MassTrak LC-MS/MS Tacrolimus Kit

ARE YOU MEETING YOUR CLINICIANS’ DEMANDS FOR ACCURATE TACROLIMUS (FK506; PROGRAF) RESULTS?

- Need enhanced specificity and increased sensitivity?
- Need to reduce annual reagent costs?
- Need to reliably measure Tacrolimus at low ng/mL levels?
- Need reliable Tacrolimus calibrators, QC materials and internal standards?

Waters has developed the MassTrak range of integrated system solutions to meet the needs of clinical laboratories, transplant hospitals and reference laboratories.

Waters MassTrak™ clinical solutions that integrate HPLC, mass spectrometry, software and support services, have now been further enhanced to include a reagent kit for monitoring Tacrolimus. The MassTrak Immunosuppressants Kit is the first commercially available kit designed specifically for use with LC-MS/MS and cleared by the FDA for monitoring Tacrolimus levels in kidney and liver transplant patients.

TACROLIMUS MONITORING – MASSTRAK LC-MS/MS ADVANTAGES

- Validated LC-MS/MS Immunosuppressants Kit for Tacrolimus
- Fast turnaround for patient results – pre-treatment and analysis take only a few minutes per sample
- Excellent specificity resulting in improved accuracy and precision
- High sensitivity enabling reliable measurement at 0.5 ng/mL level
- Total solution incorporating instrument, methodology and validated reagent kit

Introducing the MassTrak Immunosuppressants Kit with the intended use of monitoring Tacrolimus level in liver and kidney transplant patients.
BENEFITS OF MASSTRAK IMMUNOSUPPRESSANTS KIT

Waters’ LC-MS/MS method combined with the immunosuppressants kit for Tacrolimus analysis offers distinct benefits over laboratory developed tests:

- Saves valuable laboratory time by removing the need to make in-house calibrators and quality control samples.
- Eliminates the variability of results due to in-house reagents.
- Improves analytical data due to consistent quality of reagents.
- Facilitates inter and intra-laboratory comparisons.
- Enables faster startup and implementation of LC-MS/MS methods.
- Aids troubleshooting if there are problems with the assay.
- Provides a reagent kit that is CE marked for IVD use in Europe and FDA cleared in the US.

COMPONENTS OF MASSTRAK IMMUNOSUPPRESSANTS KIT

The following components are included in the MassTrak Immunosuppressants Kit (Part No. 176000898) to ensure unmatched accuracy and precision:

<table>
<thead>
<tr>
<th>Component</th>
<th>Content</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibrators</td>
<td>6 levels</td>
<td>0 to 30 µg/L Tacrolimus</td>
</tr>
<tr>
<td>Quality Controls</td>
<td>3 levels</td>
<td>2 to 22 µg/L Tacrolimus</td>
</tr>
<tr>
<td>Internal Standard</td>
<td>1 level</td>
<td>2 µg/L ascomycin</td>
</tr>
<tr>
<td>Column</td>
<td>Waters TDM C18</td>
<td>2.1 x 10 mm</td>
</tr>
<tr>
<td>Neat Solution</td>
<td>1 level</td>
<td>1 ng/µL Tacrolimus and ascomycin</td>
</tr>
</tbody>
</table>

QUICK AND SIMPLE SAMPLE PREPARATION METHOD WITHOUT COMPROMISING RESULTS

Figure 1. Tacrolimus Calibration Line: MassLynx™ with QuanLynx™ Software automatically generates the calibration line using a series of calibrators of known concentration (0 to 30 µg/L Tacrolimus) and calculates the Tacrolimus concentrations in patient samples.
PROVEN TACROLIMUS LC-MS/MS METHOD
The MassTrak Immunosuppressants Kit is designed to be used with a validated Tacrolimus method developed by Waters through a collaboration with Keevil et al. This method has now been proven in clinical laboratories worldwide and has been shown to give comparable results to methods requiring longer chromatography and more extensive sample preparation.

Taylor* reported that, using the Waters method, the Tacrolimus results for the external quality controls were in excellent agreement with the mean for all laboratories using HPLC-MS ($R^2 = 0.9943$, $n=45$). “In conclusion, the simplified sample preparation and rapid chromatography enable higher throughput and significant cost savings compared with our previous method, without compromising results. These aspects make this method suitable to facilitate current therapeutic drug monitoring practices.”

2Taylor, P.J. et al. 2005, IATDMCT. *Dr. Paul Taylor, Princess Alexandra Hospital, Brisbane, Australia.

MASSTRAK LC-MS/MS SYSTEMS
LC-MS/MS is now being used for Tacrolimus monitoring in a number of clinical laboratories. LC-MS/MS methods overcome some of the well-documented problems of Tacrolimus immunoassays, such as metabolite cross-reactivity, poor precision at low concentrations and hematocrit variability. In addition, because reagent costs for commercial Tacrolimus immunoassays can be high, LC-MS/MS is also proving to be a cost effective alternative for medium and high throughput laboratories.

The specificity provided by LC-MS/MS, which uses molecular species and specific fragments to distinguish parent drug molecules from metabolites and matrix interferences, enables accurate and precise measurement of Tacrolimus concentrations in minutes.

REAGENT RENTAL PROGRAM FOR WATERS MASSTRAK SYSTEMS
You can now benefit from the advantages of MassTrak Systems for monitoring Tacrolimus through a Reagent Rental contract. A capital system purchase or a third-party lease is not required.

The Reagent Rental program includes a Waters MassTrak LC-MS/MS system with an appropriate supply of MassTrak Immunosuppressants Kits and the Waters enhanced Connections® Clinical Service Plan. For further details and pricing information contact your local Waters representative.
CLINICAL SERVICE AND SUPPORT – MAXIMIZING INSTRUMENT PERFORMANCE AND UPTIME

Waters Connections Clinical Service has developed a unique program designed to meet the demands of clinical laboratories to minimize instrument downtime and work disruption. As such, the program sets new standards for MassTrak Systems support in your clinical laboratory.

- Guaranteed prioritized service.
- Guaranteed two-hour response* for callback after receipt of a support call.
- Guaranteed on-site response time* of two business days (48 hours).
- Single vendor support for HPLC and mass spectrometry systems and applications.

*Contact your local Waters office for availability.

References