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Reliable results for targeted tacrolimus patient monitoring

Dimension Integrated Chemistry Systems Tacrolimus (TAC) assay specifications

When survival is on the line, the quality of tacrolimus results cannot be compromised. The new Dimension® Integrated Chemistry Systems Tacrolimus (TAC) assay* provides confidence in patient results and improved productivity for complete care of transplant patients, including tacrolimus minimization.

Confidence in complete transplant-patient care

The Dimension TAC assay eliminates manual sample-pretreatment steps to deliver tangible clinical and analytical benefits. Excellent precision across the entire assay range enables care management of transplant patients at any phase of immunosuppressant drug (ISD) therapy and at any therapeutic target level.

- Count on reliable results with a proprietary automated pretreatment that minimizes the risk of matrix effect and a predecorated chrome particle that enhances the stability of the reagent
- Deliver sensitive results with a limit of quantification (1 ng/mL) specified by the clinical practice guidelines¹ for tacrolimus minimization regimens

- Provide an assay with good agreement with the LC-MS/MS reference method
- Avoid errors with a built-in software check that flags false positives

Fast tacrolimus results: whenever and wherever they are needed

Since no manual sample-pretreatment steps are required, tacrolimus testing can be added to the routine daily workload of any laboratory, eliminating the need for specialized equipment and freeing up valuable personnel.

- Increase productivity and reduce sample-handling errors with fully automated TAC results available in less than 15 minutes—anytime, day or night
- Manage the health of both the transplant patient and graft with consolidated tacrolimus testing. More than 91 assays are available on the Dimension systems, including the four most commonly monitored ISDs: mycophenolate, cyclosporine, sirolimus, and tacrolimus

*Not available for sale in the U.S. Product availability varies by country.

Answers for life.

Assay Analytical Performance

Mnemonic	TAC
Assay Principle	Affinity chrome-mediated immunoassay (ACMIA)
Pretreatment	Fully automated onboard the system. No manual sample pretreatment required
Sample Type	EDTA whole blood
Sample Volume	15 µL
Assay Range	1.0–30.0 ng/mL (1.3–39.0 nmol/L)
Limit of Blank (LoB)	0.5 ng/mL (0.7 nmol/L)
Limit of Detection (LoD)	0.7 ng/mL (0.9 nmol/L)
Limit of Quantification (LoQ)	1.0 ng/mL (1.3 nmol/L)
Reagent Onboard Stability	Closed onboard (at 2–8°C): 30 days Open well: 2 days
Calibration Stability	30 days
Dilution	1:2 (manual)
Time to First Result	15 minutes

Assay precision/Reproducibility

Material	Mean		Repeatability (%CV)	Within-lab (%CV)
	ng/mL	nmol/L		
Whole Blood Pool 1	1.8	2.3	5.0	8.8
Whole Blood Pool 2	5.4	7.0	2.9	6.3
Whole Blood Pool 3	13.1	17.1	2.2	4.6
Whole Blood Pool 4	20.7	26.9	2.3	4.9
QC Level 1	4.4	5.7	3.8	6.9
QC Level 2	11.4	14.8	2.3	4.5
QC Level 3	27.4	35.6	3.1	5.1

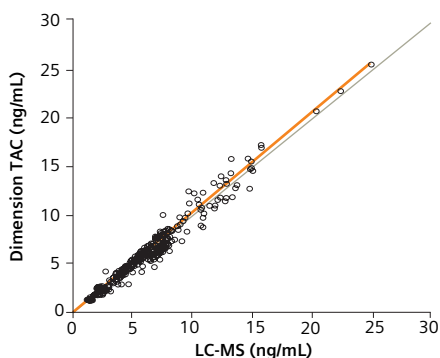
CLSI/NCCLS EP5-A2 was used. Two separate runs, with two test samples for each test material, were analyzed each day for 20 days.

Method comparison

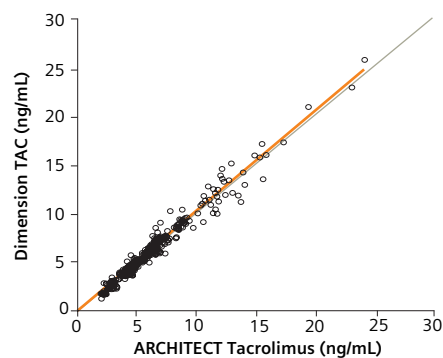
Comparative Method	Slope	Intercept		Correlation Coefficient	n
		ng/mL	Interval		
LC-MS/MS	1.04 (1.00 to 1.07)	-0.26	-0.42 to -0.00	0.982	201 ²
ARCHITECT Tacrolimus	1.05 (1.02 to 1.08)	-0.67	-0.83 to -0.48	0.980	198 ³

CLSI/NCCLS EP9-A2 was used. Ordinary least squares method was used to fit the linear regression line.

Dimension TAC vs. LC-MS, All Organ Types



Dimension TAC vs. ARCHITECT Tacrolimus, All Organ Types



Ordering information

Part Number	Description	Quantity
DF207	Dimension® TAC Flex® reagent cartridge	Four Flex cartridges 20 tests per cartridge
DC207	Dimension® TAC Calibrator (5 levels)	Level 1: 2 x 2 mL Levels 2–5: 2 x 1 mL

References

1. Therapeutic Drug Monitoring. 2009 Apr;31(2):139-52.
2. The range of LC-MS/MS tacrolimus values in the correlation study was 1.3 to 24.9 ng/mL (1.7 to 32.4 nmol/L). The number of individual patients (adults 21 to 81 years old) represented in the above method comparisons for each organ transplant group were 99 (renal) and 102 (hepatic).
3. The range of ARCHITECT tacrolimus values in the correlation study was 2.1 to 24.2 ng/mL (2.7 to 31.5 nmol/L).

Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

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