

One Resource

Multiple technologies







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The value of innovation

An enduring history of serving science

From routine chemistries to highly sensitive tests that will enable the discovery of new biomarkers for disease diagnosis, 21st Century immunoassay techniques are built on the foundation of the radio-immunoassay (RIA). This revolutionary concept was developed for measurement of endogenous plasma insulin by Solomon Berson and Rosalyn Yalow in 1959. Working together as a team, these two scientists proposed the use of the interaction between antibodies and antigens to detect the presence or quantify the concentration of specific analytes in human body fluids. An isotope of a radioactive element was used to label antibodies and antigens.

Researchers and clinicians worldwide soon began to recognize the exciting potential of this breakthrough technique and numerous laboratories were built and equipped to conduct tests that required the use of radioisotopes. As the technology was fine-tuned, RIAs for many new analytes were published.

Although the RIA technique was valued for its sensitivity and specificity, there was growing concern about workplace safety, the expense of the equipment required for handling radioactive materials and the ability to properly dispose of radioactive waste.



The limitations of the RIA combined with continued innovation in biomedical research created the perfect environment to take immunoassays in a new direction. The Enzyme Immunoassay (EIA) and the Enzyme-Linked Immunosorbent Assay (ELISA) were envisioned in the 1960s, but it took almost a decade for researchers to demonstrate conclusively that the EIA/ELISA was the next step in building a new generation in immunoassays. These techniques replaced radioisotopes with enzymes in the labeling of antigens and antibodies which could then be detected by spectrophotometric means. The first tests were not as precise and sensitive as the RIA; however, improvements in techniques accelerated during the 1970s.

Today Thermo Scientific™ CEDIA technology is the platform supporting a broad menu of immunoassays for drugs of abuse screening, therapeutic and immunosuppressant drug monitoring and toxicology testing.

Cloned Enzyme Donor Immunoassay technology (CEDIA®) was developed by Microgenics (Thermo Fisher Scientific) in the early 1980s. This homogeneous enzyme immunoassay has proven to be one of the important advancements in the

evolution of immunoassays, enabling the automation of the immunoassay test and facilitating its transition from speciality laboratories to general labs and clinical settings. Today CEDIA technology is the platform supporting a broad menu of immunoassays.

Thermo Fisher Scientific continues to forge the way with new immunoassays for drugs of abuse screening and therapeutic drug monitoring.

The full potential of the homogeneous enzyme immunoassay is just beginning to be explored. Thermo Fisher Scientific continues to forge the way with new immunoassays for drugs of abuse screening and therapeutic drug monitoring that provide customized solutions for large reference and hospital-based laboratories as well as a growing list of non-traditional testing venues such as the workplace, government institutions, drug detection and treatment programs, and physician offices and clinics.





We never forget

That behind every assay performed is a story

During the mid 1990s, Thermo Fisher Scientific introduced its DRI® product line. The marketplace reception to these liquid, ready-to-use assays was unparalleled. Increased lab productivity, low cost per test and short turnaround times without sacrificing precision, accuracy and lot-to-lot consistency were right on target with clinical laboratory needs. More recently, we have strengthened our technological leadership with the introduction of the Quantitative Microsphere System (QMS). Our cutting edge Thermo Scientific™ QMS® assays are the culmination of more than two decades of research and development in the application of microparticle technology to immunodiagnostics.

The QMS method employs advanced particle technology to develop a wide range of particle-enhanced turbidimetric immunoassays for use on automated chemistry analyzers.

Around the world thousands of Thermo Scientific assays are loaded every day on a wide range of testing platforms.

At Thermo Fisher Scientific, we have been at the forefront of enzyme-based turbidimetric immunoassay evolution for more than three decades. The spectrum of our integrated products and services offers both breadth and depth in the areas of drugs of abuse, specimen validity testing and toxicology testing; therapeutic and immunosuppressive drug monitoring; and quality control and data management.

The synergy of multiple technologies, a robust menu of homogenous enzyme immunoassays optimized for most clinical chemistry analyzers and the global reach of our customer-responsive training and product support has made Thermo Scientific products the preferred resource for reference and hospital laboratories and other drug monitoring facilities.

That's why our research and development endeavors are driven by a sense of urgency and guided by the spirit of innovation.

Around the world thousands of Thermo Scientific assays are loaded every day on a wide range of testing platforms. While we are proud of the trust our customers have placed in us we never lose sight of the fact that behind every assay performed is a story — men, women and children facing challenges and uncertainty with hope for a healthier future. That's why our research and development endeavors are driven by a sense of urgency and guided by the spirit of innovation.





One Resource

Multiple Technologies

CEDIA

Thermo ScientificTM CEDIATM method is a single phase, competitive binding process that combines analyte-specific antibodies and two genetically engineered fragments of the bacterial enzyme β-galactosidase to accurately and reliably detect the presence of drugs and their metabolites as well as other substances in serum, plasma, whole blood, urine and oral fluids.

Benefits

- Guaranteed consistency: kit-to-kit, lot-to-lot, year-to-year
- Lower limits of detection of analytes in test matrix
- Linear dose response curve

- Accurate and specific results
- Excellent low-end sensitivity and specificity
- Urine, oral fluids, serum, plasma and whole blood

DRI

Thermo Scientific[™] DRI[™] products are proven and trusted testing solutions that offer high analytical accuracy while eliminating time-consuming steps in reagent preparation.

DRI technology is based on the competition between a drug or drug metabolite labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) and free drug from the sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds to the drug labeled with G6PDH. As a result, enzyme activity is inhibited.

Benefits

- Applications for low, medium and high volume laboratories
- Assays optimized for most clinical chemistry analyzers
- Minimizes unnecessary confirmations

- Accurate and specific results
- Excellent low-end sensitivity and specificity
- Guaranteed consistency: kit-to-kit, lot-to-lot, year-to-year

QMS

Thermo Scientific™ QMS™ (Quantitative Microsphere System) assays are particularly well suited to measuring therapeutic drugs in whole blood, serum or plasma.

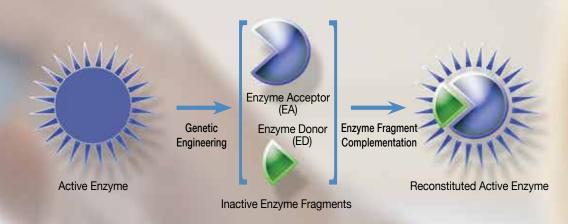
Our QMS two component assay system is based on the competitive inhibition immunoassay principle: If the drug targeted by the assay is present in the sample, these free drug molecules compete with a microparticle-bound drug in one reagent for a limited number of antibody combining sites supplied by antibody in a second reagent. The competition for antibody binding sites inhibits the ability of the antibody to agglutinate the drug-coated microparticles.

Benefits

- Excellent sensitivity and precision
- Optimal dynamic range
- High specificity and accuracy to target analyte
- Does not involve enzymes and chemical substrates
- Low interference from endogenous substances
- Whole blood, serum and plasma

Complete solutions

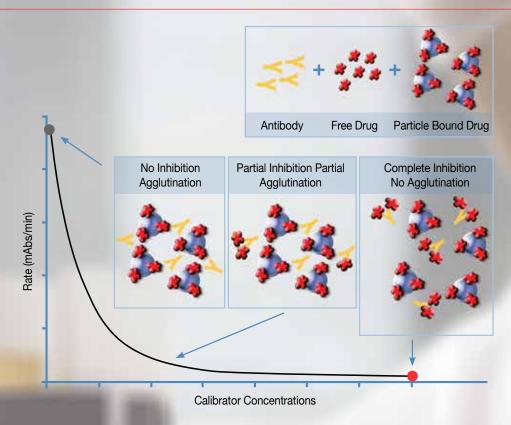
for drug monitoring

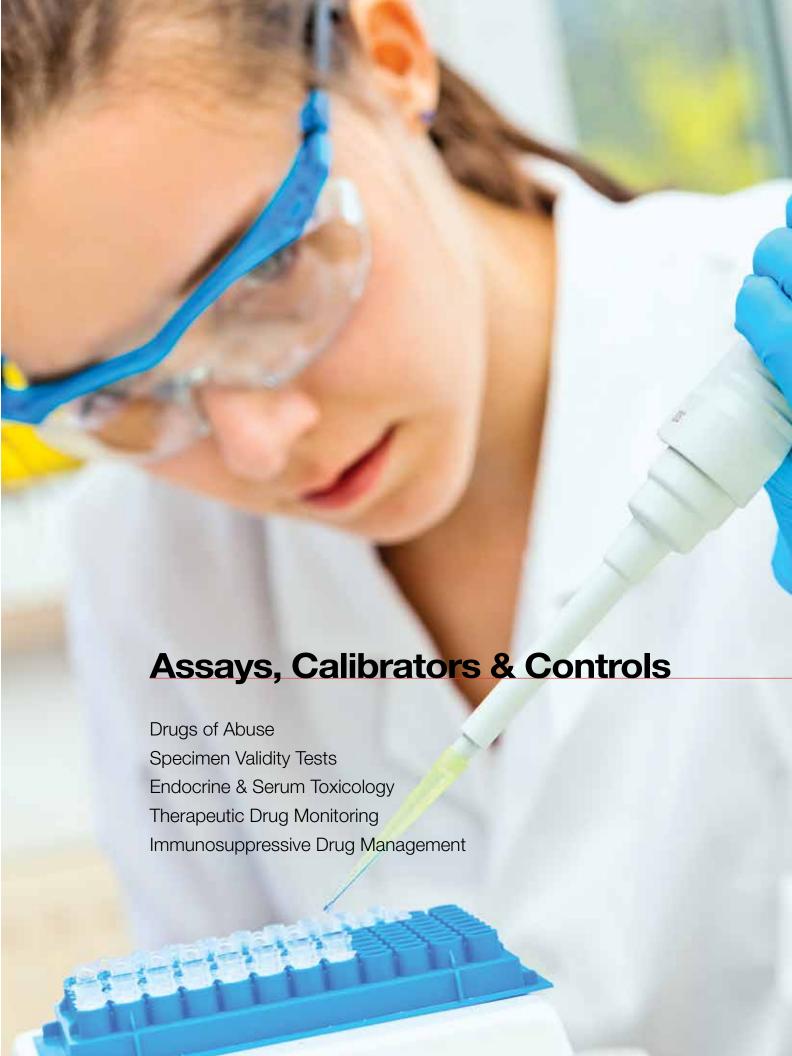


CEDIA Technology: genetic engineering of enzyme fragments.



DRI Technology
G6PDH in the presence of Cofactor and Substrate forms NADH.
The NADH absorbs light at 340 nm.







Product		CEDIA		DRI			
Troudot	TSC 3 x 17 mL	MCC 65 mL	LC 495 mL	68 mL	100 mL	500 mL	
Amphetamine					0017	0018	
Amphetamine/Ecstasy	100104	100103	100040				
Barbiturate	100084	100093	1661213		0225	0226	
Benzodiazepine	100085	100094	1775561		0039	0040	
Buprenorphine	100190	100240					
Cocaine	100086	100095	1661230		0055	0056	
Cotinine					0394	0395	
Ecstasy					100075	100076	
Ethyl Alcohol					0037	0038	
Ethyl Glucuronide (EtG) CE**				10011297			
Ethyl Glucuronide (EtG)*				10015894		10015893	
Fentanyl*						10016005	
Heroin Metabolite (6-Acetylmorphine)	100107	100108	100186				
Hydrocodone*						10018053	
LSD	1732137 (15 mL)						
Methadone	100088	100097	1730916		0596	0597	
Methadone Metabolite	100087	100096	1868217		100115	100116	
Methaqualone					0514	0515	
Opiate	100089	100098	1661248		0135	0136	
Opiate 2K		100099	1815296				
Oxycodone				100248		100249	
Phencyclidine (PCP)	100172	100173	1815784		0160	0161	
Propoxyphene	100170	100171	1661523		0432	0433	
THC (Cannabinoid)	100091	100100	1661256		0185	0186	

Specialty Products	Size	Cat #
b-Glucuronidase	5 mL	127680

^{*} For Criminal Justice and Forensic use only
** For International use only - not for sale in USA



Now, the most extensive menu of drugs of abuse assays are available as "Open and Go" system reagents on our self-contained bench-top analyzer, the Thermo Scientific Indiko. Our system packaged reagents are bar-coded to allow flexibility and ease of use for the end user.

Indiko is an efficient, cost effective, automated bench top chemistry system designed for up-load 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 in laboratories with space limitations.

	Indiko and Indiko Plus Kits			
Product	CEDIA	DRI		
	Indiko 3 x 17 mL	Indiko 3 x 18 mL		
Amphetamine		10014585		
Amphetamine/Ecstasy	10016417			
Barbiturate	10017365	10015648		
Benzodiazepine	10016409	10015644		
Buprenorphine	10015658			
Cocaine	10016413	10014593		
Cotinine		10018516		
Ecstasy		10014681		
Ethyl Alcohol		10016397		
Ethyl Glucuronide (EtG)*		10016154		
Ethyl Glucuronide (EtG) CE**		10015626		
Fentanyl*		10016006		
Fentanyl CE**		10016437		
Heroin Metabolite (6-Acetylmorphine)	10015213			
Hydrocodone*		10018054		
Methadone	10016425	10016403		
Methadone Metabolite	10016421	10018522		
Opiate	10016429	10014601		
Oxycodone		10015632		
Phencyclidine (PCP)		10014673		
Propoxyphene		10018510		
THC (Cannabinoids)	10016433	10014665		

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Thermo Scientific DAU **CEDIA Calibrators**

Calibrators	Size (mL)	Part #	Assay	ng/mL	Assay	ng/mL
Negative Calibrator	5 15	1557416 1661388	Multiple Assays	0	Multiple Assays	0
Multi-Drug Primary Clinical Calibrator	5	1730401	Amphetamine Barbiturate Benzodiazepine Cocaine	1000 300 300 300	Methadone Metabolite Opiate Phencyclidine	100 300 25
Multi-Drug Primary Calibrator	5 15	1815326 1815334	Amphetamine Barbiturate Benzodiazepine Cocaine	1000 300 300 300	Methadone Metabolite Opiate Phencyclidine	100 2000 25
Multi-Drug Secondary Calibrator	5 15	1730428 1730517	Amphetamine Barbiturate Benzodiazepine Cocaine	500 200 200 150	Methadone Metabolite Opiate Phencyclidine	100 300 25
Multi-Drug Optional Calibrator	5	100033	Amphetamine Barbiturate Benzodiazepine Cocaine	300 200 200 300	Methadone Metabolite Opiate	100 300
Multi-Drug Intermediate Calibrator	5 15	1730380 1732218	Amphetamine Barbiturate Benzodiazepine Cocaine	3000 800 800 2000	Methadone Metabolite Opiate Phencyclidine	500 800 75
Multi-Drug High Calibrator	5 15	1730398 1732226	Amphetamine Barbiturate Benzodiazepine Cocaine	5000 3000 5000 5000	Methadone Metabolite Opiate Phencyclidine	2000 2000 150
PPX/Methadone	1					
Cutoff Calibrator Intermediate Calibrator High Calibrator	5	1662848 1662856 1662864	Propoxyphene	300 1200 5000	Methadone	300 600 1000

Refer to the specific assay Application or IPS for calibration configuration. Product availability may vary by country.

