

thermoscientific



Assays for therapeutic drug monitoring

Broad menu of antibiotics, antiepileptics, antiarrhythmics, and more - designed for precise, reliable performance

ThermoFisher
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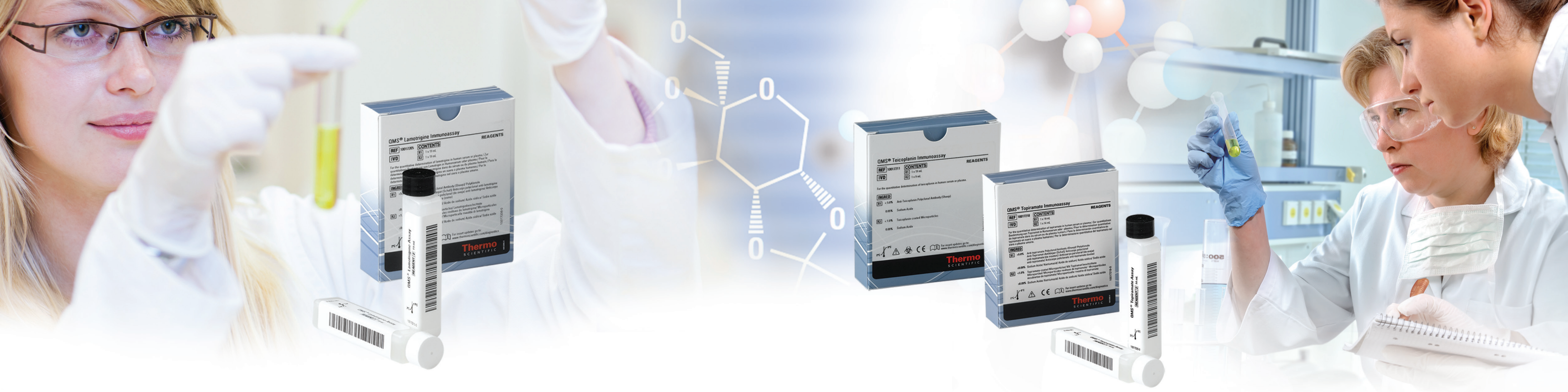
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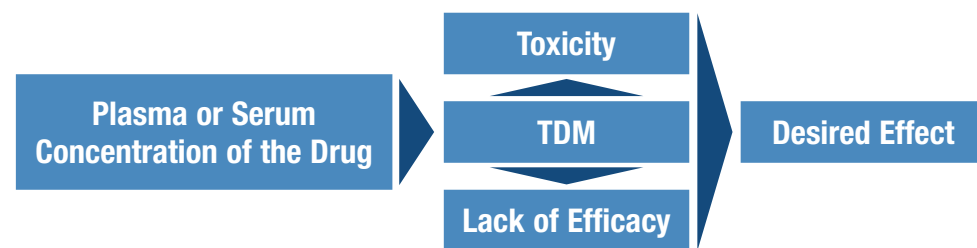


Complete solutions: Monitoring to management

We provide a broad range of therapeutic drug monitoring (TDM) assays, including an extensive menu of assays for Antibiotics, Antiepileptics, Antiarrhythmics, plus Bronchodilator, and Endocrine assays. These assays provide excellent accuracy, precision, sensitivity and specificity. Applications are available on a range of clinical and specialty chemistry analyzers and for most major laboratory instrumentation.

What are TDMs and what is their role in patient health?

TDM tests provide quantitative results to ensure beneficial therapeutic effects by determining the drug concentration in blood. Administering a higher drug dose can lead to toxicity, while a lower dose can lead to lack of efficacy. Additionally, individual patient factors such as age, ethnicity, metabolism, and history can affect drug performance. TDM assays aid physicians in determining the optimal drug dosage for an individual patient, by monitoring serum or plasma drug concentrations to ensure effectiveness and patient compliance.



Jain, K.K., Therapeutic Drug Monitoring Technologies, Companies and Markets, Jain PharmaBiotech, Basel, Switzerland, Tech Report, p.14. February 2012.

