

## CEDIA<sup>®</sup> MYCOPHENOLIC ACID APPLICATION



# ORTHO CLINICAL DIAGNOSTICS VITROS<sup>®</sup> XT 7600 INTEGRATED SYSTEM, VITROS<sup>®</sup> 5600 INTEGRATED SYSTEM, VITROS<sup>®</sup> 4600 CHEMISTRY SYSTEM, AND VITROS<sup>®</sup> 5,1 FS CHEMISTRY SYSTEM

Reference No. 100276

This Application is Intended for the Quantitative Determination of Mycophenolic Acid 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.orthoclinicaldiagnostics.com](http://www.orthoclinicaldiagnostics.com) > Ortho Care > Technical Documents > MicroTip Partnership Assays (MPA).

### Ordering Information

Please place your order with Ortho Clinical Diagnostics. Ordering information available on [www.orthoclinicaldiagnostics.com](http://www.orthoclinicaldiagnostics.com).

### Technical Support Information

Contact Ortho Clinical Diagnostics for technical support. Contact information available on [www.orthoclinicaldiagnostics.com](http://www.orthoclinicaldiagnostics.com).



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## 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)

Part Number	Description	Quantity
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
684 4449	UD11 Packs (Empty)	1 BOX/6PKS
684 4448	UD12 Packs (Empty)	1 BOX/6PKS
684 4445	UD13 Packs (Empty)	1 BOX/6PKS
684 4442	UD14 Packs (Empty)	1 BOX/6PKS
684 4447	UD15 Packs (Empty)	1 BOX/6PKS
684 4444	UD16 Packs (Empty)	1 BOX/6PKS
684 4441	UD17 Packs (Empty)	1 BOX/6PKS
684 4446	UD18 Packs (Empty)	1 BOX/6PKS
684 4443	UD19 Packs (Empty)	1 BOX/6PKS
684 4440	UD20 Packs (Empty)	1 BOX/6PKS
680 2256	UDDL1 Packs (Empty)	1 BOX/6PKS
680 2257	UDDL2 Packs (Empty)	1 BOX/6PKS

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## 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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**CEDIA Mycophenolic Acid Assay**  
**Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System,**  
**VITROS® 4600 System, and VITROS® 5,1 FS Parameters**

**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: ug/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 Parm) – Edit 2 Pt Rate Additional Parameters**  
 CuveTip Exp Time: 35 Temp Sens : No Initial Abs. Limits: -0.20 to 2.7  
 Second Abs. Limits: -0.20 to 2.7  
 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

**CEDIA Mycophenolic Acid Assay**  
**Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System,**  
**VITROS® 4600 System, and VITROS® 5,1 FS Parameters, *continued***

**Edit Calibration Parameters**

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

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**(More Cal Parm) – 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.:	<u>0.3</u>	<u>5.0</u>
Critical Conc.:	<u>5</u>	<u>8.0</u> %
Reportable Max.:	<u>10</u>	<u>8.0</u> %

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

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