Calibrators	Size (mL)	Part#	Assay	ng/mL
Multi-Level THC				
25 Calibrator		1557505		25
50 Calibrator		1557513		50
75 Calibrator	15	1557521	11-nor-Δ ⁹ THC-COOH	75
100 Calibrator		1557530		100
150 Calibrator		1557548		150
LSD				
Cut-Off Calibrator		1732153		0.5
Intermediate Calibrator	5	1732161	d-LSD	1.5
High Calibrator		1732196		3
Heroin Metabolite				
Cut-Off Calibrator	5	100031	6-Acetylmorphine	10
High Calibrator	J	100034	0-Acetylinorphine	20
Buprenorphine				
Negative Calibrator	7.5	100241		0
5 ng/mL Calibrator	5	100242		5
20 ng/mL Calibrator	5	100243	Buprenorphine	20
50 ng/mL Calibrator	5	100244		50
75 ng/mL Calibrator	5	100245		75



Thermo Scientific DAU **DRI Calibrators**

Calibrators	Size (mL)	Part#	Assay	ng/mL	Assay	ng/mL
Negative Cal	10 25	1664 1388	Multiple Assays	0	Multiple Assays	0
Multi-Drug Urine Cal 1	10 25	1588 1589	Amphetamine Barbiturate Benzodiazepine Cocaine Methadone	500 100 100 150 150	Methaqualone Opiate Phencyclidine Propoxyphene	150 1000 12.5 150
Multi-Drug Urine Cal 2	10 25	1591 1592	Amphetamine Barbiturate Benzodiazepine Cocaine Methadone	1000 200 200 300 300	Methaqualone Opiate Phencyclidine Propoxyphene	300 2000 25 300
Multi-Drug Urine Cal 3	10 25	1594 1595	Amphetamine Barbiturate Benzodiazepine Cocaine Methadone	1500 500 500 500 500	Methaqualone Opiate Phencyclidine Propoxyphene	500 4000 50 500
Multi-Drug Urine Cal 4	10 25	1597 1598	Amphetamine Barbiturate Benzodiazepine Cocaine Methadone	2000 1000 1000 1000 1000	Methaqualone Opiate Phencyclidine Propoxyphene	1000 6000 100 1000
Low Urine Cal	5	0034	Amphetamine Cocaine	1000 300	Opiate Phencyclidine	300 25
High Urine Cal	5	0036	Amphetamine Cocaine	2000 3000	Opiate Phencyclidine	1000 100

Refer to the specific assay Application or IPS for calibration configuration. Product availability may vary by country.



Calibrators	Size (mL)	Part #	Assay	ng/mL
Opiate				
150 ng/mL Cal	25	1609	Opiate	150
500 ng/mL Cal	20	1610	Οριαιο	500
Multi-Level THC				
20 ng/mL Cal		0235 1397		20
50 ng/mL Cal	5	0042 1398	14 A0THO 000H	50
100 ng/mL Cal	25	0044 1399	11-nor-Δ ⁹ THC-COOH	100
200 ng/mL Cal		0206 1400		200
Ethyl Alcohol		1.00	<u> </u>	
	5	0311		
Negative Alcohol Cal	25	1405		0 mg/dL
100 mg/dl Cal	5	0241	Ethyl Alcohol	100 m m /dl
100 mg/dL Cal	25	1406		100 mg/dL
Ethyl Glucuronide*				
ETG Negative Cal	25	10015932		0
ETG 100 Cal	10	10015933		100
ETG 500 Cal	10	10015935	Ethyl Glucuronide	500
ETG 1000 Cal	10	10015938		1000
ETG 2000 Cal	10	10015940		2000
Ethyl Glucuronide CE**				
ETG Negative Cal	25	10011207		0
ETG 100 Cal	10	10011208		100
ETG 500 Cal	10	10011210	Ethyl Glucuronide	500
ETG 1000 Cal	10	10011212	,	1000
ETG 2000 Cal	10	10011213		2000
Ecstasy				
250 ng/mL Ecstasy Cal		100082		250
500 ng/mL Ecstasy Cal	10	100081	Footooy	500
750 ng/mL Ecstasy Cal	10	100080	Ecstasy	750
1000 ng/mL Ecstasy Cal		100079		1000
Cotinine Cal Kit				
0 ng/mL Cotinine Cal				0
100 ng/mL Cotinine Cal				100
250 ng/mL Cotinine Cal	5	0404	Cotinine	250
500 ng/mL Cotinine Cal	ິວ	0404	Comme	500
1000 ng/mL Cotinine Cal				1000
2000 ng/mL Cotinine Cal				2000
Hydrocodone*				
100ng/mL Hydrocodone Cal		10018079		100
300ng/mL Hydrocodone Cal	10	10018080	11	300
500ng/mL Hydrocodone Cal	10	10018081	Hydrocodone	500
1000ng/mL Hydrocodone Cal		10018082		1000
Methadone Metabolite				
150 ng/mL Meth Metab Cal		100117		150
300 ng/mL Meth Metab Cal	10	100118	EDDD	300
1000 ng/mL Meth Metab Cal	10	100120	EDDP	1000
2000 ng/mL Meth Metab Cal		100122		2000
Oxycodone				
100 ng/mL Oxycodone Cal		100250		100
300 ng/mL Oxycodone Cal	10	100251	Overendens	300
500 ng/mL Oxycodone Cal	10	100252	Oxycodone	500
1000 ng/mL Oxycodone Cal		100253		1000
Fentanyl*				
Fentanyl 2 ng/mL Cal	10	10016023	Fentanyl	2
Fentanyl CE**				
Fentanyl 2 ng/mL Cal	10	10016485	Fentanyl	2

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Thermo Scientific DAU CEDIA, DRI & MAS Controls

Controls	Size (mL)	Part #	Assay	Low	High
MGC Primary DAU Control Set	3x5	100200	Amphetamine (d-methamphetamine) Barbiturate (secobarbital) Benzodiazepine (oxazepam) Cocaine (benzoylecgonine) Methadone (methadone) Methadone Metabolite (EDDP) Methaqualone (methaqualone) Opiate 2000 (morphine) Phencyclidine (PCP) Propoxyphene (PPX)	750 150 150 225 225 750 225 1500 19 225	1250 250 250 375 375 1250 375 2500 31 375
MGC Clinical DAU Control Set	3x5	100201	Amphetamine (d-methamphetamine) Barbiturate (secobarbital) Benzodiazepine (nitrazepam) Cocaine (benzoylecgonine) Methadone (methadone) Methadone Metabolite (EDDP) Opiate 300 (morphine) Phencyclidine (PCP) Propoxyphene (PPX)	375 225 225 225 225 75 225 19 225	625 375 375 375 375 125 375 31 375
MGC Select DAU Control Set	3 x 5	100202	Benzodiazepine (nitrazepam) Cocaine (benzoylecgonine) Ecstasy (MDMA) Heroin Metabolite (6-Acetylmorphine) LSD (LSD)	150 112.5 375 7.5 0.3	250 187.5 625 12.5 0.7
MGC Optional DAU Control Set	2 x 5	100069	Amphetamine (d-methamphetamine) Barbiturate (secobarbital) Benzodiazepine (nitrazepam) Cocaine (benzoylecgonine) Methadone Metabolite (EDDP) Opiate 300 (morphine)	225 150 150 225 75 225	375 250 250 375 125 375
MGC Specialty DAU Control Set	3 x 5	1815440	Amphetamine (d-methamphetamine) Barbiturate (secobarbital) Benzodiazepine (nitrazepam) Cocaine (benzoylecgonine) Methadone Metabolite (EDDP) Opiate 300 (morphine)	375 150 150 112.5 75 225	625 250 250 187.5 125 375



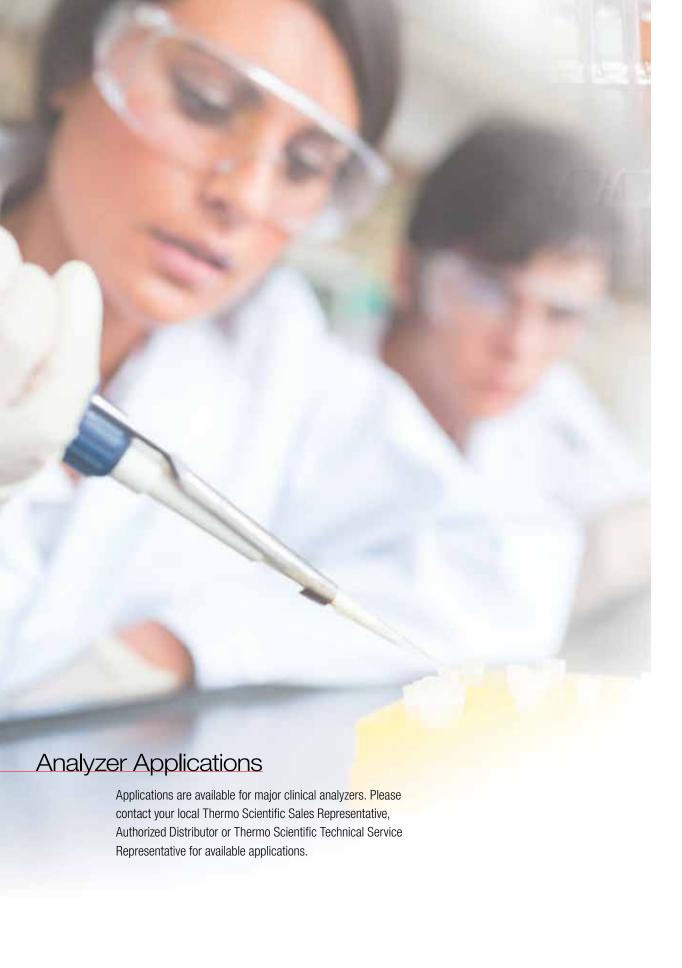






Controls	Size (mL)	Part #	Assay	Low	High
	MAS DO	A Total Contr	ols		
DOAT-1 Level 1 (Negative)		DOAT-1			
DOAT-2 Level 2		DOAT-2			
DOAT-3 Level 3		DOAT-3	Refer to MAS DOA Total C	ontrol, pa	ge 58
DOAT-4 Level 4 (SAMHSA -25%)	6 x 18	DOAT-4	for specific target analytes	and	
DOAT-5 Level 5 (SAMHSA +25%)		DOAT-5	concentrations.		
DOAT-6 Level 6		DOAT-6			
DOAT-MP Multi-Pack		DOAT-MP			
	CEDIA Singl	le Analyte Co	ntrols		
Buprenorphine Control Set	OLDIA OIIIgi	To Alluly to Oc	THE OIS		
Buprenorphine Control Set	2 x 5	100246	Buprenorphine	3	7
Multi-Level THC Control Sets	ZXO	1002.10	Вартопогрише	J	
THC 25 Control Set		1661086		18.75	31.25
THC 50 Control Set	2 x 15	1661078	11-nor-∆9THC-COOH	37.5	62.5
THC 100 Control Set		1661060		75	125
	DRI Single	Analyte Con	itrols		
Cotinine Controls	I		I	000	
Low Cotinine Control High Cotinine Control	5	0460 0470	Cotinine	300	700
Ethyl Alcohol Controls		0470			700
50 mg/dL Ethyl Alcohol Control		0239		50	
300 mg/dL Ethyl Alcohol Control	5	0243	Ethyl Alcohol		300
Ethyl Glucuronide Controls*					
ETG 375 Control		10015934		375	
ETG 625 Control	25	10015936	Ethyl Glucuronide		625
ETG 750 Control ETG 1250 Control		10015937 10015939	, , , , , , , , , , , , , , , , , , , ,	750	1050
Ethyl Glucuronide Controls CE**		10013333			1250
ETG 375 Control		10012135		375	
ETG 625 Control	0.5	10012136	FII 101 11		625
ETG 750 Control	25	10012137	Ethyl Glucuronide	750	
ETG 1250 Control		10012138			1250
Fentanyl Controls*			1	Ι .	1
1 ng/mL Fentanyl Control 3 ng/mL Fentanyl Control	25	10016022 10016024	Fentanyl	1	0
Fentanyl CE Controls**		10010024			3
1 ng/mL Fentanyl Control		10016484		1	
3 ng/mL Fentanyl Control	25	10016486	Fentanyl	· ·	3
Hydrocodone Control Set*					
Hydrocodone Control	10	10018149	Hydrocodone	225	375
Oxycodone Control Set					
100 ng/mL Oxycodone Controls	10	100254	Oxycodone	75 225	125
300 ng/mL Oxycodone Controls THC Controls		100255	<u> </u>	225	375
		0170		40	
40 ng/mL THC Urine Control		1401		40	
60 ng/mL THC Urine Control	5	0168			60
-	25	1402	11-nor-Δ ⁹ THC-COOH		60
75 ng/mL THC Urine Control		0214		75	
125 ng/mL THC Urine Control		0212			125
		1404			125

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Oral Fluid Testing using Oral-Eze®

Our innovative oral fluid collection system simplifies the collection of oral samples for routine drug testing.

The Oral-Eze® Oral Fluid Collector provides all the advantages of previous collection systems, with the added benefit of our indicator window technology. The indicator window takes the guesswork out of collecting samples and turns blue when the sample quantity is sufficient for processing, thereby reducing repeat collections.

Oral Eze Collection Devices				
Description 50 /kit 500/kit				
Oral Eze Collection Device	96100-050	96100-500		
Oral Eze Sample Extractor	96105-050	96105-500		



Collection process after the contents are removed from packaging:



1. Collect.

The donor inserts the Oral-Eze collection pad between the lower cheek and gum.



2. Check.

When the indicator window on the handle turns blue, the collector is removed.



3. Detach.

The collection pad is inserted into the transport tube and detached from the collector.



4. Cap.

The cap is pressed until completely sealed and a tamper-evident seal is placed across the top and down the sides of collection tube. Ship the specimen to the testing laboratory.



Thermo Scientific DAT Oral Fluids Oral-Eze Q&A

Reduce the risk today with Oral Fluids Immunoassay

- Q: Is the Oral-Eze® test FDA-cleared?
- A: Yes, both the Oral-Eze Oral Fluid Collection System and the drug tests using the Oral-Eze collection system are FDA-cleared.
- Q: What are the benefits of using the Oral-Eze collection device?
- A: The Oral-Eze Oral Fluid Collector has a built-in indicator for determining when a sufficient quantity of oral fluid has been collected. This will reduce the number of tests that are reported as "quantity insufficient". Another benefit is that the oral fluid collector does not have a salty or citric taste.
- Q: Is the pad safe to put in my mouth?
- A: Yes, the pad is a cotton-fiber filter paper that has not been treated with any salts or flavorings.
- Q: How long does it take to collect an oral fluid sample with Oral-Eze?
- A: The Oral-Eze collection is complete when the indicator window turns blue. This typically occurs within 3-5 minutes although all donors are different. Before beginning the collection, instruct the donor to pool their saliva. Ask them to refrain from swallowing and talking, instead directing that saliva towards the device. Ensure that they keep the device in their mouth for the allotted time or until the indicator window turns blue.