Antibiotics

Optimize patient dosages with Thermo Scientific™ Antibiotic Assays

Antibiotic TDM assays are used in life threatening infections, where serious side-effects can occur if the drug concentration exceeds the therapeutic range. Patients are often hepatically or renally impaired, causing the metabolism and clearance of the drug to be unpredictable. Therefore monitoring patients for these antibiotics is extremely important.

- Liquid, ready to use reagents
- Exclusive Thermo Scientific™ QMS™ Teicoplanin Immunoassay for Outside United States (OUS)
- Full range of assays for worldwide use
- Accurate and precise

Antibiotics Product Performance

	Assay Range µg/mL	Total Precision, %CV			Method Comparison			
		Low	Medium	High	Comparison Method	Slope	Intercept	Correlation Coefficient
Amikacin	1.5 – 50	9.9	6.2	6.3	FPIA**	1.00	0.25	0.992
Gentamicin (CEDIA)	0.24 – 12	6.2	4.1	3.0	FPIA	1.04	-0.08	0.993
Gentamicin (QMS)	0.3 – 10	3.9	3.6	2.8	FPIA	1.02	0.41	0.997
Teicoplanin*	3 – 50	5.8	4.8	5.0	FPIA	0.93	0.29	0.980
Tobramycin	0.4 – 10	7.6	4.2	4.3	FPIA	0.98	-0.09	0.984
Vancomycin	2.5 – 100	8.8	6.2	5.1	FPIA	1.03	1.12	0.970

*Teicoplanin is not available for sale in the US.
**FPIA: Fluorescence polarization immunoassay



Antiarrhythmics

Sensitive, reliable assays are the cornerstone of the Thermo Scientific Antiarrhythmics Assays

Antiarrhythmics drugs are used in the treatment of cardiac arrhythmias. Each TDM test is used to monitor patients to ensure they are receiving the optimal dosage to prevent any toxic adverse effects.

- Easy to use assays
- Long shelf life ranging from one to three years
- Excellent correlation to reference methods

Antiarrhythmics Product Performance

	Assay Range	Total Precision, %CV			Method Comparison			
		Low	Medium	High	Comparison Method	Slope	Intercept	Correlation Coefficient
Digoxin	0.5 – 5 ng/mL	12.0	3.3	2.4	FPIA**	1.00	0.01	0.970
Digitoxin	3.0 – 50 ng/mL	11.8	8.8	3.1	FPIA	1.04	-1.22	0.950
Lidocaine	0.8 – 10 µg/mL	8.1	5.1	5.3	FPIA	1.08	-0.10	0.986
NAPA	0.6 – 30 µg/mL	7.4	4.1	2.9	FPIA	1.04	0.18	0.994
Procainimide	0.4 – 20 µg/mL	3.1	3.0	2.8	FPIA	1.04	-0.01	0.991
Quinidine	0.2 – 8.0 µg/mL	9.1	6.4	5.8	FPIA	1.06	-0.21	0.978

Theophylline is a bronchodilator used in the treatment of asthma, obstructive lung disease, and neonatal apnea. The Thermo Scientific™ CEDIA™ Theophylline II assay has a proven track record providing consistent, reliable results that you can count on.

Bronchodilator Product Performance

	Assay Range µg/mL	Total Precision, %CV			Method Comparison			
		Low	Medium	High	Comparison Method	Slope	Intercept	Correlation Coefficient
Theophylline	0.8 – 40	5.1	2.4	2.0	FPIA	1.01	-0.41	0.997

**FPIA: Fluorescence polarization immunoassay

Antiepileptics

Ensure outstanding levels of performance with Thermo Scientific Antiepileptic Assays

Antiepileptic drugs (AED) are commonly used to treat seizures and are the most frequently monitored class of drug. Like many therapeutic drugs, antiepileptics are often monitored for dosage within a narrow therapeutic range, patient compliance, and challenging pharmacokinetics. Thermo Fisher Scientific offers one of the most comprehensive menus of AED TDM assays, including many of the newer generation drugs.

