



Thermo Scientific Indiko
Immunosuppressant Drug Testing

Complete solutions for patient monitoring

Thermo Scientific Indiko is an easy to use, cost-effective system designed for load-up and walk-away convenience.



Thermo Scientific Indiko

Immunosuppressant drug testing

One of the most effective therapies for patients with end-stage organ failure is solid organ transplantation. Typically, one or more immunosuppressive drugs (ISD) are used to prevent rejection of transplanted organs and tissues. Periodic measurements of a drug's concentrations are performed to allow physicians to make adjustments to the patient's drug therapy, ensuring long-term success. Immunosuppressant drug monitoring can be done by several methods; the most common is immunoassay.

Thermo Fisher Scientific offers the most comprehensive menu of Immunosuppressant Drug Monitoring assays which are recognized worldwide for their ease-of-use, quality, performance, and lot-to-lot consistency.

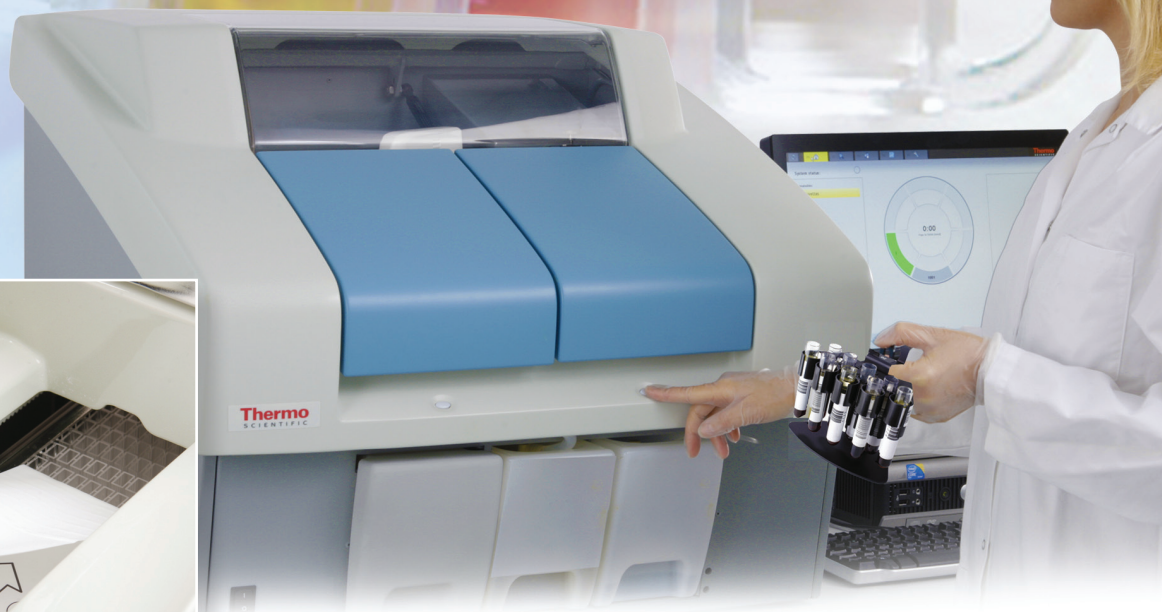
- Full ISD menu on a single analyzer
- Convenient on-site testing
- Improved laboratory efficiency and turnaround time
- Flexibility in instrument placement

Thermo Scientific Indiko analyzer and immunosuppressant drug monitoring

Thermo Scientific™ Indiko, together with a complete menu of immunosuppressant drug monitoring assays, provides an excellent solution for patient monitoring. Indiko allows for patient testing at a monitoring site, therefore improving turnaround time and enabling doctors to make critical decisions sooner. The Indiko benchtop analyzer also provides a single platform solution for all Thermo Scientific™ ISD immunoassays, improving laboratory efficiency. The continuous access allows for samples and reagents to be added without interrupting the testing process.

Description	Sample Type
CEDIA® Cyclosporine PLUS Assay	Whole blood
CEDIA Tacrolimus Assay	Whole blood
CEDIA Mycophenolic Acid Assay	Plasma
QMS® Everolimus Assay	Whole blood

The compact Indiko requires very little space



Indiko is a fully automated bench top analyzer for clinical and specialty testing

Indiko is an easy to use, cost-effective system designed for load-up and walk-away convenience. Intuitive user interface and many automated features help to manage the daily workflow. The self-contained Indiko, with its small footprint, fits ideally to laboratory space limitations.

