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CEDIA® Mycophenolic Acid Application Ortho Clinical Diagnostics VITROS® 5600 Integrated System, \VITROS® 5,1 FS and 4600 Chemistry Systems

CE

Catalog No. 100276

Intended for the Quantitative Determination of Mycophenolic Acid in Human Plasma

For In Vitro Diagnostic Use 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 storage, quality control and additional performance data.

Ordering Information

Materials available from Microgenics:

Item	Catalog Number
CEDIA® Mycophenolic Acid Assay Reagents	100276
CEDIA® Mycophenolic Acid Calibrator Kit	100277
MAS® Mycophenolic Acid Control 1	100278
MAS® Mycophenolic Acid Control 2	100279
MAS® Mycophenolic Acid Control 3	100280

To place an order or for technical service contact (North America):

Microgenics Corporation, part of Thermo Fisher Scientific
46360 Fremont Boulevard, Fremont, CA 94538 USA
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5001
U.S. Toll free fax: (800) 829-8115 / Fax: (510) 979-5002

EC REP Microgenics GmbH, Spitalhofstrasse 94D-94032 Passau Germany
Tel: +49 (0)851-88 6890/Fax: +49 (0)851-88 68910

ADD UDA Template

A new UDA template containing protocol *2PT R1-S-R2 is available on ADD DRV5604 forward and should be used for this assay. Please order ADD DRV5604 from Ortho Clinical Diagnostics; it is not available from Microgenics.

Reagent Pack Storage

Reconstituted reagents are stable for 60 days at 2-8°C when stored in their original container or in UDxx reagent packs.

Reconstituted reagents stored in UDxx reagent packs onboard the analyzer are stable for 7 days. Reagent life can be extended by storing the reagent packs in a refrigerator at 2-8°C between use.

Depending on the anticipated reagent utilization, it is recommended that reconstituted reagents be split into multiple UDxx reagent packs so that each UDxx pack contains only sufficient reagents for 7 days. To split the reconstituted reagent among reagent packs of the same UDxx ID, follow the chart below:

Number of packs	EA (mL) in UDxx/A	ED (mL) in UDxx/B	Tests/pack
2	13.0	5.5	59
3	8.6	3.6	36
4	6.5	2.7	25

Note: Once the individual UDxx pack number is selected for use during the protocol programming, it is the only UDxx pack number to use for this protocol.

Special Reagent Packs for User Defined Assays
(please order from Ortho Clinical Diagnostics; not available from Microgenics)

680 2246	UD01 Packs (Empty)	1 BOX/6PKS
680 2247	UD02 Packs (Empty)	1 BOX/6PKS
680 2248	UD03 Packs (Empty)	1 BOX/6PKS
680 2249	UD04 Packs (Empty)	1 BOX/6PKS
680 2250	UD05 Packs (Empty)	1 BOX/6PKS
680 2251	UD06 Packs (Empty)	1 BOX/6PKS
680 2252	UD07 Packs (Empty)	1 BOX/6PKS
680 2253	UD08 Packs (Empty)	1 BOX/6PKS
680 2254	UD09 Packs (Empty)	1 BOX/6PKS
680 2255	UD10 Packs (Empty)	1 BOX/6PKS

Calibration Frequency

It is recommended that recalibration occur after reagent pack change, after calibrator lot change, after performance of monthly instrument maintenance and as required following quality control procedure.

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Ortho Clinical Diagnostics VITROS® 5600. 5,1 FS and 4600 System Parameters
CEDIA® Mycophenolic Acid Assay

Configure Assay

Full Assay Name: Mycophenolic Acid Version Date: 9/15/2010

Short Assay Name: MPA Fluid Type: serum

Assay Model Type: 2 Point Rate Template: *2Pt R1-S-R2

Cal Model Type: Linear Calibrator Bottles: 2 Reagent Reps per Cal : 2

Reagent Lot Information

On-Board Stability: 7 Days

Reagent Lot Num. *Kit Lot*

Shelf Exp. Date: *Kit Exp Date*

Edit Dilution Parameters

Diluent: None Standard Dilution Factor: 1.0

Reflex Dilution: OFF Dilution Factor: 1.0

Reduction Factor: 1.0

Edit Result Parameters

Units: µg/mL Reference Interval: 0.0 to 90000000

Significant Digits: 3 Precision Digits: 3 Supplementary: 0.0 to 90000000

User Adjusted Parameters Reportable Range: 0.3 to 10

Slope: 1.0 Intercept: 0.0 **(More Assay Parms) – Edit 2 Pt Rate Additional Parameters**

CuveTip Exp Time: 35 Temp Sens : No Initial Abs. Limits: -0.20 to 2.70

Second Abs. Limits: -0.20 to 2.70

Antigen Excess Factor: 9.0

Edit Protocol Parameters

	Step	Volume	Pack ID	Seconds	Wavelength
1.	Reagent	180 uL	UDxx /A		
2.	Incubation			0.0	
3.	Sample	7.7 uL			
4.	Incubation			304.0	
5.	Reagent	58.0 uL	UDxx /B		
6.	Incubation			228.0	
7.	Read				575 nm
8.	Incubation			76.0	
9.	Read				575 nm

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Ortho Clinical Diagnostics VITROS® 5600, 5,1 FS and 4600 System Parameters, continued

CEDIA® Mycophenolic Acid Assay

Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: *Cal Kit lot*
1	1.0	0.20	Cal value: *per cal lot*
2	1.0	0.20	Cal Value: *per cal lot*

(More Cal Parms) – Edit Linear or Logit/Log Additional Parameters

Monotonicity: Increase

Max Resp High: 3.00 Min. Resp. High: 3.00 Cal Fit Goodness Limit: 0.990

Max Resp. Low: -3.00 Min Resp. Low: -3.00

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	0.3	5.0
Critical Conc.:	5	8.0 %
Reportable Max.:	10	8.0 %

Comments: Please see important assay and analyzer notes on page 2.

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VITROS Precision

Tests for within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (N=80/level):

Controls	Control 1	Control 2	Control 3
5600			
Mean (µg/mL)	1.12	3.42	6.99
Within-Run SD (µg/mL)	0.02	0.03	0.06
Within-Run CV (%)	2.0	1.0	0.9
Total SD (µg/mL)	0.07	0.10	0.16
Total CV (%)	5.9	2.8	2.3
5,1 FS/4600*			
Mean (µg/mL)	1.06	3.30	6.85
Within-Run SD (µg/mL)	0.02	0.04	0.05
Within-Run CV (%)	2.0	1.2	0.7
Total SD (µg/mL)	0.13	0.20	0.30
Total CV (%)	12.0	6.0	4.4

VITROS Accuracy and Correlation

Forty-nine (49) plasma samples were assayed using the CEDIA Mycophenolic Acid Assay on the Ortho Clinical Diagnostics VITROS 5600, Ortho Clinical Diagnostics VITROS 5,1 FS and Hitachi 917 analyzers.

A Deming's linear regression analysis yielded the following:

5600 = 1.04 (Hitachi 917) + 0.2, with a correlation coefficient of 0.998

5,1 FS/4600* = 1.03(Hitachi 917) + 0.3, with a correlation coefficient of 0.998

*Analytical processing hardware and software algorithms on the VITROS 4600 Chemistry System are desinged to the same specifications as those applied to the VITROS 5,1 Chemistry System. Assay performance on the VITROS 4600 System has been demonstrated to be comparable to that on the VITROS 5,1 FS System. All performance characteristics for the VITROS 5,1 FS System are therefore applicable to the VITROS 4600 System.

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