

CEDIA™ Mycophenolic Acid (MPA) APPLICATION Beckman Coulter DxC 500 AU®



Beckman Coulter Reagent REF B01460

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



For In Vitro Diagnostic Use Only
Rx 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 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.

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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 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
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	<input type="text" value="MPA"/>		Calculated Result	<input type="checkbox"/>
LIS Code	<input type="text" value="MPA"/>		Result Type	<input type="text" value="Quantitative"/>

UNITS AND RANGE SETTINGS

Use Settings from	<input type="text" value="Serum"/>	Units	<input type="text" value="ug/mL"/>	Decimal Places	<input type="text" value="x.xx"/>	<input type="text" value="Plasma"/>
Test Kind	<input type="text" value="General"/>	Revision	<input type="text" value="02"/>	<input checked="" type="checkbox"/> Multi Reagent Switch		
Reagent Name	<input type="text" value="MPA"/>	Reagent ID	<input type="text" value="562"/>	<input type="checkbox"/> FSE Test		
ABB Name	<input type="text" value="MYA1G"/>	Parameter Long Name	<input type="text" value="Mycophen Acid B01460 MYA1G Serum"/>			

Region US OUS AP JP EU Other

GENERAL PARAMETERS

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

Reagent Name: CEDIA Mycophenolic Acid (MPA) Assay REF B01460 DxC 500 AU
 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

Use highest calibrator for Upper AMR

Formula

MB Factor

Calibrator Name

Positive Cutoff

SLOPE CHECK Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours
 Calibration Stability Days Hours

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

	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

Limit Points
 Limit 1
 Limit 2

Check Pattern
 Pattern

Logic Check 2

Decision Values
 Value 1
 Value 2
 Value 3

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Logic Check 3

Decision Values
 Value 1
 Value 2

Check Points
 Point 1
 Interval

Limit Points
 Limit 1
 Limit 2

Decision Values
 Value 1
 Value 2

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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