Flexible, easy operation

- Intuitive user interface with touch-screen option
- Streamlined information management with various reporting options, and advanced result inventory management
- A mix of sample cups and bar-coded primary tubes can be used
- Automatic start-up protocol
- Loadable application data and calibrator and control values

True walk-away analysis

- Different sample types can be analyzed at the same time
- Real-time QC program with multiple Westgard rules
- Continuous access to samples, reagents and cuvettes without interrupting the testing process
- Up to two hours walk-away time

Cost-effective solution

- Unique, low-volume cuvette technology
- Very low volume of samples (2 to 120uL) and reagents (2 to 240uL) result in overall low waste
- Real-time QC program assures reliable performance
- Minimal daily maintenance maximizes analyzer uptime
- Water consumption: 1.5 liter/hour

Thermo Scientific CEDIA Cyclosporine PLUS Assay



Accurate: Lot-to-lot consistency

Efficient: Two-point calibration curve

Convenient: Both high and low range assays use same reagents

Rapid: Single lysing step sample preparation

Limit of Quantitation (LOQ): Limit of Quantitation is 25 ng/mL

Reportable Range: 25 to 2000 ng/mL

Precision: N=80

Sample	Mean (ng/mL)	Within-Run		Total	
		SD (ng/mL)	% CV	SD (ng/mL)	% CV
Control 1	84.8	4.1	4.8	6.2	7.3
Control 2	186.4	4.1	2.2	10.0	5.4
Control 3	319.7	5.9	1.8	13.2	4.1
Control 4	744.3	20.0	2.7	34.4	4.6
Control 5	1508.4	20.7	1.4	57.3	3.8

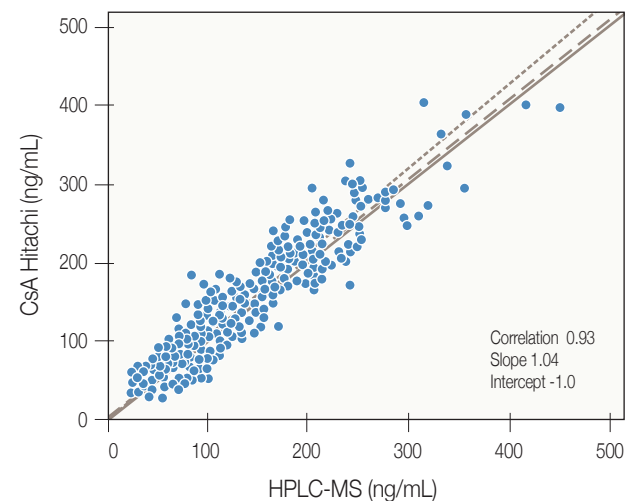
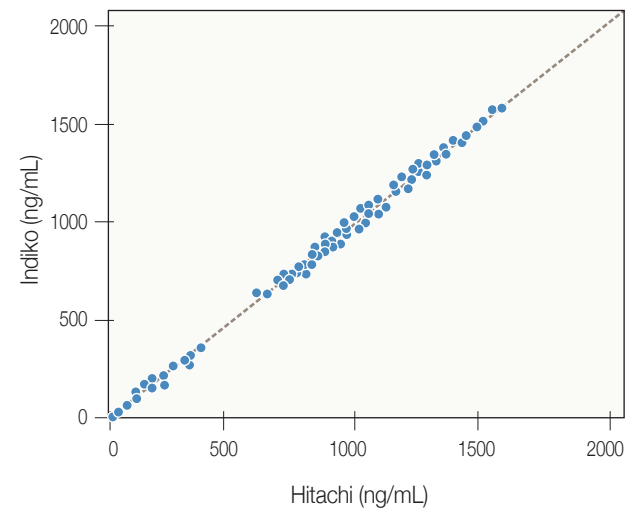
Ordering:

Item Number	Description	Format
100147	CEDIA® Cyclosporine PLUS Assay includes Low Range Calibrators A & B	R1 41 mL, R2 19 mL 1 vial, 2 mL each level
100012	CEDIA Cyclosporine PLUS High Range Calibrator Kit	2 levels, 4 mL 2 vials each
100207	Cyclosporine High Range Control Level 4	2 mL, 6 vials, diluent 8 mL, 2 vials
100208	Cyclosporine High Range Control Level 5	2 mL, 6 vials, diluent 8 mL, 2 vials
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

Method Comparison

115 samples (LR) and 148 samples (HR) were run on the Indiko application analyzer and the reference analyzer (Hitachi). Deming's regression was performed on the data.