Q: What is the liquid in the vial?

- A: The liquid is a buffer, preservative solution that stabilizes the oral fluid sample and helps prevent the sample and drugs/metabolites from deteriorating during storage or shipping to the laboratory.
- Q: Will recent oral surgery (root canals, extraction's, etc.) or sutures make a difference?
- A: Neither will affect the collection; however, if sutures are located between the lower cheek and gum, it is better to collect the sample from the opposite side of the mouth.
- Q: When collecting an oral fluid specimen, I noticed a small amount of blood on the collection pad. Is this normal?
- A: Although this is not common, it may occur in some individuals and should not adversely affect the specimen collected.
- Q: What is the best practice for transferring the pad from the collector to the tube?
- A: Once the indicator window turns blue, instruct the donor to remove the pad from the mouth. Place the pad of the device into the buffer tube. Using the thumb, place on the ridge of the collector handle and slide toward the pad to detach the pad into the buffer. If the pad does not immediately detach, use the lid on the tube to withdraw the pad from the collection handle. It may be more difficult to detach if the pad is not sufficiently saturated.
- Q: How long is the specimen stable after it has been collected?
- A: The specimen and any drugs in the specimen are stable for 21 days after collection. Non-negative specimens tested by the laboratory are stable for at least one year when stored frozen.



Oral Fluids for North America

Reagent Kits	Indiko Reagent Kits	
Description	MCC (1 x 65 mL)	3 x 17 mL
Amphetamine OFT	10014947	10018579
Cannabinoids OFT	10014910	10018585
Cocaine OFT	10014764	10018590
Methamphetamine OFT	10014949	10018595
Opiate OFT	10014873	10018600
PCP OFT	10014888	10018605

Oral Fluids for International**

Reagent Kits						
Description	TSC (3 x 18 mL)	MCC (1 x 65 mL)				
Amphetamine OFT	10011931	10011932				
Cannabinoids OFT	10010883	10010888				
Cocaine OFT	10014734	10014740				
Methamphetamine OFT	10011934	10011936				
Opiate OFT	10010612	10010659				
PCP OFT	10010619	10010665				

^{**} For International use only - not for sale in USA Product availability may vary by country

Thermo Scientific DAU Oral Fluids Calibrators & Controls

Oral Fluid Calibrators & Controls for North America

Catalog #	Kit Size (mL)	Description	Amphetamine	Cocaine (Benzoylecgonine)	Opiates (Morphine)	Phencyclidine
10014954	20	CEDIA Multi-Drug OFT Negative Calibrator	0	0	0	0
10014955	10	CEDIA Multi-Drug OFT Cutoff Calibrator	50	5	10	1
10014957	2 x 15	CEDIA Multi-Drug OFT Control Set- Low	25	2.5	5	0.5
10014937	Z X 13	CEDIA Multi-Drug OFT Control Set- High	75	7.5	15	1.5

Catalog #	Kit Size (mL)	Description	Methamphetamine
10014950	10	CEDIA Methamphetamine OFT Negative Calibrator	0
10014951	5	CEDIA Methamphetamine OFT Cutoff Calibrator	40
10014052	2 x 10	CEDIA Methamphetamine OFT Low Control	20
10014953	2 X 10	CEDIA Methamphetamine OFT High Control	60

Catalog #	Kit Size (mL)	Description	THC
10014922	10	CEDIA THC OFT Negative Calibrator	0
10014923	5	CEDIA THC OFT Cutoff Calibrator	1
10014925	2 x 10	CEDIA THC OFT Low Control	0.5
10014925	2 x 10	CEDIA THC OFT High Control	1.5

Oral Fluid Calibrators & Controls for Australia**

Catalog #	Kit Size (mL)	Description	Amphetamine	Cocaine (Benzoylecgonine)	Opiates (Morphine)
10016864	20	CEDIA Multi-Drug OFT Negative Calibrator	0	0	0
10016882	10	CEDIA Multi-Drug OFT Calibrator 1	10	10	10
10016883	10	CEDIA Multi-Drug OFT Calibrator 2	17	17	17
10016884	10	CEDIA Multi-Drug OFT Calibrator 3	40	30	40
10017711	15	CEDIA MultiDrug OFT Control 1	13	13	13
10017712	15	CEDIA MultiDrug OFT Control 2	17	17	17
10017713	15	CEDIA MultiDrug OFT Control 3	25	25	25

Catalog #	Kit Size (mL)	Description	Methamphetamine
10016344	10	CEDIA Methamphetamine OFT Negative Calibrator	0
10016362	5	CEDIA Methamphetamine OFT Calibrator 1	10
10016363	5	CEDIA Methamphetamine OFT Calibrator 2	17
10016364	5	CEDIA Methamphetamine OFT Calibrator 3	40
10017686	10	CEDIA Methamphetamine OFT Control 1	13
10017687	10	CEDIA Methamphetamine OFT Control 2	17
10017688	10	CEDIA Methamphetamine OFT Control 3	25

Catalog #	Kit Size (mL)	Description	THC
10016643	10	CEDIA THC Negative Calibrator	0
10016700	5	CEDIA THC OFT Calibrator 1	5
10016701	5	CEDIA THC OFT Calibrator 2	8
10016702	5	CEDIA THC OFT Calibrator 3	13
10017702	10	CEDIA THC OFT Control 1	6
10017703	10	CEDIA THC OFT Control 2	8
10017704	10	CEDIA THC OFT Control 3	10

Oral Fluid Calibrators & Controls for United Kingdom**

Catalog #	Kit Size (mL)	Description	Amphetamine	Cocaine (Benzoylecgonine)	Opiates (Morphine)
10016894	10	CEDIA Multi-Drug OFT Cutoff Calibrator	10	5	10
10016895	2 x 15	CEDIA Multi-Drug OFT Control Set	5 & 15	2.5 & 7.5	5 & 15

Catalog #	Kit Size (mL)	Description	Methamphetamine
10016807	5	CEDIA Methamphetamine OFT Cutoff Calibrator	10
10016808	2 x 10	CEDIA Methamphetamine OFT Control Set	5 & 15

Catalog #	Kit Size (mL)	Description	THC
10016730	5	CEDIA THC OFT Cutoff Calibrator	1
10016731	2 x 10	CEDIA THC OFT Control Set	0.5 & 1.5

Oral Fluid Calibrators & Controls for Europe**

Catalog #	Kit Size (mL)	Description	Amphetamine	Cocaine (Benzoylecgonine)	Opiates (Morphine)	PCP
10016864	20	CEDIA Multi-Drug OFT Negative Calibrator	0	0	0	0
10016865	10	CEDIA Multi-Drug OFT Calibrator 1	6.7	5	6.7	2
10016866	10	CEDIA Multi-Drug OFT Calibrator 2	13.3	10	13.3	3.3
10016867	10	CEDIA Multi-Drug OFT Calibrator 3	40	30	40	10
10016868	10	CEDIA Multi-Drug OFT Calibrator 4	100	75	100	20
10016869	2 x 15	CEDIA Multi-Drug OFT Control Set	6.7 & 20	5.0 & 15	6.7 & 20	1.7 & 5.0

Catalog #	Kit Size (mL)	Description	Methamphetamine
10016344	10	CEDIA Methamphetamine OFT Negative Calibrator	0
10016345	5	CEDIA Methamphetamine OFT Calibrator 1	6.7
10016346	5	CEDIA Methamphetamine OFT Calibrator 2	13.3
10016347	5	CEDIA Methamphetamine OFT Calibrator 3	40
10016348	5	CEDIA Methamphetamine OFT Calibrator 4	100
10016349	2 x 10	CEDIA Methamphetamine OFT Control Set	6.7 & 20

Catalog #	Kit Size (mL)	Description	THC
10016643	10	CEDIA THC OFT Negative Calibrator	0
10016644	5	CEDIA THC OFT Calibrator 1	1.7
10016646	5	CEDIA THC OFT Calibrator 2	3.3
10016647	5	CEDIA THC OFT Calibrator 3	10
10016648	5	CEDIA THC OFT Calibrator 4	20
10016649	2 x 10	CEDIA THC OFT Control Set	1.7 & 5.0

^{**} For International use only - not for sale in USA Product availability may vary by country



Reagent Kits		
Catalog #	Description	Kit Size (mL)
1797	Creatinine-Detect®	500
10015638 DRI Creatinine-Detect for Indiko 3 x 18		3 x 18

Catalog #	Description	Kit Size (mL)
10009958	009958 General Oxidant-Detect™	
10018528	DRI General Oxidant-Detect for Indiko	6 x 18
Catalog #	Description	1(1.0) - (-1)
Galaioy #	Description	Kit Size (mL)
1194	Gravity-Detect®	2 x 500

Catalog #	Description	Kit Size (mL)
100054	pH-Detect®	2 x 500
10015654	DRI pH-Detect for Indiko	6 x 18

Catalog #	Description	Kit Size (mL)
1815555	CEDIA Sample Check**	83
10016443	Indiko Sample Check**	3 x 18

^{**}For International use only - not for sale in USA $\,$

Calibrators & Controls			
Catalog #	Kit Size (mL)	Description (mg/dL)	Cut-off Levels
100272	2 x 25	Creatinine Calibrator Set	2.0 & 20
100273	25	Creatinine 1.3 Control	1.3
100274	25	Creatinine 7.5 Control	7.5
100275	25	Creatinine 23.0 Control	23

Catalog #	Kit Size (mL)	Description (μg/mL)	Cut-off Levels
10009971	2 x 25	General Oxidant Cal Set	0 & 200
10009972	2 x 25	General Oxidant Control Set	100 & 300

Catalog #	Kit Size (mL)	Description	Cut-off Levels
1754	2 x 25	Low Gravity Calibrator	1.010
1755	25	High Gravity Calibrator	1.025
1756	25	Level 1 Gravity Control	1.015
1757	25	Level 2 Gravity Control	1.030

Catalog #	Kit Size (mL)	Description	pH Level
100283	2 x 25	pH Calibrator Set	3.0 & 11.0
100282	25	pH 3.6 Control	3.6
100284	25	pH 7.0 Control	7
100285	25	pH 10.0 Control	10
100281	25	pH 11.5 Control	11.5

Catalog #	Kit Size (mL)	Description	Cut-off Levels
1557416	5	CEDIA Negative Cal	0
1661388	15	CEDIA Negative Cal	0
1815571	3 x 5	CEDIA Sample Check** Control Set	Multilevel - See package insert



Analyzer Applications

Applications are available for major clinical analyzers. Please contact your local Thermo Scientific Sales Representative, Authorized Distributor or Thermo Scientific Technical Service Representative for available applications.



Endocrine Assays

To round out your routine chemistry profile, the T4 and T Uptake endocrine products are available in both CEDIA and DRI formats. They are packaged in convenient sizes and have applications on a multitude of clinical chemistry analyzers. Similar to our TDM and Drugs of Abuse products, these products provide excellent workflow management, cost savings, and superior performance.

CEDIA Assays*		
Catalog #	Description	Kit Size (mL)
100050	T4 SC Open System	39, 24
100049	T Uptake LC Open System	2 x 588, 2 x 191

^{*} Calibrators are included in the reagent kit.

DRI Reagents			
Catalog #	Description	Kit Size (mL)	
0723	T Uptake	100, 34	
0454	Total Thyroxine (T4) 100, 34		
10013070 Total Thyroxine (T4) 500, 170			



Calibrators & Controls for DRI T4 Assay							
Catalog # Kit Size (mL) Description Thyroxine (μg/dl							
		Thyroxine Negative Cal	0				
		Thyroxine Cal 1	2				
0.476	6 bottles x 2 mL ea	Thyroxine Cal 2	4				
0476	6 DOLLIES X 2 IIIL ea	Thyroxine Cal 3	8				
		Thyroxine Cal 4	12				
		Thyroxine Cal 5	20				

MAS Liquimmune Controls							
Catalog #	Kit Size (mL)	Description	T Uptake (%)				
MAS Control LIG-101	6 x 5	Liquimmune Level 1	Coo pogo E 4 for				
MAS Control LIG-202			See page 54 for more information				
MAS Control LIG-303	6 x 5	6 x 5 Liquimmune Level 3					

Analyzer Applications

Applications are available for major clinical analyzers. Please contact your local Thermo Scientific Sales Representative, Authorized Distributor or Thermo Scientific Technical Service Representative for available applications.



Serum Toxicology

The Serum Toxicology assays are excellent tools for physicians in an emergency room situation. When urine specimens are not conveniently available, these serum-based assays are used to identify the class of drug of the overdose. The Serum Toxicology Tricyclics assay has the added flexibility of analyzing serum or urine samples.

Assays		
Catalog #	Description	Kit Size (mL)
1086	Acetaminophen	25, 8
0911	Barbiturate	25, 8
0920	Benzodiazepine	25, 8
0977	Salicylate	25
1128	Tricyclics	25, 8

Calibrators & Controls for Serum Toxicology							
Catalog #	Kit Size (mL)	Description (ng/mL)	Serum Barbiturate	Serum Benzodiazepine	Serum Tricyclics		
0962	10 Negative Calibrator 0		0	0			
0963	5	Calibrator 1	500	25	150		
0965	5	Calibrator 2	1000	50	300		
0967	5	Calibrator 3	3000	100	500		
0976	5	Calibrator 4	rator 4 6000 200 100				
10011608	6 x 5	MAS TOX Control Level 1 - 3	See page 58 for more information				



Calibrators & Controls for Acetaminophen Assay					
Catalog #	Catalog # Kit Size (mL) Description Analyte				
1091	5	Acetaminophen Neg Calibrator	0		
	2	Acetaminophen 10 Calibrator	10		
	2	Acetaminophen 25 Calibrator	25		
	2	Acetaminophen 50 Calibrator	50		
	2	Acetaminophen 100 Calibrator	100		
	2	Acetaminophen 200 Calibrator	200		

Calibrators & Controls for Salicylate Assay					
Catalog # Kit Size (mL) Description Analyte Salicylate (µg/mL)					
0980	1 x 5	Salicylate Negative Calibrator	0		
บลอบ	1 x 2	Salicylate 800 Calibrator	800		

MAS PAR TDM Controls						
Catalog # Kit Size (mL) Description Analyte (µg/mL)			Salicylate			
PTD1-1001*	6 x 5	PAR TDM Level 1	Defer to make FF for			
PTD2-2002*	6 x 5	PAR TDM Level 2	Refer to page 55 for more information			
PTD3-3003*	6 x 5	PAR TDM Level 3	more imormation			

^{*} Refer to page 66 for list of analytes.

