The Most Convenient Tacrolimus (TACR) Assay

Turn to the proven drug testing expert

The proven Viva® drug testing systems and Emit® reagents and the Dimension® integrated chemistry systems – for monitoring Cyclosporine C0 and C2, Mycophenolic Acid¹ and Tacrolimus – have the flexibility and capacity to meet all your immunosuppressant drug monitoring needs. Tailor your instrument and reagent combination to ideally suit your lab’s needs.

Your solution is accompanied by the strong support network of Siemens Healthcare Diagnostics with more than 30 years of experience in drug testing. Our support provides your laboratory with a high level of service, education and training materials that enable you to keep up-to-date with the latest advancements in your field of expertise.

Enhance your productivity: Streamline your ISD monitoring workflow

The Emit 2000 Tacrolimus Assay is designed for quantitative analysis of Tacrolimus in human whole blood as an aid in the management of Tacrolimus therapy in transplant patients.

Assay characteristics:

• Good correlation with LC/MS/MS
• No significant hematocrit interference²,³
• Simple pre-treatment procedure
• No reagent pre-treatment
• Rapid results – 10 minutes to first results, up to 130 tests per hour on Viva-E® and 260 tests per hour on V-Twin®
• 3 ISD assays on one analyzer

Prograf®, the drug

Prograf® (Tacrolimus) is a macrolide immunosuppressant of fungal origin. It is a calcineurin inhibitor with selective action on T lymphocytes. Tacrolimus undergoes hepatic metabolism before immediate biliary excretion, which is the major route of elimination.

Emit® 2000 Tacrolimus (TACR) Assay

Answers for life.
Meeting the need – the Emit 2000 Tacrolimus (TACR) Assay

Assay performance data

No significant cross-hematocrit interference

<table>
<thead>
<tr>
<th>Tacrolimus Level</th>
<th>15% hct</th>
<th>% Tacrolimus Recovery at % Hematocrit</th>
<th>25% hct</th>
<th>35% hct</th>
<th>45% hct</th>
<th>5% hct</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 ng/mL</td>
<td>121</td>
<td>111</td>
<td>107</td>
<td>100</td>
<td>101</td>
<td></td>
</tr>
<tr>
<td>15 ng/mL</td>
<td>111</td>
<td>108</td>
<td>101</td>
<td>100</td>
<td>99</td>
<td></td>
</tr>
</tbody>
</table>

Precision

<table>
<thead>
<tr>
<th>Control Level (ng/mL)</th>
<th>Within-run Precision</th>
<th>Total Precision</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>SD</td>
<td>%CV</td>
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<tr>
<td>5.10</td>
<td>0.40</td>
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<tr>
<td>9.98</td>
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<td>23.87</td>
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</tr>
</tbody>
</table>

Patient correlation

Quality Control

BioRad or MORE

Stability

Eighteen (18) months

Assay Principle

Homogenous enzyme immunoassay technique

Type of Measurement

Photometric

Sample Type

EDTA Whole Blood (200 µl)

Reportable Range

2-30 ng/mL

Sensitivity

Analytical: 2.0 ng/mL
Functional: 2.8 ng/mL

Ordering Information:

Product code: 8R019UL

Packaging: 22mL, 10mL, 10mL

International independent proficiency samples

1 Emit MPA assay is available outside the US; Dimension MPA is in development.
3 LeGatt, C E S: Comparison of Two Tacrolimus Immuno assays (Emit: Viva and MEIA: IMx®) in Four Transplant Groups. AACC 2002; Topic 19, Presentation B-7.
4 Proficiency Testing Scheme; Analytical Services International; www.bioanalytics.co.uk

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