	Low-Range Performance	High-Range Performance
Slope	1.01	1.00
Correlation	0.99	0.995
Intercept	-2.60	-1.80



Thermo Scientific CEDIA Tacrolimus Immunoassay



Accurate: Correlates well with gold standard methods

Efficient: Two-point linear calibration

Convenient: Mix and Run reagent systems, controls available

Limit of Quantitation: (LOQ): 2 ng/mL

Reportable Range: 2 to 30 ng/mL

Precision: N=80

Sample	Within-Run			Total	
	Mean (ng/mL)	SD (ng/mL)	%CV	SD (ng/mL)	%CV
Control 1	6.98	0.47	6.8	1.37	19.6
Control 2	13.50	0.75	5.5	1.39	10.3
Control 3	19.92	1.02	5.1	1.80	9.0

Ordering:

Item Number	Description	Format
10008656	CEDIA® Tacrolimus Assay	R1 26 mL, R2 11mL
10008666	CEDIA Tacrolimus Calibrator Set	2 levels, 2 vials each LR 4mL, HR 2 mL 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

Method Comparison

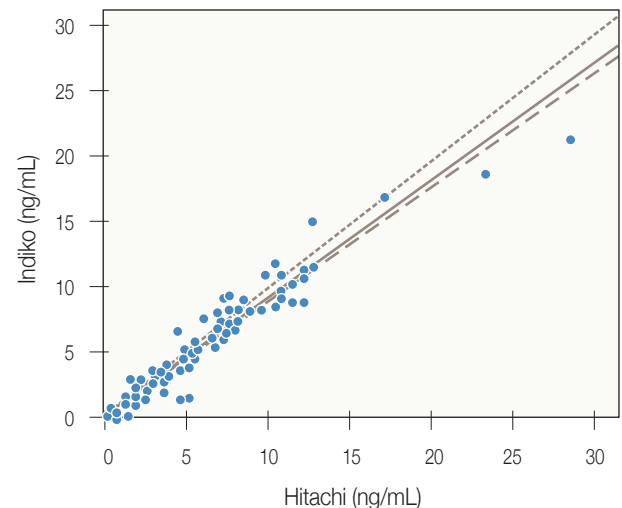
A comparison was performed between the CEDIA Tacrolimus Assay and LC-MS/MS. This method comparison was performed using samples (concentrations range from 0 to 30 ng/mL tacrolimus) obtained from liver and renal transplant patients.

Regression

A comparison of data between Hitachi and LC-MS/MS.

CEDIA vs.	Transplant Type	N	Slope	Intercept	Correlation (r)
LC-MS/MS	Kidney & Liver	187	1.19	0.70	0.964
LC-MS/MS	Kidney	118	1.157	2.02	0.978
LC-MS/MS	Liver	69	1.193	2.04	0.962

Deming's regression of the correlation the Indiko to the Hitachi yields slope and intercept of 0.92+0.2 and r=0.962,



Thermo Scientific CEDIA Mycophenolic Acid (MPA) Immunoassay



Accurate: Correlates well with gold standard methods

Efficient: Two-point linear calibration

Rapid: No extraction step

Limit Of Quantitation (LOQ): 0.3 µg/mL

Reportable Range: 0.3 to 10 µg/mL

Precision: N=80

Sample	Mean (µg/mL)	Within-Run		Total	
		SD (µg/mL)	%CV	SD (µg/mL)	%CV
Control 1	0.875	0.045	5.1	0.071	8.1
Control 2	2.840	0.055	1.9	0.083	2.9
Control 3	6.550	0.112	1.7	0.188	2.9

Ordering:

Item Number	Description	Format
100276	CEDIA® Mycophenolic Acid Assay	R1 26 mL, R2 11 mL
100277	CEDIA Mycophenolic Acid Calibrator Set	2 levels, 5.0 mL 2 vials each
100278	MAS® Mycophenolic Acid Control 1 Kit	1 level, 5.0 mL 4 vials each
100279	MAS Mycophenolic Acid Control 2 Kit	1 level, 5.0 mL 4 vials each
100280	MAS Mycophenolic Acid Control 3 Kit	1 level, 5.0 mL 4 vials each