Analyzer Applications

Applications are available for major clinical analyzers. Please contact your local Thermo Scientific Sales Representative, Authorized Distributor or Thermo Scientific Technical Service Representative for available applications.



Backed by a proven track record of reliable results and trouble-free performance on a wide range of analyzers, we have been manufacturing TDM Assays since 1986.

CEDIA TDM Assays					
Catalog #	Description	Kit Size (mL)			
100006	Carbamazepine	17, 17			
100016	Gentamicin II	13, 11			
100015	NAPA	17, 17			
100003	Phenobarbital II	17, 17			
100002	Phenytoin II	17, 17			
100014	Procainamide 17, 17				
100008	Theophylline II	17, 17			
100018	Tobramycin II	13, 11			
100013	Valproic Acid	13, 11			

DRI TDM Assays					
Catalog #	Description	Kit Size (mL)			
1669	Digoxin**	25, 8			
1669-A	Digoxin#	25, 8			

[#] Calibrators are included in the reagent kit.

^{**} For International Use only - not for sales in USA

MAS PAR TDM [†] Controls for TDMs					
Catalog # Description Kit Size (mL)					
PTD1-1001	Par TDM Level 1	6 x 5			
PTD2-2002 Par TDM Level 2 6 x 5					
PTD3-3003	Par TDM Level 3	6 x 5			

[†] Refer to analyte lists beginning on page 66.



CEDIA TDM Assays with Multi Constituent Calibrators

CORE	CARDIAC	ANTIBIOTIC
Carbamazepine Phenobarbital Phenytoin Theophylline Valproic Acid	Digoxin NAPA Procainamide	Gentamicin Tobramycin

CEDIA MultiDrug Calibrators											
Catalog #	Kit Size (mL)	Description	NAPA* µg/mL	Procainamide* µg/mL	Carbamazepine* µg/mL	Phenobarbital II* µg/mL	Phenytoin II* µg/mL	Theophylline II* µg/mL	Valproic Acid µg/mL	Gentamicin II µg/mL	Tobramycin II µg/mL
100001	2 x 7.5	TDM Cardiac Cal Low	•	+							
100001	2 x 5.0	TDM Cardiac Cal High	•	٠							
100007	2 x 7.5	TDM Core Cal Low			+	+	•	+	+		
100007	2 x 5.0	TDM Core Cal High			•	•	•	+	+		
100017	2 x 7.5	TDM Antibiotic Cal Low								•	•
100017	2 x 5.0	TDM Antibiotic Cal High								+	*

^{*} Calibrator concentrations for each assay are printed on a calibrator value assignment card and are located in each TDM calibrator kit.

Analyzer Applications

Applications are available for major clinical analyzers. Please contact your local Thermo Scientific Sales Representative, Authorized Distributor or Thermo Scientific Technical Service Representative for available applications.



Thermo Scientific TDM QMS Assays, Calibrators & Controls

Advanced microparticle technology is the foundation for a rapidly growing menu of QMS® particle enhanced turbidimetric immunoassays for therapeutic and immunosuppressive drug management. Clinicians in the fields of infection, epilepsy, cardiology and organ transplantation have found QMS assays are particularly well suited to measuring therapeutic drugs in whole blood, serum or plasma.

Developed for use on general chemistry analyzers, the QMS liquid-ready-to-use format has been proven to be a convenient alternative to more expensive and time-consuming assays employing HPLC or LC/MS technologies. In side-by-side comparisons, QMS assays have demonstrated:

Excellent correlation to reference methods

Optimal sensitivity, precision and dynamic range

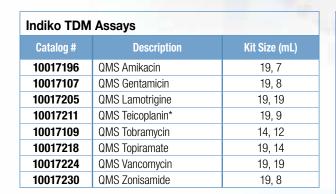
Exceptional reliability, precision and lot-to-lot consistency

Low cross-reactivity with metabolites and commonly co-administered drugs

Low interference from endogenous substances

Our QMS two-component assay system is based on the competitive inhibition immunoassay principle: If the drug targeted by the assay is present in the sample, these free drug molecules compete with a microparticle-bound drug in one reagent for a limited number of antibody combining sites supplied by antibody in a second reagent. The competition for antibody binding sites inhibits the ability of the antibody to agglutinate the drug-coated microparticles. The degree that agglutination is inhibited is directly related to the concentration of the target drug in the sample.

In the absence of competing free-drug in the sample, the drug-coated microparticle reagent is rapidly agglutinated in the presence of the antibody reagent. The rate of absorbance change is measured photometrically and is proportional to the rate of agglutination of the microparticles.



QMS TDM Assays			
Catalog #	Description	Kit Size (mL)	
0373910	Amikacin Reagent Kit	2 x 19, 2 x 7	
0373795	Lamotrigine Reagent Kit	19, 19	
0374686	Lidocaine Reagent Kit	2 x 18, 2 x 9	
0373936	Quinidine Reagent Kit	2 x 19, 2 x 7	
0374645	Teicoplanin Reagent Kit*	21, 9	
0374140	Topiramate Reagent Kit	22, 16	
0373589	Vancomycin Reagent Kit	22, 22	
0373571	Zonisamide Reagent Kit	2 x 22, 2 x 8	

QMS TDM Calibrators			
Catalog #	Description	Kit Size	
0374157	Amikacin Calibrators	Levels A-F 1 x 1 mL ea	
0373902	Gentamicin Calibrators	Levels A-F 1 x 1 mL ea	
0373787	Lamotrigine Calibrators	Level A 1 x 2 mL ea Levels B-F 1 x 1 mL ea	
0374678	Lidocaine Calibrators	Levels A-F 1 x 1 mL ea	
0374165	Quinidine Calibrators	Levels A-F 1 x 1 mL ea	
0374652	Teicoplanin* Calibrators	Levels A-F 1 x 1 mL ea	
0374116	Tobramycin Calibrators	Levels A-F 1 x 1 mL ea	
0374173	Topiramate Calibrators	Levels A-F 1 x 1 mL ea	
0373597	Vancomycin Calibrators	Levels A-F 1 x 1 mL ea	
0373381	Zonisamide Calibrators	Level A 1 x 2.5 mL ea Levels B-F 1 x 1 mL ea	

QMS TDM Controls			
Catalog #	Description Kit Size		
0374090	Lamotrigine Control Set	3 Levels 1 x 2.5 mL ea	
0374660	Teicoplanin* Control Set 3 Levels 1 x 2.0 mL ea		
0374181	Topiramate Control Set	3 Levels 1 x 2.0 mL ea	
0373373	Zonisamide Control Set	3 Levels 1 x 2.5 mL ea	

For additionI TDM controls for the QMS Assays, refer to page 59. * For International use only - not for sale in USA

Analyzer Applications

Applications are available for major clinical analyzers. Please contact your local Thermo Scientific Sales Representative, Authorized Distributor or Thermo Scientific Technical Service Representative for available applications.



Immunosuppressant drug testing

One of the most effective therapies for patients with endstage 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.

Accurate

- Excellent low-end sensitivity
- Correlation with gold standard methods
- ✓ Lot-to-lot consistency

Efficient

- ✓ Improved turn-around-time
 - Applications for a variety of analyzers

Convenient

- Simple sample preparation step
- Broad dynamic range for Cyclosporine (25–2000 ng/mL)
- Mix and Run reagent systems or liquid, ready to use

Multiconstituent Immunosuppressant Controls for use with Cyclosporine and Tacrolimus			Target Values	
Catalog #	Description Kit Size (mL) CsA TACRO		TACRO	
280-1	Rap/Tac/CsA Control Level 1 - blue	4 x 4		
280-2	280-2 Rap/Tac/CsA Control Level 2 - green 4 x 4 Refer to value assignmen			
280-3	Rap/Tac/CsA Control Level 3 - red	4 x 4	value assignment sheet	
280-Q	Rap/Tas/CsA Contol Level Q - yellow	4 x 4		



ISD Assays		
Catalog #	Description	Kit Size (mL)
100147	CEDIA Cyclosporine PLUS*	41, 19
0380000	QMS Everolimus	22, 8
0373852	QMS Everolimus**	22, 8
100276	CEDIA Mycophenolic Acid	26, 11

^{*} Low Range CsA calibrators are included in the reagent kit

^{**} For International use only - not for sale in USA

ISD Reagents for the Indiko			
Catalog #	Description	Kit Size (mL)	
10016283	CEDIA Cyclosporine	41, 19	
10015987	QMS Everolimus	22, 8	
10015993	QMS Everolimus**	22, 8	
10016265	CEDIA Mycophenolic Acid	26, 11	
10015556	QMS Tacrolimus	18, 12	

 $^{^{\}star\star}$ For International use only - not for sale in USA

ISD Calibrators & Controls			
Catalog #	Description	Kit Size	
100207	CsA Control High Level 4	6 x 2 mL ea, 2 x 8 diluent	
100208	CsA Control High Level 5	6 x 2 mL ea, 2 x 8 diluent	
100012	CsA PLUS High Cal Set	4 x 2 mL each level, low & high	
100277	Mycophenolic Acid Calibrator Set	2 x 5 mL 2 ea level	
100278	Mycophenolic Acid Control 1	4 x 5 mL each level, low and high	
100279	Mycophenolic Acid Control 2 4 x 5 mL each level, low and high		
100280	Mycophenolic Acid Control 3 4 x 5 mL each level, low and high		
0380005	QMS Everolimus Calibrator Set	6 levels, 1 bottle each 3 mL	
0373860	QMS Everolimus Calibrator Set**	6 levels, 1 bottle each 3 mL	
0380010	QMS Everolimus Control Set	3 Levels, 1 bottle each, 3 mL	
0373878	QMS Everolimus Control Set**	3 levels, 1 bottle each 3 mL	
10015573	QMS Tacrolimus Calibrator Set	6 levels, A 4 mL, B-F 2 mL ea	

^{**} For International use only - not for sale in USA See Multiconstituent ISD Controls on page 38 for levels 1, 2, and 3

Analyzer Applications

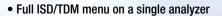
Applications are available for major clinical analyzers. Please contact your local Thermo Scientific Sales Representative, Authorized Distributor or Thermo Scientific Technical Service Representative for available applications.



Thermo Scientific Indiko Specialty Chemistry Systems

Thermo Scientific Indiko and Indiko Plus analyzers and immunosuppressant and therapeutic drug monitoring

Thermo Scientific[™] Indiko, together with a complete menu of immunosuppressant and therapeutic drug monitoring assays, provide 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 bench top analyzer also provides a single platform solution for all Thermo Scientific[™] ISD and TDM immunoassays, improving laboratory efficiency. The continuous access allows for samples and reagents to be added without interrupting the testing process.



- · Convenient on-site testing
- Improved laboratory efficiency and turnaround time
- Flexibility in instrument placement



ISD Menu	TDM Menu
CEDIA® Cyclosporine PLUS Assay	Antiepileptics/Anticonvulsants Assays
CEDIA® Mycophenolic Acid Assay	Antibiotic Immunoassays
QMS® Everolimus Assay	Antiarrythmics/Cardiacs Assays
QMS® Tacrolimus	Bronchodilator Assay

Ready-to-use Drugs of Abuse screening assays for Indiko benchtop analyzers

Our experience in drugs of abuse testing allows us to anticipate new drug screening challenges and have leading edge solutions available when needed. Our multiple technologies provide important advantages of integrating both Thermo ScientificTM DRI[®] and/or Thermo ScientificTM CEDIA[®] technologies into your testing program.

	URINE		ORAL FLUID	SERUM
DRI Assays	CEDIA Assays	Specimen Validity Tests	CEDIA Oral Fluid (OFT) Assays	Toxicology Assays*
Amphetamine	Amphetamine/Ecstasy	Creatinine	Amphetamine	Barbiturate
Barbiturate	Barbiturate	General Oxidant	Cannabinoid	Benzodiazepine
Benzodiazepine	Benzodiazepine	рН	Cocaine	Tricyclics
Cannabinoid	Buprenorphine	Sample Check**	Methamphetamine	
Cocaine	Cannabinoid	Specific Gravity	Opiate	
Cotinine	Cocaine		PCP	
Ecstasy	Heroin Metabolite			
Ethyl Alcohol	Methadone		More OFT under development	
Ethyl Glucuronide**	Methadone Metabolite			
Fentanyl**	Opiate			
Methadone				
Methadone Metabolite				
Opiate				
Oxycodone				
PCP				
PPX				

^{*} Coming soon

^{**} For International and Criminal Justice, Forensic use only



Indiko and Indiko Plus are fully automated bench top analyzers for drug monitoring 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 barcoded 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 120 uL) and reagents (2 to 240 uL) 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 Indiko Specialty Chemistry Systems

The same of the sa		
Indiko System 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 ± 10%, 50 - 60 Hz, ± 5%, 250 W	
Average Noise Level at 1 meter	< 60 dB (A)	
Deionized Water Consumption	1.5 liters/hour	
Environmental Conditions	Operating temperature range 18 to 30 °C, humidity 40 - 80% (non condensing)	
	Confirms with CAN/CSA-C22.2 No. 61010-1-04	
Regulatory	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 µL	
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 μL	
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 μL	
Reagent Containers	10 mL and 20 mL vials	
Sample & Reagent Dispensing	CV ≤ 2% for volumes ≥ 2 µL	
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)	

Catalog Number	Description	
98630000	Indiko	
98631000	Indiko with ISE**	
98640000 Indiko Plus		
98641000 Indiko Plus with ISE**		
PC accessories ordered based on geographic area		

^{**} For International use only - not for sale in USA

Indiko Plus System Specifica	Indiko Plus System Specifications					
Capacity	Up to 350 tests per hour for 1 reagent assays, approximately 200 tests per hour for 2 reagent assays					
Dimensions & Weight	37 in / 94 cm (W) x 27.6 in / 70 cm (D) x 24.4 in / 62 cm (H), 51 in / 130 cm (H) with cover open, 242 lbs / 110 kg					
Power Supply	100 - 240 V ± 10%, 50 - 60 Hz, ± 5%, 250 W					
Average Noise Level at 1 meter	< 60 dB (A)					
Deionized Water Consumption	2.5 liters/hour					
Environmental Conditions	Operating temperature range 18 to 30 °C, humidity 40 - 80% (non condensing)					
	Confirms with CAN/CSA-C22.2 No. 61010-1-04					
Regulatory	FDA clearance, 510(k) number: k110035 (Indiko 98360000)					
	98/79/EC IVD MD Directive					
Filter Rate	340 - 700 nm					
Measurement Temperature	37 ℃					
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 µL					
Samples & Reagents						
Sample On-board Capacity	54 Samples, - 9-position sample rack; maximum 6					
Sample Volume Size	2 - 120 μL					
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					
Sample Dispensing	CV ≤ 2% for volumes ≥ 2 µL					
Reagent Volumes	2- 240 µL					
Reagent Containers	10 mL and 20 mL vials, reagent rack with 42 reagent positions					
Sample & Reagent Dispensing	CV ≤ 2% for volumes ≥ 2 μL					
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 (10,800 pcs)
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
SP06662	Reagent rack	3 pcs
SP06666	Sample rack	6 pcs
984030	Washing solution 4.5%	4 x 20 mL
981712	Tubing maintenance solution	6 x 20 mL
10017332	Sample tubes 13 x 75 mL	1000/pk
10017331	Nesting cups 1 mL	1000/pk





