Thermo Scientific

QMS Tacrolimus Immunoassay

- Reagent: Liquid, ready-to-use format
- Calibrators: Liquid, frozen
- Precise low-end sensitivity: 1 ng/mL
- Excellent correlation to LC-MS/MS, the gold standard
- Reportable Range: 1-30 ng/mL
- Dependable results across assay range

Improving patient care with second generation assay enhancements

The Thermo Scientific™ QMS™ Tacrolimus Immunoassay is intended for the quantitative determination of tacrolimus in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of kidney, liver, and heart transplant patients receiving tacrolimus therapy. This in vitro diagnostic device is intended for clinical laboratory use only.

A therapeutic range of 5 to 20 ng/mL in whole blood is generally recommended for patients at standard risk of rejection.

Large intra-patient variability as well as inter-patient variability in tacrolimus concentrations in whole blood has been reported[1]. Monitoring for tacrolimus is important for effective use of the drug in the prevention of renal, liver, and heart allograft rejection, especially in high-risk patients. The measurement of tacrolimus concentrations in whole blood in conjunction with other laboratory data and clinical evaluation is the preferred approach to optimize immunosuppressive effects and minimize adverse side effects for patients[2].

The QMS Tacrolimus Immunoassay is optimized for use on automated clinical chemistry analyzers and is a dependable alternative to LC-MS/MS methods, providing improved turn-around-time and long term calibration stability. Applications are available on our compact Indiko™ and Indiko Plus clinical and specialty chemistry systems, as well as a wide variety of other laboratory instrumentation.

Overview of technology

The QMS Tacrolimus Immunoassay is a homogeneous particle-enhanced turbidimetric immunoassay. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the tacrolimus antibody reagent.

The tacrolimus-coated microparticle reagent is rapidly agglutinated in the presence of the anti-tacrolimus antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance change is measured photometrically. When a sample containing tacrolimus is added, the agglutination reaction is partially inhibited, slowing the rate of absorbance change.

A concentration-dependent classic agglutination inhibition curve can be obtained with the maximum rate of agglutination at the lowest tacrolimus concentration and the lowest agglutination rate at the highest tacrolimus concentration.

1. Staatz CE, Willis C, Taylor PJ, and Tett SE. Population pharmacokinetics of tacrolimus in adult kidney transplant recipients. Clin Pharmacol Ther. 2002;72:660-669.

2. Christians U, Pokaiyavanichkul T, Chan L, Tacrolimus, Applied Pharmacokinetics and Pharmacodynamics: Principals of Therapeutic Drug Monitoring. 4th Edition. Lippincott Williams & Wilkins, Philadelphia, PA 2005: 529-562.

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Precision: The within-run CV% was ≤ 4.9% and the total-run CV% was ≤ 7.1% for all samples.

Determined as described in the Clinical & Laboratory Standards Institute (CLSI) protocol EP5-A2[3]. Studies were conducted using whole blood pooled patient and spiked samples. Each level was assayed in duplicate, twice a day for 20 days. Each run per day was separated by at least two hours. The means and the within-run and total-run standard deviation (SD) and % coefficient of variation (CV) were calculated. Representative results are shown below (N=80).

Samples	Mean (ng/mL)	Within-Run SD (%)	Within-Run CV (%)	Total-Run SD (%)	Total-Run CV (%)
Spiked Sample 1	3.0	0.2	4.9	0.2	7.1
Spiked Sample 2	10.0	0.2	1.9	0.4	3.6
Spiked Sample 3	20.9	0.4	1.9	1.1	5.0
Patient Pooled Sample 1	3.2	0.1	4.1	0.2	6.2
Patient Pooled Sample 2	10.4	0.2	2.2	0.4	3.6
Patient Pooled Sample 3	24.2	0.5	2.1	1.1	4.6

Method Comparison

Method comparison studies were performed between the QMS Tacrolimus Immunoassay and LC-MS/MS method for 136 kidney, 133 liver, and 114 heart transplant patient samples. Additional method comparison studies were performed between the QMS Tacrolimus Immunoassay and the Abbott Architect® Tacrolimus Assay for a total of 208 kidney and liver transplant patient samples. Results of the Deming regression analyses for the studies are shown below.

Comparative Method	N	Slope (Deming)	Intercept (Deming)	Correlation (R)
LC-MS/MS Site 1	383	1.111 (1.084 to 1.137)	0.53 (0.31 to 0.76)	0.972
LC-MS/MS Site 2	232	1.130 (1.092 to 1.167)	0.71 (0.42 to 1.01)	0.967
Abbott ARCHITECT Tacrolimus	208	1.126 (1.071 to 1.181)	-0.03 (-0.63 to 0.56)	0.937

Ordering Information

Part Number	Description	Format
10015556	QMS Tacrolimus Immunoassay	R1 18 mL, R2 12 mL Extraction reagent 50 mL
10015573	QMS Tacrolimus Calibrators	6 levels Level A - 4 mL, 1 vial Levels B to F - 2 mL, 1 vial each
280-1	Rap/Tac/CsA Control Level 1	4 mL, 4 vials
280-2	Rap/Tac/CsA Control Level 2	4 mL, 4 vials
280-3	Rap/Tac/CsA Control Level 3	4 mL, 4 vials

Call 1-800-232-3342 option 2, option 3 or your local Thermo Fisher Scientific representative for application sheets for your specific analyzer.

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3. Clinical and Laboratory Standards Institute. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. 2008.

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