Method Comparison

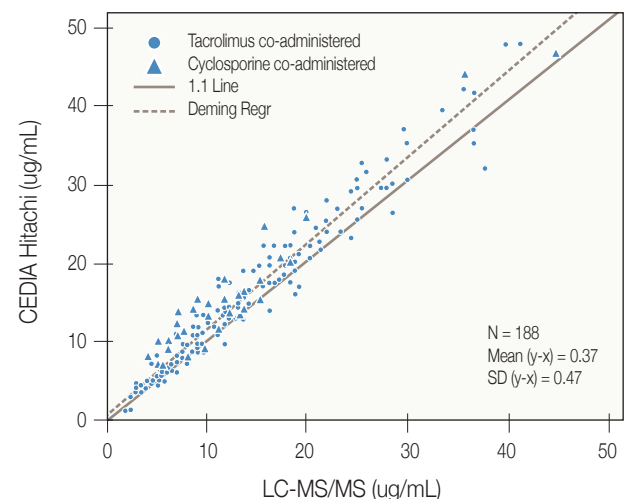
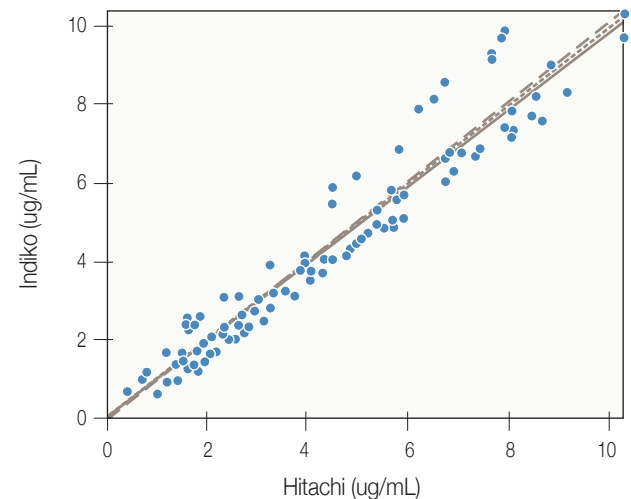
115 samples were run on the application analyzer (Thermo Scientific Indiko Analyzer) and the reference analyzer (Hitachi). Deming's regression was performed on the data.

Regression

A comparison of data between Hitachi and LC-MS/MS.

Sample	N	Regression Method				r
		Least Square		Deming		
		Slope	Intercept	Slope	Intercept	
Heart	96	1.114 (1.061 to 1.166)	0.20 (0.05 to 0.36)	1.147 (1.094 to 1.200)	0.12 (-0.04 to 0.28)	0.974
Kidney	92	1.027 (0.974 to 1.080)	0.16 (-0.03 to 0.36)	1.060 (1.006 to 1.113)	0.06 (-0.13 to 0.25)	0.971
All	188	1.054 (1.015 to 1.092)	0.22 (0.09 to 0.34)	1.089 (1.051 to 1.128)	0.12 (-0.01 to 0.25)	0.969

Deming's regression of the correlation the Indiko to the Hitachi yields slope and intercept of 1.02-0.01 and r=0.97,



Thermo Scientific QMS Everolimus Immunoassay



Accurate: Correlates well with gold standard methods

Efficient: Excellent accuracy across assay range

Rapid: Quick turn-around-time

Limit Of Quantitation (LOQ): 2 ng/mL

Reportable Range: 2 to 20 ng/mL

Precision: N=80

Sample	Mean (ng/mL)	Within-Run		Total	
		SD (ng/mL)	%CV	SD (ng/mL)	%CV
Control 1	4.56	0.2	4.6	0.3	7.3
Control 2	8.67	0.3	2.9	0.4	5.0
Control 3	14.72	0.5	3.5	0.7	5.1

Ordering: for IVD use

Item Number	Description	Format
380000	QMS [®] Everolimus Assay	R1 22 mL, R2 8 mL
380005	QMS Everolimus Calibrator Set	6 levels, 3 mL 1 vial each
380010	QMS Everolimus Control Set	3 levels 3 mL 1 vial each

Ordering: for use in European Union

Item Number	Description	Format
373852	QMS Everolimus Assay*	R1 22 mL, R2 8 mL
373860	QMS Everolimus Calibrator Set	6 levels, 3 mL 1 vial each
373878	QMS Everolimus Control Set	3 levels 3 mL 1 vial each

* not available in US

Method Comparison

102 blood samples were assayed with the QMS Everolimus Assay on the Thermo Scientific Indiko and tested with reference method Hitachi. Passing-Bablok regression was performed on the data.