Omni Controls







General Chemistry QC Serum Protein / Immunology QC

consolidated into: Omni•CORE

MAS Omni•CARDIOTM

Thermo Scientific™ MAS® Omni • CARDIO consolidates a comprehensive cardiac marker panel with the new generation of STAT analytes including D-Dimer, hCG, Myeloperoxidase and Procalcitonin. Value assignment is provided for key instrument systems including Abbott Architect, Beckman Coulter Access, AU and UniCel systems, Ortho Clinical Diagnostics VITROS, Roche Cobas and Elecsys systems and Siemens Advia, Dimension, Dimension Vista, Immulite and Stratus systems.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix	
OCRD-UL	Ultra Low				
OCRD-L	Low	6 x 3 mL Assayed	36 months @ -25 to -15 °C		
OCRD-101	1		15 days @ 2-8 °C (for BNP-32, CK-MB, D-Dimer,		
0CRD-202	2		Proc		Human Serum
OCRD-303	3				Procalcitonin, Total CK, Troponin-I and Troponin-T)
OCRD-MP	Tri-Level Multi-Pack (2 vials each level 1/2/3)		10 days @ 2-8 °C (for Myoglobin and NT-proBNP)	10 days @ 2-8 °C (for Myoglobin and NT-proBNP)	

Analytes

Beta Human Chorionic Gonadotropin (b-hCG) Brain Natriuretic Peptide-32 (BNP-32) Creatine Kinase (CK) Creatine Kinase-MB (CK-MB) D-Dimer

Digitoxin
High Sensitivity C-Reactive Protein (hsCRP)
Human Chorionic Gonadotropin (hCG)
Myeloperoxidase (MPO)
Myoglobin

N-Terminal Brain Natriuretic Peptide (NT-proBNP) Procalcitonin (PCT) Troponin I Troponin T

MAS Omni•IMMUNE™

Thermo Scientific MAS Omni•IMMUNE & Omni•IMMUNE PRO Controls provide consolidation for routine immunoassay, tumor marker and specialty immunoassay QC processing into a single product, offering three distinct levels. Value assignment is provided for key integrated instrument systems including Abbott Architect, Beckman Coulter Access and UniCel, Ortho Clinical Diagnostics Vitros, Roche Cobas and Elecsys systems and Siemens Centaur, Dimension, Dimension Vista and Immulite.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
OIM-101	1		00	
0IM-202	2	6 x 5 mL Assayed	36 month shelf life @ -25 to -15 °C 30 days open vial @ 2 to 8 °C	Human Serum
OIM-303	3		oo dayo opon viai @ 2 to 0 0	

Analytes

See list on opposite page under MAS Omni•IMMUNE PRO

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.

Dropper Tips - Pkg 100 - MAS P/N 286-606

MAS Omni•IMMUNE PRO™

Thermo Scientific MAS Omni•IMMUNE PRO Control provides Anti-Thyroglobulin (Anti-Tg), Anti-Thyroid Peroxidase (Anti-TPO) and Sex Hormone Binding Globulin (SHBG), in addition to the same analyte panel provided in the MAS Omni•IMMUNE product.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
OPRO-101	1	6 x 5 mL Assayed	36 month shelf life @ -25 to -15°C	
OPRO-202	2		30 days open vial @ 2 to 8°C	Human Serum
OPRO-303	3		OU days open viai S 2 to 0 0	

Analytes

17-OH-Progesterone	DHEA Sulfate	Lithium	Sex Hormone-Binding Globulin (SHBG) (PRO)
25-OH-Vitamin D	Digoxin	Lutenizing Hormone (LH)	Testosterone
Acetaminophen	Disopyramide	N-acetylprocainamide (NAPA)	Theophylline
Adrenocorticotropic Hormone (ACTH)	Estradiol	Parathyroid Hormone (PTH)	Thyroglobulin
Aldosterone	Estriol, Free	Phenobarbital	Thyroid Uptake (T-Uptake)
Alpha-fetoprotein	Ethosuximide	Phenytoin	Thyroid-Stimulating Hormone (TSH)
Amikacin	Ferritin	Phenytoin, Free	Thyroxine-Binding Globulin (TBG)
Anti-Thyroglobulin (Anti-Tg) (PRO)	Folate (vitamin B9)	Pregnancy Associated Plasma Protein (PAPP-A)	Thyroxine, Free (FT4)
Anti-Thyroid Peroxidase (Anti-TPO) (PRO)	Follicle Stimulating Hormone (FSH)	Primidone	Thyroxine, Total (TT4)
Beta Human Chorionic Gonadotropin (b-hCG)	Fructosamine*	Procainamide	Tobramycin
Beta-2-microglobulin	Gastrin	Procalcitonin	Tricyclic Antidepressants (TCA)
C-Peptide	Gentamicin	Progesterone	Triiodothyronine, Free (FT3)
CA 125	Growth Hormone	Prolactin	Triiodothyronine, Total (TT3)
CA 15-3	Human Chorionic Gonadotropin (hCG)	Prostate Specific Antigen, Free (FPSA)	Valproic Acid
CA 19-9	IGF-1 (insulin-like growth factor 1)	Prostate Specific Antigen, Total (TPSA)	Valproic Acid, Free
Carbamazepine	Immunoglobulin E (IgE)	Prostatic Acid Phosphatase (PAP)	Vancomycin
Carcinoembryonic Antigen (CEA)	Insulin*	Quinidine	Vitamin B12
Cortisol	Lidocaine	Salicylate	

^{*} 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 Omni•CORE™

Thermo Scientific MAS Omni•CORE Control consolidates general chemistry and serum protein QC processing into a single product, offering three distinct levels. Value assignment is provided for key integrated instrument systems, including Abbott Architect, Beckman Coulter AU, Synchron and UniCel, Ortho Clinical Diagnostics Vitros, Roche Cobas and Elecsys systems and Siemens Advia, Dimension and Dimension Vista.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix	
OCR-101	1	6 x 5 mL Assayed	36 month shelf life @ -25 to -15 °C		
0CR-202	2		6 x 5 mL Assayed	6 x 5 mL Assayed	30 days open vial @ 2 to 8 ℃
OCR-303	3		(Bilirubin is 15 days open vial @ 2 to 8 °C)		

Analytes

Acetaminophen Alanine Aminotransferase (ALT) Albumin Alkaline Phosphatase (ALP) Alpha-1-Acid Glycoprotein Alpha-1-Antitrypsin Alpha-2-Macroglobulin Amikacin Amylase Amylase (pancreatic) Antistreptolysin O (ASO) Apolipoprotein A1 Apolipoprotein B Aspartate Aminotransferase (AST) Beta-2-Microglobulin Bile Acids Bilirubin, Conjugated Bilirubin, Direct (DBIL) Bilirubin, Neonatal Bilirubin, Unconjugated Blood Urea Nitrogen (BUN)	C3 Complement C4 Complement C4 Complement Caffeine Calcium Carbamazepine Carbon Dioxide (CO2) Ceruloplasmin Chloride Cholesterol Copper Cortisol Creatine Kinase (CK) Creatinine Digoxin Disopyramide Ethanol Ethosuximide Ferritin Gamma-Glutamyl Ttransferase (GGT) Gentamicin Glucose Haptoglobin	Immunoglobulin A (IgA) Immunoglobulin E (IgE) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Iron Iron Binding Capacity (IBC) Iron Binding Capacity, Total (TIBC) Iron Binding Capacity, Unsaturated (UIBC) Lactate Dehydrogenase (LDH) Lactic Acid LDL Cholesterol Lidocaine Lipase Lipase Lipoprotein(a) Lithium Magnesium Methotrexate N-acetylprocainamide (NAPA) Osmolality Phenobarbital Phenytoin Phospholipids	Potassium Prealbumin Primidone Procainamide Pseudocholinesterase (PCHE) Quinidine Rheumatoid Factor Salicylate Sodium Theophylline Thyroid Uptake (T-Uptake) Thyroid-Stimulating Hormone (TSH) Thyroxine, Total (TT4) Tobramycin Total Protein Transferrin Tricyclic Antidepressants (TCA) Triglycerides Uric Acid Valproic Acid Vancomycin Zinc
Blood Urea Nitrogen (BUN)	Haptoglobin	Phospholipids	Zinc
C-Reactive Protein (CRP)	HDL Cholesterol	Phosphorus	

Thermo Scientific MAS Serum Chemistry Controls



MAS chemTRAK® • H

This is a comprehensive multi-analyte control, designed to monitor general chemistry and TDM methods. Available in an assayed or unassayed format. Both formats are liquid, ready-to-use and no additional preparation is required. Assayed values are available for most major platforms.

Part Number	Level	Bottles & Size	Storage & Stability*	Matrix				
CHA-1	1	G v E ml						
CHA-2	2	6 x 5 mL Assayed	00					
CHA-3	3		30 month shelf life @ -25 to -15 °C 14 days open-vial @ 2 to 8 °C; unassayed	Human Serum				
CHU-1	1	10 x 15 mL Unassayed	10 v 15 ml	10 v 15 ml	10 v 15 ml	10 v 15 ml	7 days open-vial @ 2 to 8 °C; anassayed	Human Serum
CHU-2	2		7 days open-vial @ 2 to 0 0, assayed					
CHU-3	3	Ullassayeu						

Analytes

Acetaminophen Alanine Aminotransferase (ALT) Albumin Alkaline Phosphatase Amikacin Amylase Amylase (Pancreatic) Apolipoprotein A Apolipoprotein B Aspartate Aminotransferase (AST) Bilirubin Unconjugated Bilirubin, Conjugated Bilirubin, Neonatal Bilirubin, Neonatal Bilirubin, Total (TBIL) Blood Urea Nitrogen (BUN) C3 Complement* C4 Complement* C4 Complement* Caffeine Calcium Carbamazepine	Carbon Dioxide (CO2) Chloride Cholesterol Creatine Kinase (CK) Creatinine Digoxin Disopyramide Ethanol Ethosuximide Ferritin* Gamma-Glutamyl Transferase Gentamicin GLDH* Glucose Haptoglobin* HBDH* HDL Cholesterol Immunoglobulin A (IgA)* Immunoglobulin G (IgG)* Immunoglobulin M (IgM)* Iron	Iron Binding Capacity, Total (TIBC) Iron Binding Capacity, Unsaturated (UIBC)* Lactate Dehydrogenase (LDH) Lactic Acid LDL Cholesterol Lidocaine Lipase Lipoprotein (a) Lithium Magnesium Methotrexate N-acetylprocainamide (NAPA) Osmolality Phenobarbital Phenytoin Phosphorus Potassium Prealbumin Primidone	Procainamide Pseudocholinesterase Quinidine Salicylate Sodium Theophylline Thyroid Stimulating Hormone Thyroid Uptake (T-Uptake) Thyroxine, Free (FT4)* Thyroxine, Total (TT4) Tobramycin Total Protein Transferrin* Tricyclic Antidepressants Triglycerides Triiodthyronine, Free (FT3)* Triiodthyronine, Total (TT3)* Uric Acid Valproic Acid Vancomycin
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Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.

^{*} 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 Alcohol/Ammonia

An assayed, bi-level control for monitoring ethanol and ammonia levels in serum. This ready-to-use product is packed in convenient multipacks and has been assayed for most major instruments. Normal Ammonia values in Level 1.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
AAC-MP	Bi-level, Multi-Pack	6 x 3.5 mL	24 month shelf life @ 2 to 8 °C 30 days open-vial @ 2 to 8 °C	Human Serum

Analytes

Ammonia Ethanol

MAS Bilirubin

This assayed, tri-level control has been designed to monitor the performance of total, direct, conjugated, unconjugated and neonatal bilirubin. There are no additional preparation steps required for this liquid, ready-to-use product. An elevated Bilirubin is included in level 3 for neonatal applications.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
BC101	1		24 month shelf life @ 2 to 8 °C	
BC102	2	6 x 5 mL	14 days open-vial @ 2 to 8 °C	Bovine Serum
BC103	3		when stored in the dark	

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.

Analytes

Bilirubin, Conjugated Bilirubin, Direct (DBIL) Bilirubin, Neonatal Bilirubin, Total (TBIL) Bilirubin, Unconjugated

Dropper Tips - Pkg 100 - MAS P/N 286-606



Thermo Scientific MAS

Urine Chemistry Controls

MAS UA Control

A bi-level control that is liquid and ready-to-use with improved room temperature storage capability. This urine control was designed for monitoring urine dipstick and microscopic components and is assayed for most major reagent strips and strip systems. It includes ten commonly tested dipstick tests plus Microalbumin, Creatinine and hCG.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
UAB-115	1	6 x 15 mL		
UAB-160	(normal)	4 x 60 mL	24 month shelf life @ 2 to 8 °C	
UAB-215	2	6 x 15 mL	Open Vial:	Human
UAB-260	(abnormal)	4 x 60 mL	Refrigerated 3 months @ 2 to 8 °C	Urine
UAB-MP	Bi-level, Multi-Pack	6 x 15 mL	Room temperature 6 weeks @ 18 to 25 °C	

Analytes

Bilirubin Osmolality
Blood pH
Creatinine Potassium
Crystals Protein

Glucose Protein-to-creatinine ratio
Human Chorionic Red Blood Cells
Operate tracia (1909)

Gonadotropin (hCG)

Ketones
Specific Gravity
Leukocyte Esterase
Urobilinogen
Microalbumin
White Blood Cells

Nitrite

MAS UA DipTube

MAS UA product packed into convenient dip tubes to simplify manual testing of urinalysis strips.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
UAT-MP	Bi-level, Multi-Pack	10 x 12 mL	24 months shelf life @ 2 to 8 °C Open Vial: Refrigerated 8 weeks or 20 dips @ 2 to 8 °C Room temp 2 weeks or 10 dips @ 18 to 30 °C	Human Urine

MAS Urinalysis

A bi-level urine control designed for monitoring urine dipstick and microscopic components. This liquid control is assayed for most major reagent strips and strip systems.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
024222	1	4 x 15 mL	12 month shelf life @ 2 to 8 °C	
024225	(abnormal)	4 x 60 mL	30 days open-vial @ 2 to 8 °C	Human
024224	3	4 x 15 mL	18 month shelf life @ 2 to 8 °C	Urine
024227	(normal)	4 x 60 mL	30 days open-vial @ 2 to 8 °C	

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.

