CEDIA MYCOPHENOLIC ACID (MPA)

The Thermo Scientific™ 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.

The CEDIA MPA Assay uses recombinant DNA technology to produce a unique homogenous enzyme immunoassay system. The assay is based on the enzyme β-galactosidase, which has been genetically engineered into two inactive fragments termed enzyme donor (ED) and enzyme acceptor (EA). These fragments spontaneously re-associate to form fully active enzymes that, in assay format, cleave a substrate, generating a color change that can be measured spectrophotometrically.

In the assay, analyte in the specimen competes with analyte conjugated to ED of β-galactosidase for limited numbers of antibody binding sites. If analyte is present in the sample, it binds to the antibody leaving the ED conjugate free to form active enzymes with the EA. If analyte is not present in the sample, the antibody binds to analyte conjugated to ED, inhibiting the re-association of ED to EA, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of drug present in the sample.

FEATURES OF THE MYCOPHENOLIC ACID ASSAY

› Ready-to-Use liquid calibrators
› 2-Point calibration
› EDTA plasma sample type
› Low-End sensitivity (LDD = 0.07 µg/mL)
› Reportable range (0.3 – 10 µg/mL)
CEDIA Mycophenolic Acid Assay may not be available in all geographies.

CEDIA® is a registered trademark of Roche Diagnostics.

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Distributed by: Beckman Coulter, Inc. for AU Clinical Systems
Manufactured by: Microgenics Corporation
(a subsidiary of Thermo Fisher Scientific)
46500 Kato Rd.
Fremont, CA 94538 U.S.A.

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For Beckman Coulter’s worldwide office locations and phone numbers, please visit www.beckmancoulter.com/contact


**PRECISION**

Each control was assayed in duplicates, twice a day for 20 days, total N=80. Representative results are shown below:

**AU480**

<table>
<thead>
<tr>
<th>Samples</th>
<th>Mean (µg/mL)</th>
<th>Within-Run SD (µg/mL)</th>
<th>CV (%)</th>
<th>Total SD (µg/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control 1</td>
<td>0.9</td>
<td>0.03</td>
<td>3.0%</td>
<td>0.05</td>
<td>5.2%</td>
</tr>
<tr>
<td>Control 2</td>
<td>2.8</td>
<td>0.05</td>
<td>1.8%</td>
<td>0.07</td>
<td>2.4%</td>
</tr>
<tr>
<td>Control 3</td>
<td>6.4</td>
<td>0.07</td>
<td>1.1%</td>
<td>0.11</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

**AU680**

<table>
<thead>
<tr>
<th>Samples</th>
<th>Mean (µg/mL)</th>
<th>Within-Run SD (µg/mL)</th>
<th>CV (%)</th>
<th>Total SD (µg/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control 1</td>
<td>0.9</td>
<td>0.06</td>
<td>6.1%</td>
<td>0.07</td>
<td>7.7%</td>
</tr>
<tr>
<td>Control 2</td>
<td>3.0</td>
<td>0.07</td>
<td>2.2%</td>
<td>0.10</td>
<td>3.2%</td>
</tr>
<tr>
<td>Control 3</td>
<td>6.6</td>
<td>0.13</td>
<td>1.9%</td>
<td>0.16</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

**AU5800**

<table>
<thead>
<tr>
<th>Samples</th>
<th>Mean (µg/mL)</th>
<th>Within-Run SD (µg/mL)</th>
<th>CV (%)</th>
<th>Total SD (µg/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control 1</td>
<td>0.9</td>
<td>0.05</td>
<td>5.3%</td>
<td>0.06</td>
<td>6.7%</td>
</tr>
<tr>
<td>Control 2</td>
<td>2.8</td>
<td>0.07</td>
<td>2.3%</td>
<td>0.09</td>
<td>3.0%</td>
</tr>
<tr>
<td>Control 3</td>
<td>6.4</td>
<td>0.14</td>
<td>2.2%</td>
<td>0.15</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

**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 a commercially available clinical chemistry analyzer.

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

**ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>Item</th>
<th>Size</th>
<th>Beckman Coulter Reference Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEDIA Mycophenolic Acid Assay (approximately 130 tests)</td>
<td>R1 26 mL</td>
<td>B01460</td>
</tr>
<tr>
<td></td>
<td>R2 11 mL</td>
<td></td>
</tr>
<tr>
<td>AU Bottle</td>
<td>15 mL, 20 each</td>
<td>63165</td>
</tr>
<tr>
<td>AU Bottle</td>
<td>30 mL, 20 each</td>
<td>63094</td>
</tr>
<tr>
<td>CEDIA Mycophenolic Acid Calibrator Set</td>
<td>2 levels 5.0 mL - 2 bottle each level</td>
<td>B37609</td>
</tr>
<tr>
<td>MAS® Mycophenolic Acid Control 1 Kit</td>
<td>4 x 5.0 mL</td>
<td>B37611</td>
</tr>
<tr>
<td>MAS Mycophenolic Acid Control 2 Kit</td>
<td>4 x 5.0 mL</td>
<td>B01543</td>
</tr>
<tr>
<td>MAS Mycophenolic Acid Control 3 Kit</td>
<td>4 x 5.0 mL</td>
<td>B01544</td>
</tr>
</tbody>
</table>

To learn more about Beckman Coulter’s comprehensive Chemistry offering, visit www.beckmancoulter.com/chemistry.