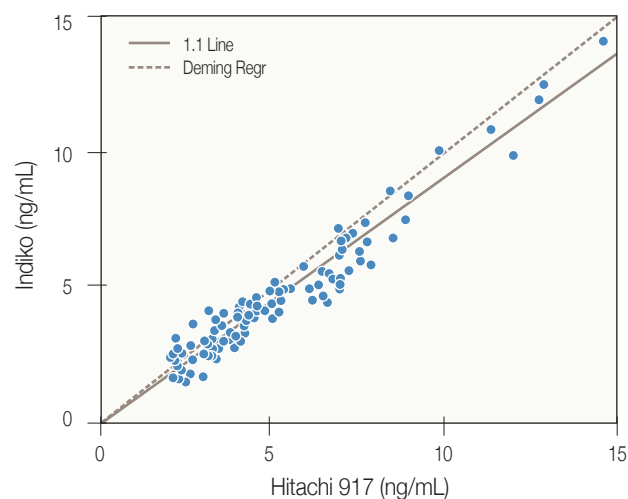
Regression

A comparison of data between Hitachi and LC-MS/MS.

Method	N	Regression Method				r	S y/x (ng/mL)
		Deming		Passing-Bablok			
		Slope (95% CI)	Intercept (95% CI)	Slope (95% CI)	Intercept (95% CI)		
QMS vs. System 1*	124	0.93 (0.87 to 0.98)	0.03 (-0.41 to 0.46)	0.92 (0.87 to 0.98)	0.17 (-0.15 to 0.54)	0.94	0.95
QMS vs. System 2*	124	1.00 (0.95 to 1.06)	-0.08 (-0.48 to 0.33)	1.01 (0.95 to 1.08)	-0.15 (-0.50 to 0.17)	0.95	0.88

* System 1 and System 2 refer to two LC-MS/MS Systems

Passing Bablok regression of the correlation the Indiko to the Hitachi yields slope and intercept of 0.91-0.07 and r=0.97.



Thermo Scientific Indiko

Instrument Specifications

Capacity	Up to 200 tests per hour for 1 reagent assays, approximately 100 tests per hour for 2 reagent assays
Dimensions & Weight	29.5 in / 75 cm (W) x 27.6 in / 70 cm (D) x 24.4 in / 62 cm (H), 51 in / 130 cm (H) with cover open, 187 lbs / 85 kg
Power Supply	100 - 240 V \pm 10%, 50 - 60 Hz, \pm 5%, 250 W
Average Noise Level at 1 meter	< 60 dB (A)
Dionized Water Consumption	1.5 liters/hour
Environmental Conditions	Operating temperature range 18 to 30 °C, humidity 40 - 80% (non condensing)
Regulatory	Confirms with CAN/CSA-C22.2 No. 61010-1-04 FDA clearance, 510(k) number: k110035 (Indiko 98360000) 98/79/EC IVD MD Directive
Filter Rate	340 - 700 nm
Measurement Temperature	37 °C
Light Source	Flash Lamp
Absorbance Range	0 - 3.5 A, resolution of 0.001 A and reproducibility of SD <0.005A at 2A

Reaction Vessels

On-board Capacity	360 measurement cells - 36 cuvettes with 10 reaction cells each, up to 2 hour walk-away time
Reaction End Volume	120 - 300 μ L

Samples & Reagents

On-board Capacity	Maximum 6 racks - 9-position sample rack or 6-position reagent rack in disk cooled about 8 °C below ambient temperature
Sample Volume Size	2 - 120 μ L
Sample Containers	0.5 mL, 2.0 mL cups and sample tubes (diameter 12 - 16 mm, length 75 - 100 mm)
Sample Barcode	Code 128 and barcodes USS Codabar, Interleaved 2 of 5 and Code 39 with a check digit
Reagent Volumes	2- 240 μ L
Reagent Containers	10 mL and 20 mL vials
Sample & Reagent Dispensing	CV \leq 2% for volumes \geq 2 μ L
Calibration	Factor, Bias, linear, logit-log, spline, polynomial and point-to-point calibration
Data Management	Windows® workstation - data input online, via mouse, keyboard, barcode reader, and touch screen (optional)

Consumable Ordering Information

Part Number	Description	Kit Configuration
986000	TENCELL cuvettes	1 box (10,800pcs)
989220	0.5 mL sample cups	1000 pcs
989221	2 mL sample cups	1000 pcs
984050	10 mL reagent bottles	5 pcs
981456	20 mL reagent bottles	16 pcs
SPO6662	Reagent rack	3 pcs
SPO6666	Sample rack	6 pcs
984030	Washing solution 4.5%	4 x 20 mL
981712	Tubing maintenance solution	6 x 20 mL

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