Analytes

Bilirubin Osmolality
Blood pH
Creatinine Potassium
Crystals Protein

Glucose Protein-to-creatinine ratio

Human Chorionic Red Blood Cells
Gonadotropin (hCG) Sodium

Ketones Specific Gravity
Leukocyte Esterase Urobilinogen

Microalbumin White Blood Cells

Nitrite

Nitrite

Osmolality

Analytes

Bilirubin
Blood
Creatinine
Crystals
Glucose
Human Chorionic Gonadotropin (hCG)
Ketones
Leukocyte Esterase
Microalbumin

pH Potassium Protein Red Blood Cells Sodium Specific Gravity Urobilinogen White Blood Cells

Dropper Tips - Pkg 100 - MAS P/N 286-606



Sentry Urine Dipstick Control

Ideal for use outside the clinical laboratory where refrigerated storage isn't always available. The Sentry Urine Dipstick Control offers 12 months room temperature stability for an immediate, ready to use urinalysis strip control. Suitable for Mutistix, Chemstrips, Diascreen and other urinalysis strips as well as automated strip readers. Supplied in two levels, normal and abnormal.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
URN5005	Bi-level, Multi-Pack	4 x 25 mL	18 months shelf life 2 to 8 °C 12 months open-vial @ room temperature	Synthetic

Analytes

Bilirubin
Blood
Glucose
Human Chorionic Gonadotropin (hCG)
Leukocytes
Ketones

Microalbumin Nitrite pH Protein Specific Gravity Urobilinogen

MAS UrichemTRAK®

UrichemTRAK is designed to quantitatively monitor the most commonly tested urine chemistry analytes. This liquid, assayed control is ready-to-use, requires no additional preparation and the non-azide formulation will not interfere with ISEs. It includes general chemistry, physical properties and hCG tests.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
UR11001	1	6 x 15 mL		
UR22002	2		24 month shelf life @ 2 to 8 °C	Human
UR-MP	Bi-level, Multi-Pack		opened and unopened	Urine

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.

Dropper Tips - Pkg 100 - MAS P/N 286-606

Analytes

Amylase
Calcium
Chloride
Cortisol
Creatinine
Glucose
Human Chorionic Gonadotropin (hCG)
Magnesium
Microalbumin
Osmolality

pH Phosphorus Potassium Sodium Specific Gravity Total Protein Urea Nitrogen Uric Acid



Thermo Scientific MAS Immunoassay Controls

MAS Liquimmune®

Save time and extra costs associated with lot changes using the MAS Liquimune controls now with an extended shelf life. This multi-analyte immunoassay control is liquid based and designed to monitor immunoassay test procedures on automated instruments. Provides coverage of fertility, thyroid, iron deficiency, endocrine and allergy parameters. Assayed values are provided for major instrument systems.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
LIG-101	1		60 month shelf life @ -25 to -15 °C	
LIG-202	2	6 x 5 mL	90 days unopened @ 2 to 8 °C	Human Serum
LIG-303	3		30 days open-vial @ 2 to 8 °C	

Analytes

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

^{*} 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.

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.

Dropper Tips - Pkg 100 - MAS P/N 286-606



MAS PTH Control offers three distinct PTH levels for evaluation of automated PTH methods across the assay range. Provided in a liquid format for ease of use, the MAS PTH Control offers 10 days open vial stability when stored at 2-8 °C. Value assignment is provided for the key automated PTH methods available in today's clinical laboratory.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
PTH-MP	Tri-level Multipack	6 x 3 mL	24 months @ -25 to 15 °C 10 days open-vial @ 2 to 8 °C	Human Serum

Analytes

Parathyroid Hormone (PTH)

MAS PAR TDM

This liquid therapeutic drug control is a multi-analyte control with assayed values designed for therapeutic drugs and common immunoassay test procedures on most automated instruments. No additional preparation is required for this liquid, ready-to-use product that offers three significant levels.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
PTD1-1001	1		00	Day day a
PTD2-2002	2	6 x 5 mL	36 month shelf life @ 2 to 8 °C 30 days open-vial @ 2 to 8 °C	Bovine Serum
PTD3-3003	3		30 days open-viai @ 2 to 8 °C	Strulli

Analytes

Acetaminophen Phenobarbital Amikacin Phenytoin Caffeine Primidone Carbamazepine Procainamide Digoxin Quinidine Disopyramide Salicylate Estriol Theophylline

Ethanol Thyroid Stimulating Hormone (TSH)

Ethosuximide Thyroxine, Total (TT4) Gentamicin Tobramycin

Lidocaine Tricyclic Antidepressants Triiodthyronine, Total (TT3) Lithium

Methotrexate N-acetylprocainamide (NAPA)

Valproic Acid Vancomycin

MAS T-Marker

This liquid, assayed, multi-analyte control is designed to monitor performance of various cancer antigen tests on automated instruments, such as Abbott Architect®, Beckman Access/Dxl®, Ortho Vitros ECi®, Roche Modular Elecsys®, Siemens Advia Centaur® and Immulite®, and Tosoh AIA 600II[®]. No additional preparation steps are required for these ready-to-use products.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
TUM-101	1		36 month shelf life @ -25 to -15 °C 90 days unopened @ 2 to 8 °C 30 days open-vial @ 2 to 8 °C	
TUM-202	2	6 x 3 mL		Human Serum
TUM-303	3			Octum

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.

Dropper Tips - Pkg 100 - MAS P/N 286-606

Analytes

ACTH* Cortisol Aldosterone Alpha-Fetoprotein (AFP) Estradiol Beta Human Chorionic Ferritin Gonadotroopin (beta-hCG) Gastrin

Beta-2-Microglobulin CA 125 CA 15-3

CA 19-9 CA 27-29 CA 72-4

Calcitonin Carcinoembryonic Antigen (CEA) CyFRA 21-1*

Human Chorionic Gonadotroopin (hCG)

Insulin NSE* Prolactin

> Prostate Specific Antigen, Total (TPSA) Prostate Specific Antigen, Free (FPSA) Prostatic Acid Phosphatase (PAP)

Thyroglobulin

^{*} Not cleared by FDA. No claims can be made.



Cardiac & Diabetes Controls

MAS CardioImmune® • XL

This multi-analyte control is designed to monitor serum cardiac marker test methods. No additional preparation is required for this liquid, ready-to-use product. It offers four distinct levels, and is also available in a tri-level multipack.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
CAI-XLL	L	6 x 3 mL	36 month shelf life @ -25 to- 15 °C	
CAI-XL1	1		30 days open-vial @ 2 to 8 °C (for hsCRP, Digitoxin, Troponin I and Homocysteine)	
CAI-XL2	2			Human Serum
CAI-XL3	3		15 days open-vial @ 2 to 8 °C	numan serum
CAI-XL4	Tri-level Multi-Pack		for BNP32, Myoglobin (when a dropper tip is used), NT-proBNP, Troponin T, CK-MB	

Analytes

BNP 32 CK-MB Digitoxin Homocysteine C-Reactive Protein high sensitivity (hs-CRP) Myoglobin NT-pro BNP Troponin I Troponin T

MAS CardioImmune® Ultra Low

A single analyte control designed to challenge the low end sensitivity of the next generation high sensitivity Troponin assays.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
CAI-UL	UL	6 x 3 mL	36 month shelf life @ -25 to -15 °C 30 days open-vial @ 2 to 8 °C	Human Serum

Analytes

Troponin I

MAS Diabetes

This liquid assayed diabetes control is a bi-level control designed to monitor hemoglobin A1c methods. Assayed for most major instrument systems. The liquid, ready-to-use product requires no additional preparation.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
DBCL-MP	Bi-level Multi-Pack	6 x 1 mL	24 month shelf life @ -25 to -15 °C 60 days unopened @ 2 to 8 °C 30 days open-vial @ 2 to 8 °C	Human Whole Blood

Analytes

Hemoglobin A1c (HbA1c)

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.

Dropper Tips - Pkg 100 - MAS P/N 286-606



Thermo Scientific MAS Immunology & Protein Controls

MAS Immunology

This multi-analyte immunology liquid assayed control is designed to monitor the performance of various serum protein and serology test procedures including Antistreptolysin O, C-Reactive Protein, Prealbumin and Rheumatoid Factor. It is assayed for major instrument systems and is ready-to-use, requiring no additional preparation. Three levels provide monitoring of the full assay range.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
IC-101	1	6 x 3 mL		
IC-202	2		24 month shelf life @ 2 to 8 °C 30 days open-vial @ 2 to 8 °C	Human Serum
IC-303	3			

Analytes

Albumin
Alpha-1-Antitrypsin
Alpha-2-Macroglobulin
Antistreptolysin O
Antithrombin III
Apha-1-Acid-Glycoprotein
Apolipoprotein A-1*
Apolipoprotein B*
Beta-2-Microglobulin
C-Reactive Protein (CRP)
C3 Complement
C4 Complement
Ceruloplasmin

Ferritin*
Haptoglobin
Immunoglobulin A (IgA)
Immunoglobulin E (IgE)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Kappa Light Chain
Lambda Light Chain
Prealbumin
Properdin Factor B
Rheumatoid Factor (RF)
Total Protein
Transferrin

MAS CSF

This assayed, bi-level control is designed to monitor the performance of quantitative and manual chemical analysis of human cerebrospinal fluid. Multiple oligoclonal bands are present in Level 2. Assayed for major instrument systems as well as for cellulose acetate and agarose gel electrophoresis. These products are liquid, ready-to-use and require no additional preparation.

	Part Number	Level	Bottles & Size	Storage & Stability	Matrix
	CSF-MP	Bi-level,	6 x 3.5 mL	24 month shelf life @ 2 to 8 °C	Human Serum
		Multi-Pack	U X J.J IIIL	30 days open-vial @ 2 to 8 °C	

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.
* 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.

Dropper Tips - Pkg 100 - MAS P/N 286-606

Analytes

Albumin
Alpha-1-Globulin
Alpha-2-Globulin
Beta-Globulin
Chloride
Gamma-Globulin
Glucose
Glutamine
Immunoglobulin A (IgA)*
Immunoglobulin G (IgG)*
Immunoglobulin M (IgM)*
Lactate Dehydrogenase (LDH)

Lactic Acid Oligoclonal Bands Potassium Prealbumin Sodium Total Protein

Thermo Scientific MAS Toxicology Controls



MAS DOA TOTAL®

This multi-constituent urine toxicology control offers 19 analytes with 4 distinct levels at drug concentrations 25% below and above commonly used screening and SAMHSA* cutoffs. A drug-free level and high positive level are also available (6 levels total). The control is a liquid, ready-to-use product available for use on a variety of instrument platforms. Each level of control is individually packed which gives you the flexibility to choose your levels according to your drug screen panel cutoffs while keeping the number of control vials to a minimum.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
DOAT-1	1			
DOAT-2	2			
DOAT-3	3	C v 10 ml		Human Urine
DOAT-4	4	6 x 18 mL	24 month shelf life @ 2 to 8 °C 30 days open vial @ 2 to 8 °C	
DOAT-5	5			
DOAT-6	6			
DOAT-MP	Multi Pack	1 bottle per level, 18 mL each		

Analytes

11-nor-9-COOH-D9-THC
Benzoylecgonine
Buprenorphine
Cotinine
d-Methamphetamine
EDDP
Ethanol
Ethyl Glucuronide
LSD
Methadone

Methaqualone Morphine, free Nitrazepam Nortriptyline Oxazepam Oxycodone Phencyclidine Propoxyphene Secobarbital

MAS TOX Control

This multi-analyte control is developed for use with the Thermo Scientific MAS Toxicology immunoassays for the semi-quantitative measurement of barbiturates, benzodiazepine, and tricyclic antidepressants in either serum or plasma.

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
10011608	Multi-Pack 3 levels	6 x 5 mL	24 months shelf life @ 2 to 8 °C 20 days open vial @ 2 to 8 °C	Bovine Plasma

Analytes

Barbiturate (Secobarbital) Benzodiazepine (Diazepam) Tricyclic Antidepressants (Nortriptyline)

(for use with DRI Reagents)

Dropper Tips - Pkg 100 - MAS P/N 286-606

Thermo Scientific MAS

Quality Control Solutions for Vista

Designed for use with the Siemens Dimension Vista® instrumentation

Thermo Scientific MAS quality control products are available in vials specifically designed for use with the Siemens Dimension Vista® instrumentation. Fully validated onboard QC stability claims provide assurance that long-term quality assurance is maintained when performing routine quality control on the Dimension Vista instrument.

Nine individual Thermo Scientific MAS quality control products are available in a Dimension Vista specific format covering the instrument assay portfolio. Six vials are provided in each kit for convenience.

MAS Alcohol/Ammonia

	Part Number	Level	Bottles & Size	Storage & Stability	Matrix
	10014443	Bi-level,	6 x 2 mL	24 month shelf life @ 2 to 8 °C	Human Serum
		Multi-Pack	UXZIIIL	7 davs onboard instrument	

MAS CardioImmune®•XL

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
10014179	L			
10014180	1	G v O ml	36 month shelf life @ -25 to -15 °C 7 days onboard instrument	Human Serum
10014181	2	6 x 2 mL		
10014182	3			

Analytes

Ammonia Ethanol

Analytes

C-Reactive Protein high sensitivity (hsCRP) CK-MB Digitoxin Homocysteine Myoglobin NT-pro BNP Troponin I



Thermo Scientific MAS

Quality Control Solutions for Vista

MAS chemTRAK® • H

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
10014150	1	CvOm	30 month shelf life @ -25 to -15 °C 7 days onboard instrument	Human Serum
10014151	2	6 x 2 mL Assaved		
10014152	3	Assayeu		

Analytes

Acetaminophen

Alanine Aminotransferase (ALT)

Albumin

Alkaline Phosphatase

Amylase Apolipoprotein A Apolipoprotein B

Aspartate Aminotransferase (AST)

Bilirubin Direct (DBIL) Bilirubin Total (TBIL) Blood Urea Nitrogen (BUN)

C3 Complement* C4 Complement*

Calcium Carbamazepine Carbon Dioxide (CO2)

Chloride Cholesterol

Creatine Kinase (CK) Creatinine

Digoxin Ethanol Ferritin*

Gamma-Glutamyl Transferase (GGT)

Gentamicin Glucose Haptoglobin HDL Cholesterol Immunoglobulin A (IgA)*

Immunoglobulin G (IgG)* Immunoglobulin M (IgM)*

Iron Binding Capacity, Total (TIBC) Lactate Dehydrogenase (LDH)

Lactic Acid LDL Cholesterol Lidocaine

Lipase Lithium Magnesium

N-acetylprocainamide (NAPA)

Phenobarbital Phenytoin Phosphorus

Potassium

Prealbumin Procainamide

Pseudocholinesterase

Salicylate Sodium Theophylline

Thyroid Stimulating Hormone (TSH)

Thyroid Uptake (T-Uptake) Thyroxine, Free (FT4)* Thyroxine, Total (TT4) Tobramycin