- Test menu includes traditional and second generation AEDs
- Reagents optimized for long shelf life and lot-to-lot consistency
- Sensitive and specific tests help provide accurate results

Antiepileptics Product Performance

	Assay Range µg/mL	Total Precision, %CV			Method Comparison			
		Low	Medium	High	Comparison Method	Slope	Intercept	Correlation Coefficient
Carbamazepine	0.5 – 20	3.5	2.0	1.7	FPIA**	1.00	0.87	0.986
Lamotrigine	2.0 – 40	2.8	2.0	2.4	HPLC	1.03	0.11	0.960
Phenobarbital	1.2 – 80	5.3	3.8	3.6	FPIA	1.08	-2.01	0.988
Phenytoin*	0.6 – 40	5.1	3.1	2.3	FPIA	1.00	-0.19	0.998
Topiramate	1.5 – 32	4.2	3.4	4.4	FPIA	0.96	0.23	0.986
Valproic Acid	3 – 150	3.4	2.0	1.8	FPIA	1.08	-0.61	0.972
Zonisamide	3 – 50	8.3	7.9	7.5	HPLC	0.92	1.67	0.910

*Run-to Run precision listed

**FPIA: Fluorescence polarization immunoassay



MAS Quality Controls

Thermo Scientific™ MAS™ third party quality controls are available for the TDM assays and provide an unbiased and independent assessment of the laboratory's testing system. We are simplifying QC by providing:

- Products that are liquid, ready to use
- Target levels optimized for all key analytes
- Consolidated multi-constituent controls
- Thermo Scientific™ LabLink xL™, an easy to use, real-time, web-based quality assurance program

MAS™ Liquimmune™ Controls

Save time and extra costs associated with lot changes by using MAS Liquimmune controls with 60-month shelf life at -25° to -15° C and 30-day open vial stability at 2 – 8° C. This multi-analyte immunoassay control uses a human serum matrix and is designed to monitor immunoassay test procedures on automated instruments. It covers all of our TDM assays as well as fertility, thyroid, iron deficiency, endocrine, and allergy parameters. Assayed values are supplied for most major analyzers. The control is available in three distinct levels, each which can be ordered separately.

Part Number	Description	Kit Size
LIG-101	MAS Liquimmune Level 1	6 x 5 mL
LIG-202	MAS Liquimmune Level 2	6 x 5 mL
LIG-303	MAS Liquimmune Level 3	6 x 5 mL

Analytes

17-a-OH-Progesterone	DHEA-Sulfate	Human Chorionic Gonadotropin (beta-hCG)	Lithium	Prostate Specific Antigen, Total (TPSA)	Thyroxine, Total (TT4)
Acetaminophen	Digoxin	Human Chorionic Gonadotropin (hCG)	Luteinizing Hormone (LH)	Total (TPSA)	Tobramycin
Aldosterone	Disopyramide	Human Growth Hormone	N-acetylprocainamide (NAPA)	Quinidine	Tricyclic Antidepressants
Alpha-Fetoprotein (AFP)	Estradiol	Immunoglobulin A (IgA)*	Phenobarbital	Salicylate	Triiodothyronine, Free (FT3)
Amikacin	Ethosuximide	Immunoglobulin E (IgE)	Phenytoin	Testosterone	Triiodothyronine, Total (TT3)
Carbamazepine	Ferritin	Immunoglobulin G (IgG)*	Primidone	Theophylline	Valproic Acid
Carcinoembryonic Antigen (CEA)	Folate	Immunoglobulin M (IgM)*	Procainamide	Thyroglobulin	Vancomycin
CK-MB (activity)	Follicle Stimulating Hormone (FSH)	Insulin	Progesterone	Thyroid Stimulating Hormone (TSH)	Vitamin B12
CK-MB (mass)	Gentamicin	Lidocaine	Prolactin	Thyroid Uptake (T-Uptake)	
Cortisol	Homocysteine		Prostate Specific Antigen, Free (FPSA)	Thyroxine, Free (FT4)	

*These constituent levels have not been adjusted but are at levels found in the source material used in preparation of the controls. No claim is made for expected values of these constituents.



MAS PAR TDM Controls

MAS Par TDM is a multi-constituent, assayed TDM control designed for use on automated analyzers. It is liquid, ready-to-use, and available in three distinct levels. Each level can be ordered separately.

