolic Acid (MPA) APPLICATION

Beckman Coulter DxC 500 AU / 500i



Beckman Coulter Reagent REF B01460

The Application is Intended for the Determination of Mycophenolic Acid (MPA) in human Plasma.



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 preparation, specimen storage, quality control, and additional performance data. For package inserts, visit www.thermofisher.com and enter the assay name in the *Search* field.

Ordering Information

Item	Size	Beckman Coulter Reorder Number
CEDIA Mycophenolic Acid (MPA) Assay	R1: 1 x 26 mL R2: 1 x 11 mL	B01460
CEDIA Mycophenolic Acid (MPA) Calibrators	2 x 5 mL	B37609
CEDIA Mycophenolic Acid (MPA) Control 1	4 x 5 mL	B37611
CEDIA Mycophenolic Acid (MPA) Control 2	4 x 5 mL	B01543
CEDIA Mycophenolic Acid (MPA) Control 3	4 x 5 mL	B01544
AU Bottle	20 x 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. For package inserts, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field.

Continued on next page

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 Mycophenolic Acid (MPA) Assay Kit	AU Reagent Bottle	
	R1 Compartment	R2 Compartment
Antibody/Substrate Reagent R1	One Bottle (30 mL)	
Enzyme Conjugate Reagent R2		One Bottle (30 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 ug/mL.

Specimen Preparation

Refer to the package insert for the complete specimen preparation. The product insert can be found at the Thermo Fisher Scientific website: For package inserts, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field.

Calibration

Use the CEDIA Mycophenolic Acid (MPA) Calibrator kit. The calibrators are liquid and ready-to-use. Refer to the package insert for the concentration of each calibrator.

Reagent Name: CEDIA Mycophenolic Acid (MPA) Assay REF B01460 DxC 500 AU / 500i
Plasma Settings
Calibrator Name: CEDIA Mycophenolic Acid (MPA) Calibrator Kit REF B37609

Reagent ID 562

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	MPA		Calculated Result	<input type="checkbox"/>
LIS Code	MPA		Result Type	Quantitative ▼
UNITS AND RANGE SETTINGS				
Use Settings from	Serum ▼	Units	ug/mL ▼	Decimal Places
				x.xx ▼
Test Kind	General ▼	Revision	02	<input checked="" type="checkbox"/> Multi Reagent Switch
Reagent Name	MPA	Reagent ID	562	<input type="checkbox"/> FSE Test
ABB Name	MYA1G	Parameter Long Name	Mycophen Acid B01460 MYA1G Serum	
Region	<input checked="" type="checkbox"/> US	<input checked="" type="checkbox"/> OUS	<input checked="" type="checkbox"/> AP	<input type="checkbox"/> JP
	<input checked="" type="checkbox"/> EU	<input type="checkbox"/> Other		

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume	7.5	μL	Dilution	0	μL	REACTION OD LIMIT	Low	-2.0000	High	3.0000
	Predilution Rate	1					REACTION BLANK OD LIMIT	First: Low	-2.0000	High	3.0000
REAGENT VOLUME	R1-1	150	μL	Dilution	0	μL		Last: Low	-2.0000	High	3.0000
	R2-1	60	μL	Dilution	0	μL	ANALYTICAL MEASURING RANGE	Low	0.30	High	10.00
WAVELENGTH	Primary	570	nm	Secondary	660	nm	MANUFACTURER FACTOR	A	1	B	0
METHOD	FIXED 1 ▼						REAGENT ONBOARD STABILITY	31 Days 0 Hours			
REACTION SLOPE	+						LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check			
MEASURING POINT	Point 1: First	24		Last	27		Lipemia	+	▼		
	Point 2: First			Last			Icterus	+	▼		
							Hemolysis	+	▼		
Linearity Limit											
Lag Time Check	<input type="checkbox"/> Perform Lag Time Check										

Reagent Name: CEDIA Mycophenolic Acid (MPA) Assay REF B01460 DxC 500 AU / 500i
Plasma Settings

Reagent ID 562

Calibrator Name: CEDIA Mycophenolic Acid (MPA) Calibrator Kit REF B37609, *Continued*

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
ug/mL	2	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

Formula

MB Factor

Calibrator Name

Positive Cutoff

☒ SLOPE CHECK

Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours

Interval

Calibration Stability Days Hours

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

☐ Use highest calibrator for Upper AMR

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	MPA CAL-1		-9999999	9999999
Point 2	MPA CAL-2			
Point 3				
Point 4				
Point 5				
Point 6				
Point 7				

OD DELTA CHECK

☐ Reagent Blank

☐ Calibration

PROZONE CHECK PARAMETERS

☐ Logic Check 1

Check Points

Point 1
Point 2
Point 3

Decision Values

Value 1
Value 2
Value 3

☐ Logic Check 2

Check Points

Point 1
Interval

Limit Points

Limit 1
Limit 2

☐ Logic Check 3

Check Points

Point 1
Interval

Limit Points

Limit 1
Limit 2

Decision Values

Value 1
Value 2

Limit Points

Limit 1
Limit 2

Check Pattern

Pattern

Additional Information

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.

Shipping Damage

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

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