Total Protein Transferrin*

Tricyclic Antidepressants

Trialvcerides

Triiodthyronine, Free (FT3)* Triiodthyronine, Total (TT3)*

Uric Acid Valproic Acid Vancomycin

MAS CSF

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
10014444	Bi-level, Multi-Pack	6 x 2 mL	24 month shelf life @ 2 to 8 °C 7 days onboard instrument	Human Serum

Analytes

Albumin	Immunoglobulin A (IgA)*	Lactate Dehydrogenase (LDH)	Prealbumin
Chloride	Immunoglobulin G (IgG)*	Lactic Acid	Sodium
Glucose	Immunoglobulin M (IgM)*	Potassium	Total Protein

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture. * These constituent levels have not been adjusted but are at levels



MAS Diabetes

	Part Number	Level	Bottles & Size	Storage & Stability	Matrix
	DBCL-V	Bi-level	6 x 2 mL	24 month shelf life @ -25 to -15 °C	Human Whole
L		Multi-Pack		7 days onboard instrument	Blood

Analytes

Hemoglobin A1c (HbA1c)

MAS Immunology

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
IC-V1	1		04 month shalf life @ 0 to 0 00	
IC-V2	2	6 x 2 mL	24 month shelf life @ 2 to 8 °C 7 days onboard instrument	Human Serum
IC-V3	3		r days onboard instrument	

Analytes

Albumin Alpha-1-Acid-Glycoprotein Alpha-1-Antitrypsin Alpha-2-Macroglobulin Antistreptolysin 0 (AS0) Apolioprotein A1*	Apolipoprotein B* Beta-2-Microglobulin C-Reactive Protein (CRP) C3 Complement C4 Complement	Ferritin* Haptoglobin Immunoglobulin A (IgA) Immunoglobulin E (IgE) Immunoglobulin G (IgG)	Kappa Light Chain Lambda Light Chain Prealbumin Rheumatoid Factor (RF) Total Protein Transferrin
Apolipoprotein A1*	Ceruloplasmin	Immunoglobulin M (IgM)	Iransferrin

MAS Liquimmune®

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
10013876	1		CO month shalf life @ OF to 1500	
10013877	2	6 x 2 mL	60 month shelf life @ -25 to -15 °C 7 days onboard instrument	Human Serum
10013878	3		r days onboard instrument	

Analytes

Gentamicin	Phenobarbital	Thyroxine, Free (FT4)
Homocysteine	Phenytoin	Thyroxine, Total (TT4)
Human Chorionic Gonadotropin (beta-HCG)	Procainamide	Tobramycin
Immunoglobulin A (IgA)	Prolactin	Tricyclic Antidepressants
Immunoglobulin E (IgE)	Prostate Specific Antigen (PSA)	Triiodthyronine, Free (FT3)
Immunoglobulin G (IgG)	Prostate Specific Antigen Free (FPSA)	Triiodthyronine, Total (TT3)
Immunoglobulin M (IgM)	Salicylate	Valproic Acid
Lidocaine	Testosterone	Vancomycin
Lithium	Theophylline	Vitamin B12
Lutenizing Hormone (LH)	Thyroid Stimulating Hormone (TSH)	
N-acetylprocainamide (NAPA)	Thyroid Uptake (T-Uptake)	
	Homocysteine Human Chorionic Gonadotropin (beta-HCG) Immunoglobulin A (IgA) Immunoglobulin E (IgE) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Lidocaine Lithium Lutenizing Hormone (LH)	Homocysteine Phenytoin Human Chorionic Gonadotropin (beta-HCG) Procainamide Immunoglobulin A (IgA) Prolactin Immunoglobulin E (IgE) Prostate Specific Antigen (PSA) Immunoglobulin G (IgG) Prostate Specific Antigen Free (FPSA) Immunoglobulin M (IgM) Salicylate Lidocaine Testosterone Lithium Theophylline Lutenizing Hormone (LH) Thyroid Stimulating Hormone (TSH)

MAS UrichemTRAK®

Part Number	Level	Bottles & Size	Storage & Stability	Matrix
10014127	Bi-level, Multi-Pack	6 x 2 mL	24 month shelf life @ 2 to 8 °C 7 days onboard instrument	Human Urine

Analytes

Amylase Calcium Chloride	Creatinine Glucose Magnesium	Phosphorus Potassium Sodium	Total Protein Urea Nitrogen Uric Acid
Chloride Cortisol	Magnesium Microalbumin	Sodium	Uric Acid
COLUSO	MICIOAIDUITIII		

Refer to package insert for specific analyte and stability claims. Shelf life starts from the date of manufacture.
* 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.



Used in conjunction with the Thermo Scientific™ MAS™ quality controls, LabLink xL offers a 100% web-based quality assurance solution comprised of four integrated modules:

- 1. LabLink xL Web (interlaboratory QC program)
- 2. LabLink xL Communicator (fully and semi-automated QC data transfer from instrument, LIS or middleware)
- 3. LabLink xL Daily (day-to-day QC analysis)
- 4. LabLink Extra (online access to package inserts and other documents)

FEATURES	BENEFITS
Fully web based	 Instant access to your QC data, anytime and anywhere
	 Immediate access to reports and comparative peer data for improved troubleshooting turnaround time
QC data is processed in real-time	Early detection of shifts, trends and system errors in quality system
	No monthly cutoff dates - your QC data submission is never late
Peer comparison to a worldwide peer group	 Participation in an interlaboratory QC program helps meet requirements as specified by local regulatory agencies and accreditation organizations.
	Provides added assurance and certainty in EQA and proficiency testing results.
User friendly screen layout and intuitive to use	 Setting up your laboratory's LabLink xL account for data submission is quick and simple
	One-on-one training is offered to new users
Available in multiple languages	Convenience of navigating the website in your local language

LabLink xL Web is an interlaboratory QC program that offers an external perspective on your internal day-to-day QC.

• 100% Real-time data processing

- QC data that is submitted is immediately included with the peer statistics and available for peer comparison

Simple to setup

- Fully web-based therefore no software to install
- Instrument, QC and tests configured within minutes

• Easy data entry by day or month with shift option

Superior reporting capabilities

- Real-time report generation
- Reports generated on-demand showing the latest up to the minute peer comparison data
- Basic and complex statistical calculations and indices provided for cumulative and current months data
- Mean
- Standard Deviation Index (SDI)
- SD
- Coefficient of Variation Index (CVI)
- CV
- Various inter and intralaboratory reports available for review
- Reports built on-line in PDF format
- Interactive reports with e-signature capabilities

• Instant access to worldwide peer groups

• Comparison of QC data across affiliate laboratories

- QC submission by affiliate laboratories can be conveniently managed by the Laboratory Manager or QC Coordinator
- Separate affiliate comparison and exception reports are available

• Each user has their own unique login credentials

- Locally defined access privileges
- Accessibility determined by the Laboratory Manager



LabLink xL Daily

LabLink xL Daily is a fully integrated module of the LabLink xL quality assurance solution which allows laboratories to perform routine QC day-to-day performance verification and maintain stringent quality control by employing multi-rule QC procedures.

- Integrated module within LabLink xL
- Web-based application for daily QC comparison
 - No software to install
- Option to setup Westgard and Rilibäk multi-rule criteria for QC performance tracking
- Advanced reporting and review features
 - Interactive Levey-Jennings plotting tool provides a single screen for QC review and approval
 - Interactive QC Exclusion report for quick review and convenient commenting
- Option to setup and evaluate non-MAS QC products
- Real-time data processing / report production
 - Allowing for immediate review of QC data and performance check against Westgard Rule criteria

LabLink Extra

LabLink Extra is an online information portal that works in unison with the LabLink xL Quality Assurance Program providing easy access to package inserts and other support documentation for QC products manufactured by Thermo Scientific.

- Instant access to package inserts, MSDS's and Certificates of Analysis
- Receive product updates and Rilibäk updates via e-mail
- Additional information on QC related topics such as QC handling quidelines

LabLink xL Communicator

Option for both semi-automated or fully-automated connectivity for the transfer of QC data from laboratory instrument, LIS and middleware to LabLink xL.

- Completely integrated module within LabLink xL
 - Easy and efficient installation and setup completed remotely by the LabLink xL support organization
- Upload data from instrument, LIS or middleware
- Hassle free automatic upload
 - Eliminates QC transcription error
 - No manual data entry is necessary
 - Saves time and reduces cost
- Real-time transfer of QC data
 - Instantaneous access to data in LabLink xL
 - Immediate comparison, review and approval of QC data

LabLink xL Cloud Communicator

An enhancement of the existing LabLink communicator module. The LabLink xL Cloud Communicator offers fully automated connectivity for the real-time transfer of QC data from Data Innovations Instrument Manager[™] to LabLink xL.

MAS LabLink xL Modules

Part Number	Module
LLXLW	LabLink xL Web
LLXLC	LabLink xL Communicator
LLXLDM	LabLink xL Daily
LLXLF	LabLink xL Auto-Connectivity License Fee (Annual)
LLXLFA	LabLink xL Auto-Connectivity License Fee - For Affiliate Labs (Annual)

Thermo Scientific MAS

QC Value Assignment Program



Value assignment is an important requirement when rolling over to a new lot of QC material. The ability to provide full coverage of instrument target values involves the partnership of Thermo Fisher Scientific with laboratories performing the required testing. Without involvement of these external laboratories, the ability to provide value assignment coverage is significantly reduced.

Thermo Fisher Scientific is actively looking for new laboratories that are willing to assist with MAS® QC Value Assignment in return for monetary compensation or free QC products. The results received from the participating laboratories are used to establish QC ranges in the lot specific package inserts for the MAS Quality Controls.

Testing Guidelines

- Each new lot of QC will utilize a different group of value assignment partner laboratories as participants are not required to test every QC lot.
- Advance notification of when to expect samples will be sent out prior to testing.
- Instructions for testing and data entry forms are sent with all value assignment samples.
- Most tests are run in duplicate over three separate days.
- All testing must to be completed within 4-6 weeks of receiving the samples.

Compensation Options

- Monetary: This is typically based upon a flat fee per data point plus reagent costs. As this
 varies between test systems and methods, there is no standard amount. The different
 reimbursement options will be discussed prior to product shipment.
- Free of charge MAS QC product: This is based upon the number of tests and MAS
 products being value assigned. Free QC product is given at the discretion of your sales
 representative. Further details will be provided by a member of the value assignment team.

Participation Requirements

- CLIA certification or equivalent local accreditation.
- A completed W-9 form (US only).
- A completed survey noting instruments and testing capabilities.

Steps to follow if you are interested in participating in the MAS Value Assignment Program

- **Step 1:** Complete the form below.
- **Step 2:** Fax this page to +1 510-771-1539 or e-mail to MGC-VA@thermofisher.com.
- **Step 3:** A value assignment introduction pack will be sent via mail or e-mail. Please complete the forms and return to us.
- **Step 4:** Once the introduction pack is received, a member of the value assignment team will notify you to discuss acceptance into the program and the different methods of compensation.

Lab Name:		
Lab Address:		
Contact Name:	Alternate Contact:	
Phone Number:	Fax Number:	
E-mail:	Accreditation #:	
Fax to: +1 510-771-1539		
E-mail to: MGC-VA@thermofisher.com	n	



Thermo Scientific MAS **References**

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Analyte	Alcohol/Ammonia	Bilirubin	Cardiolmmune•XL	chemTRAK∙H	CSF	Diabetes	DOA TOTAL	Immunology	Liquimmune	Omni•CARDIO	Omni•CORE	Omni•Immune	Omni•Immune PRO	PAR TDM	PTH Control	Sentry Urine Dipstick Control	TOX Control	T-Marker	UA Control	UA Dip Tube	Urinalysis	UrichemTRAK	Vista Alcohol/Ammonia	Vista Cardiolmmune•XL	Vista chemTRAK•H	Vista CSF	Vista Diabetes	Vista Immunology	Vista Liquimmune	Vista UrichemTRAK
17-OH-Progesterone									•			•	•																	П
25-OH-Vitamin D												•	•																	
Acetaminophen				•					•		•	•	•												٠				•	
Acid Phosphatase				•																										
Adrenocorticotropic Hormone				_								•	•																	
Albumin (BCG)				•	•			•			•							_							•	•		•		
Albumin (BCP)				*				•			•														•	Ė				
Aldosterone								-	•		•	•	•		\vdash															
Alkaline Phosphatase (ALP)				•					Ť		•	_	_						\vdash						•					
alpha-1- Acid Glycoprotein				Ť				•			*														Ť			•		
alpha-1-Antitrypsin								•			•				\vdash													•		
alpha-2-Macroglobulin								*			*																	•		
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alpha-Fetoprotein (AFP)									•			•	•					•											•	\vdash
Aldosterone	_											•	•																	
Alanine Aminotransferase (AST)				•							•														•				_	
Amikacin				•					•		•	•	•	•																
Amitriptyline				•										•																
Ammonia	•																						•							
Amphetamines							•																						_	<u> </u>
Amylase				•							•											•			•					•
Amylase (Pancreatic)				•							•																			L
Antistreptolysin O (ASO)								•			•																	•		L
Anti-Thyroglobulin (anti-Tg)													•																	
Anti-Thryroid Peroxidase (anti-TPO)													•																	
Antithrombin III								•																						
Apolipoprotein A1				٠				•			٠														٠					
Apolipoprotein B				٠				•			•														٠					
Appearance																			•	•	*									
Aspartate Amonitransferase (ALT)				•							•														•					
Barbiturates							٠										٠													
Benzodiazepines							•		٠			•	•				٠													
beta-2-Microglobulin								•			•	•	•					•										٠		
Human Chorionic Gonadotropin (beta-hCG)									*	٠		•	•					•											٠	
Bile Acids											*																			
Bilirubin, Conjugated		•		٠							•																			
Bilirubin, Direct		٠		٠							•														٠					
Bilirubin, Neonatal		•		•							*																			
Bilirubin, Total		•		•							•														٠					
Bilirubin, Unconjugated		•		•							•																			
Bilirubin, Urine																•			•	•	•									
BNP 32			•							•										-	*									
Blood Urea Nitrogen (BUN)				•						Ė	•				\vdash										•					

^{◆ -} Analyte present.

 $[\]blacksquare$ - No claim is made for expected values or the stability of these constituents.