Part Number	Description	Kit Size	Analytes
PTD1-1001	Par TDM Level 1	6 x 5 mL	Acetaminophen, Amikacin, Caffeine, Carbamazepine, Digoxin, Disopyramide, Ethanol, Ethosuximide, Gentamicin
PTD2-2002	Par TDM Level 2	6 x 5 mL	Lidocaine, Lithium, Methotrexate, N-acetylprocainamide (NAPA), Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine
PTD3-3003	Par TDM Level 3	6 x 5 mL	Salicylate, Theophylline, Thyroid Stimulating Hormone (TSH), Thyroxine, Total (TT4), Tobramycin, Tricyclic Antidepressants, Triiodothyronine, Total (TT3), Valproic Acid, Vancomycin

QMS TDM Specialty Controls

These specialty controls are liquid, ready-to-use, human serum controls with low, medium, and high ranges of the analytes. The controls come in kits containing three levels.

Part Number	Description	Kit Size
0374090	Lamotrigine Control Set	3 levels 1 x 2.5 mL each
0374660	Teicoplanin Control Set*	3 levels 1 x 2.0 mL each
0374181	Topiramate Control Set	3 levels 1 x 2.0 mL each
0373373	Zonisamide Control Set	3 levels 1 x 2.0 mL each

*Teicoplanin is not available for sale in the US.

Alternative controls for our TDM analytes are also include MAS™ chemTRAK•HT™ and MAS™ Omni•Immune™. Please refer to our catalog or thermofisher.com/qc for a complete listing of controls.



Thermo Scientific Complete Solutions for Therapeutic Drug Monitoring

Assay Type	Assay Name	Technology	Reagent Part Number	Calibrator Part Number	Control Part Number
Antibiotic	Amikacin	QMS	0373910	0374157	LIG-101
					LIG-202
					LIG-303
Antibiotic	Gentamicin	CEDIA QMS	100016 10014390	100017 0373902	LIG-101
					LIG-202
					LIG-303
Antibiotic	Teicoplanin*	QMS	0374645	0374652	0374660
Antibiotic	Tobramycin	QMS	10017109	0374116	LIG-101
					LIG-202
					LIG-303
Antibiotic	Vancomycin	QMS	0373589	0373597	LIG-101
					LIG-202
					LIG-303
Antiepileptic	Carbamazepine	CEDIA	100006	100007	LIG-101
					LIG-202
					LIG-303
Antiepileptic	Lamotrigine	QMS	0373795	0373787	0374090
Antiepileptic	Phenobarbital	CEDIA	100003	100007	LIG-101
					LIG-202
					LIG-303
Antiepileptic	Phenytoin	CEDIA	100002	100007	LIG-101
					LIG-202
					LIG-303
Antiepileptic	Topiramate	QMS	0374140	0374173	0374181

Assay Type	Assay Name	Technology	Reagent Part Number	Calibrator Part Number	Control Part Number
Antiepileptic	Valproic Acid	CEDIA	100013	100007	LIG-101
					LIG-202
					LIG-303
Antiepileptic	Zonisamide	QMS	0373571	0373381	0373373
Antiarrhythmics	Digoxin	DRI	1669	included in kit	LIG-101
					LIG-202
					LIG-303
Antiarrhythmics	Digitoxin	CEDIA	100004	included in kit	LIG-101
					LIG-202
					LIG-303
Antiarrhythmics	Lidocaine	QMS	0374686	0374678	LIG-101
					LIG-202
					LIG-303
Antiarrhythmics	N-Acetylprocainamide (NAPA)	CEDIA	100015	100001	LIG-101
					LIG-202
					LIG-303
Antiarrhythmics	Procainamide	CEDIA	100014	100001	LIG-101 LIG-202 LIG-303
Antiarrhythmics	Quinidine	QMS	0373936	0374165	LIG-101
					LIG-202
					LIG-303
Bronchodilator	Theophylline	CEDIA	100008	100007	LIG-101 LIG-202 LIG-303

*Teicoplanin is not available for sale in the US.



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