Page	51	51	56	50	57	56	58	57	54	48	49	48	49	55	55	53	58	55	52	52	52	53	59	59	60	60	61	61	61	61
Analyte	Alcohol/Ammonia	Bilirubin	Cardiolmmune•XL	chemTRAK•H	CSF	Diabetes	DOA TOTAL	Immunology	Liquimmune	Omni•CARDIO	Omni•CORE	Omni•Immune	Omni•Immune PRO	PAR TDM	PTH Control	Sentry Urine Dipstick Control	TOX Control	T-Marker	UA Control	UA Dip Tube	Urinalysis	UrichemTRAK	Vista Alcohol/Ammonia	Vista Cardiolmmune•XL	Vista chemTRAK•H	Vista CSF	Vista Diabetes	Vista Immunology	Vista Liquimmune	Vista UrichemTRAK
Buprenorphine		П					•																						$\overline{}$	
C-Peptide												•	•																	
C-Reactive Protein (CRP)			•					•			•													•				•		
C3 Complement			<u> </u>	•				•			•																	•		
C4 Complement				•				•			•																	•		\vdash
CA 15-3				Ť				Ť			Ť	•	•					•							-			Ť		\vdash
	-											•	•					•												
CA 19-9	\vdash											_	•												_		_		_	
CA 27-29																		•											_	
CA 72-4	-											-						•											_	
CA 125												•	•					•												
Caffeine				•							•			•																
Calcitonin																		•												
Calcium				•							•											•			•					•
Cannabinoids (THC)							•																							
Carbamazepine				•					•		•	•	•	•											•				•	
Carbamazepine (Free)														•																
CEA (carcinoembryonic antigen)									•			•	•					•											•	
Ceruloplasmin								•			•																	•		
Chloramphenicol									•																				•	
Chloride				•	•						•											•			•	•				•
Cholesterol	\vdash			•	i i						•											•			•					Ė
	\vdash			•						•	•														•					
Creatine Kinase (CK)			•	•					•		_													•	Ť				•	
CK-MB	-		•						•	•														•	_				•	
Carbon Dioxide (CO2)	-			•							•														•				_	
Cocaine (Benzoylecgonine)							•																							
Color																			•	•	•									
Cortisol	_								•		•	•	•					•				•								•
Cotinine							•																							
Copper											•																			
Creatinine				•							•								•	•	•	•			•					•
Crystals																			•	•	•									
CYFRA 21-1																		•												
d-Dimer										•																				
d-Methamphetamine							•																							
Diazepam																	•													
DHEA-Sulfate									•			•	•																	
Digitoxin			•						Ė	•		Ė	Ť											•						
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Digoxin																									+				_	
Disopyramide	-			•					•		•	•	•	•											_		_			
EDDP (Methadone Metabolite)	-						•					_													_				_	
Estradiol	_								•			•	•					•											•	
Estriol	_													•																L
Estriol (Free)												•	•																	

^{◆ -} Analyte present.

^{■ -} No claim is made for expected values or the stability of these constituents.

Thermo Scientific MAS **References**

Page	51	51	56	50	57	56	58	57	54	48	49	48	49	55	55	53	58	55	52	52	52	53	59	59	60	60	61	61	61	61
Analyte	Alcohol/Ammonia	Bilirubin	Cardiolmmune•XL	chemTRAK•H	CSF	Diabetes	DOA TOTAL	Immunology	Liquimmune	Omni•CARDIO	Omni•CORE	Omni•Immune	Omni•Immune PRO	PAR TDM	PTH Control	Sentry Urine Dipstick Control	TOX Control	T-Marker	UA Control	UA Dip Tube	Urinalysis	UrichemTRAK	Vista Alcohol/Ammonia	Vista Cardiolmmune•XL	Vista chemTRAK•H	Vista CSF	Vista Diabetes	Vista Immunology	Vista Liquimmune	Vista UrichemTRAK
Ethanol	•			•			•																							
Ethanol Ethyl Glucuronide (EtG)							•																							
Ferritin				•				•	•		٠	٠	•					•							•			•	•	
Folate (Vitamin B9)									٠			٠	•																٠	
Fructosamine												•	•																	
FSH (folicle stimulating hormone)									٠			٠	•																٠	
Gastrin												٠	•					•												
Gentamicin				•					•		•	•	•	•											•				•	
Gamma-Glutamyl Transferase (GGT)				•							٠														•					
Globulins					•																					•				
Glucose				•	•						•					•			•	•	•	•			•	•				•
Haptoglobin				•				•			•														•			•		
Human Chorionic Gonadotropin (hCG)									٠	•		٠	٠			٠		•	•	•	•	٠								
HDL Cholesterol				•							•														•					
Hemoglobin (Urine Test)																•			•	•	•									
Hemoglobin A1c (HbA1c)						•																					•			
Homocysteine			•						٠			٠	•											•					٠	
hsC-Reactive Protein (hsCRP)										٠																				
Human Growth Hormone									٠			٠	•																	
Imipramine				•							٠																			
Immunoglobulin A (IgA)				•	•			•	•		٠														•	•		•	•	
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IGF-1 (insulin-like growth factor 1)												٠	•																	
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Lactate Dehydrogenase (LDH)				•	•						٠														•	٠				
LDL Cholesterol				•							٠														•					
Leukocyte Esterase																•			•	•	•									
Lidocaine				•					•		٠	٠	٠	•											•				•	
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Lipoprotein (a)				•							٠																			
Lithium				•					•		٠	٠	٠	•											•				•	
LSD							•																							

^{◆ -} Analyte present.

^{■ -} No claim is made for expected values or the stability of these constituents.

Magy results Magy	Page	51	51	56	50	57	56	58	57	54	48	49	48	49	55	55	53	58	55	52	52	52	53	59	59	60	60	61	61	61	61
Magnetism	Analyte	Alcohol/Ammonia	Bilirubin	Cardiolmmune•XL	chemTRAK•H	CSF	Diabetes	DOA TOTAL	Immunology	Liquimmune	Omni•CARDIO	Omni•CORE	Omni•Immune	Omni•Immune PRO	PARTDM	PTH Control	Sentry Urine Dipstick Control	TOX Control	T-Marker	UA Control	UA Dip Tube	Urinalysis	UrichemTRAK	Vista Alcohol/Ammonia	Vista Cardiolmmune **XL	Vista chemTRAK•H	Vista CSF	Vista Diabetes	Vista Immunology	Vista Liquimmune	Vista UrichemTRAK
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^{◆ -} Analyte present.

^{■ -} No claim is made for expected values or the stability of these constituents.

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Analyte	Alcohol/Ammonia	Bilirubin	CardioImmune•XL	chemTRAK∙H	CSF	Diabetes	DOA TOTAL	Immunology	Liquimmune	Omni•CARDIO	Omni•CORE	Omni•Immune	Omni•Immune PRO	PAR TDM	PTH Control	Sentry Urine Dipstick Control	TOX Control	T-Marker	UA Control	UA Dip Tube	Urinalysis	UrichemTRAK	Vista Alcohol/Ammonia	Vista Cardiolmmune•XL	Vista chemTRAK•H	Vista CSF	Vista Diabetes	Vista Immunology	Vista Liquimmune	Vista UrichemTRAK
Pseudocholinesterase (PCHE)				•							•														•					
Quinidine				•					•		•	•	•	•																
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Secobarbital							•										•													
Sex Hormone Binding Globulin (SHBG)													٠																	
Sodium				•	•						•								•	•	•	•			•	•				•
Specific Gravity																٠			•	•	•	•								
Testosterone									•			•	•																•	
Thyroid Uptake (T-Uptake)				•					•		•	•	•												•				*	
Triiodothyroxine, Total (TT3)				•					•			•	•												•				*	
Triiodothyroxine, Free (FT3)				•					•			٠	•												•				•	
Thyroxine, Total (TT4)				•					•		•	٠	•												•				•	
Thyroxine, Free (FT4)				•					•			٠	•												•				•	
TBG (Thyroxine-Binding Globulin)												٠	•																	
Theophylline				•					•		•	•	•	•											•				•	
Thyroglobulin									•			•	•					•												
Iron Binding Capacity, Total (TIBC)				•							•																			
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Total Protein				•	•			•			•					•			•	•	•	•			•	•		•		•
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Tricyclic Antidepressants				•					•		•	•	•	•			•								•				•	
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Thyroid Stimulating Hormone (TSH)				•					•		•	•	•	•											•				•	
Iron Binding Capacity, Unsaturated (UIBC)				•							•																			
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White Cells (Urine Test)																			•	•	•									
Zinc											•																			

^{◆ -} Analyte present.

^{■ -} No claim is made for expected values or the stability of these constituents.

Page	51	51	56	50	57	56	58	57	54	48	49	48	49	55	55	53	58	55	52	52	52	53	59	59	60	60	61	61	61	61
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Instrument	Alcohol/Ammonia	Bilirubin	Cardiolmmune•XL	chemTRAK•H	CSF	Diabetes	DOA TOTAL	Immunology	Liquimmune	Omni•CARDIO	Omni•CORE	Omni•Immune	Omni•Immune PRO	PAR TDM	PTH Control	Sentry Urine Dipstick Control	TOX Control	T-Marker	UA Control	UA Dip Tube	Urinalysis	UrichemTRAK	Vista Alcohol/Ammonia	Vista Cardiolmmune•XL	Vista chemTRAK•H	Vista CSF	Vista Diabetes	Vista Immunology	Vista Liquimmune	Vista UrichemTRAK
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^{◆ -} Analyte present.

 $[\]blacksquare$ - No claim is made for expected values or the stability of these constituents.

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Instrument	Alcohol/Ammonia	Bilirubin	Cardiolmmune•XL	chemTRAK∙H	CSF	Diabetes	DOA TOTAL	Immunology	Liquimmune	Omni•CARDIO	Omni•CORE	Omni•Immune	Omni•Immune PRO	PAR TDM	PTH Control	Sentry Urine Dipstick Control	TOX Control	T-Marker	UA Control	UA Dip Tube	Urinalysis	UrichemTRAK	Vista Alcohol/Ammonia	Vista Cardiolmmune•XL	Vista chemTRAK•H	Vista CSF	Vista Diabetes	Vista Immunology	Vista Liquimmune	Vista UrichemTRAK
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Instrument	Alcohol/Ammonia	Bilirubin	Cardiolmmune•XL	chemTBAK•H	CSF	Diabetes	DOA TOTAL	Immunology	Liquimmune	Omni•CARDIO	Omni•CORE	Omni•Immune	Omni•Immune PRO	PAR TDM	PTH Control	Sentry Urine Dipstick Control	TOX Control	T-Marker	UA Control	UA Dip Tube	Urinalysis	UrichemTRAK	Vista Alcohol/Ammonia	Vista Cardiolmmune•XL	Vista chemTRAK•H	Vista CSF	Vista Diabetes	Vista Immunology	Vista Liquimmune	Vista UrichemTRAK
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Instrument	Alcohol/Ammonia	Bilirubin	Cardiolmmune•XL	chemTRAK•H	CSF	Diabetes	DOA TOTAL	DOA-XSE	Immunology	Liquimmune	Omni•CARDIO	Omni•CORE	Omni•Immune	Omni•Immune PRO	PAR TDM	PTH Control	Sentry Urine Dipstick Control	TOX Control	T-Marker	UA Control	UA Dip Tube	Urinalysis	UrichemTRAK	Vista Alcohol/Ammonia	Vista Cardiolmmune•XL	Vista chemTRAK•H	Vista CSF	Vista Diabetes	Vista Immunology	Vista Liquimmune	Vista UrichemTRAK
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Thermo Electron Pocketchem																				٠	•	٠									

^{◆ -} Analyte present.

Aeroset™, Architect™ and AxSYM™: Abbott Laboratories, Abbott Park, IL

Access®, AU® Series, Immage®, CX/LX®, ICON®, ICON 11/25/20®, SYNCHRON® UniCel Dxl® and UniCel DxC®: Beckman Coulter Inc., Brea, CA

DiaSTAT®, D-10® and Variant/Variant® II: Bio-Rad Laboratories, Hercules, CA

Biovation®: Biovation Inc., Hercules, CA

SPAplus®; The Binding Site Group Ltd, Birmingham, UK

Add after Biovation in the list above

Fisherbrand®, UriSystem® and Sure-Vue®: Fisher Scientific, Pittsburgh, PA

CONTRAST II $\! \! \mathbb{R}$, OSOM $\! \! \! \mathbb{R}$ and Signify $\! \! \! \! \mathbb{R}$: Genzyme Corp. Cambridge, MA

DiaScreen® 10 and DiaScreen® 50: Hyoguard, Minneapolis, MN

iChem100® and IQ200®: International Remote Imaging Systems Inc., Chatsworth, CA

Vitros®, Vitros® ECi, Vitros 5,1 FS and Vitros 5600®: Ortho Clinical Diagnostics, Rochester, NY

QuickVue® and UrinQuick™: Quidel Corporation, San Diego, CA

Cobas 6000[™], Elecsys®, Hitachi® Series, Cobas Integra®, Modular Analytics E170, Criterion 1/11®, CUA/SUA, MiniUA®, Chemstrip 101®, Urisys 1100/1800®, Urisys 2400 and Micral®: Roche Diagnostics, Indianapolis, IN

ACETEST®, Advia Centuar®, Advia 1650/2400®, Atlas®, BNA/BN II™, BN ProSpec™, Clinitek Series®, Clinitest®, DCA 2000®, Dimension®, Dimension® VISTA, Dimension® Xpand, Ictotest®, Immulite®/Immulite®200, Microbumintest®, Status® and Stratus® CS: Siemens Healthcare Diagnostics, Los Angles, CA; Glasgow, DE; and Tarrytown, NY

AIA® Series, A1c 2.2 Plus and G7/G8: Tosoh Medics Inc., S. San Francisco, CA

URISCAN (Visual), URISCAN Pro II, URISCAN Optima II, URISCAN Mini, URISCAN Super: YD Diagnostics Corp. Songpa-ku, Seoul, Korea

A1CNow®: Bayer Healthcare, Tarrytown, NY.

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e-mail: sales.diagnostics.fmt@thermofisher.com

Technical Service & Support

In most cases, technical assistance is available, 24 hours a day, 7 days a week.

Phone: 1-800-232-3342- press 2 for technical service options

For non-urgent inquiries:

e-mail: LabLink Support - lablink.qap@thermofisher.com

MAS - mas.controls@thermofisher.com

CEDIA, DRI, QMS and Instrumentation - techservice.mgc@thermofisher.com

International: For International Service & Support: - contact your local sales office. Refer to back page for contact information.

Terms

Payment: Payment terms are NET 30 days. Payment is expected within 30 days from the date of the invoice. Thermo Fisher Scientific

reserves the right to require payment in advance, C.O.D., credit card or otherwise modify credit terms.

Prices: Prices are subject to change without notice.

Shipment: Shipping terms are Free on Board (FOB) shipping point. Customer is responsible for transportation costs from our facility to

customer facility; freight is prepaid, then billed on invoice. Transfer of ownership occurs when the shipment leaves our facility.

Damaged Goods: Be sure to inspect your shipment immediately upon arrival. Please notify the Thermo Fisher Scientific Customer Service

Department of any product discrepancy or damage within 10 working days of shipment receipt.

Product Claims: Failure to use the product as set forth in the product labeling and application sheets can affect performance.

NOTE: Sales are subject to the other terms and conditions on Thermo Fisher Scientific invoice. All sales are final. Returned products

require a Return Materials Authorization and may be subject to a Restocking Fee. Call Thermo Fisher Scientific prior to

returning any material.

The value of innovation A history of quality

Product availability may vary by country.

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