

A blue-tinted molecular structure background with spheres and connecting lines, overlaid on a white background with a hexagonal pattern on the left and right sides.

Small Molecule Drugs Monitoring

 1-631-624-4882 (USA) 44-161-818-6441 (Europe)

 1-631-938-8221

 info@creative-diagnostics.com

 45-1 Ramsey Road, Shirley, NY 11967, USA

What is Therapeutic Drug Monitoring?

Therapeutic drug monitoring (TDM) is generally defined as the clinical laboratory measurement of a chemical parameter that, with appropriate medical interpretation, will directly influence drug prescribing procedures. Otherwise, TDM refers to the individualization of drug dosage by maintaining plasma or blood drug concentrations within a targeted therapeutic range or window.

Performing TDM requires a multidisciplinary approach. The process assumes that there is a definable relationship between dose and plasma or plasma drugs concentration and between concentration and therapeutic effect. TDM begins with the first prescription of a drug and involves determining an initial dosage regimen appropriate for the clinical condition and patient characteristics such as age, weight, organ function, and concomitant medication. Factors that need to be considered when interpreting concentration measurements include sampling times associated with drug dose, dose history, patient response, and desired drug goals. The amount of certain prescription drugs in the blood is a serious health problem for both patients and health care workers. By detecting the concentration of the drug in the patient's blood, the doctor can monitor and adjust the prescribed dose to help ensure the safety and effectiveness of the drug. In addition, doctors can also guide drug use by detecting the amount of drug in the urine.

The TDM Process

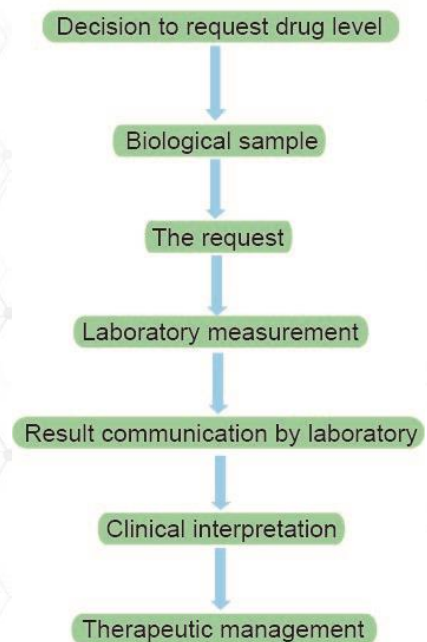
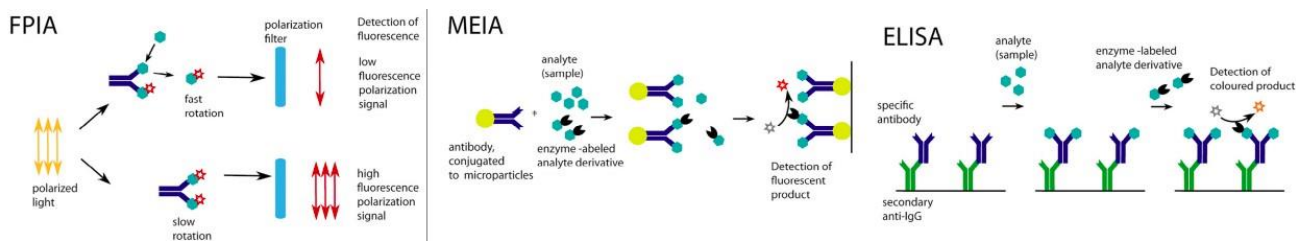


Figure 1. The process of therapeutic drug monitoring.

The Methods Applied in Small Molecule Drugs Monitoring



Historically, drug testing laboratories developed their assay procedures using a variety of analytical methods ranging from radioimmunoassay to high-performance liquid chromatography (HPLC) procedures. Currently however, the vast majority of drug assays performed in the clinical setting are some variant of commercially available immune-binding assay procedures. The most commonly used procedures are fluorescence polarization immunoassay (FPIA), enzyme immunoassay (eg. MEIA), and enzyme-linked immunosorbent assay (ELISA).

■ Blood test

Blood testing is the older of methods and typically involves a preliminary screening test using enzyme-linked immunosorbent assay (ELISA) technology that combines the specificity of the antibody with the enzyme or antigen and the enzyme that is readily assayed. The sensitivity of a simple enzyme assay performed in conjunction. This makes it possible to detect very low levels of drugs in solutions such as whole blood, serum, urine and tissues. The results of ELISA assays were confirmed and quantified by gas chromatography/mass spectrometry (GC/MS), and their unique drug separation chromatography and mass spectrometry were used for identification and quantification, which is considered as the gold standard for drug detection. The biggest benefit of blood tests is that it has a small margin of error. In addition, the level of drug found in a person's blood sample is directly related to the current dose in his or her body. Therefore, reports found at the level of quantification can be used to accurately calculate the current drug dose in the body.

■ Urine drug test

The drug can be filtered through the blood in just a few hours, even if the patient follows the blood monitoring program, it can lead to negative results. For these reasons, urine drug testing is the doctor's favorite choice. Screening for a variety of different substances using immunoassays or ELISA, including alcohol, amphetamine, barbitol, benzodiazepine, cannabinoids, cocaine, fentanyl, methadone, opioids, benzocycline and propoxyphene. Although a urine test is not as effective as a blood test, it can determine whether a drug is present in the body system.

Therefore, clinical treatment requires the monitoring kits to guide the use of these drugs. Creative Diagnostics provides highly sensitive and cost-effective therapeutic drug conjugates and antibodies for multiple applications. We also offer customized services, which can assist customers to achieve their immunoassay development.

Which Therapeutic Drugs Should Be Under Monitoring?

Related Products

Drug Function	Drug	Cat. No.	Product Name	
Antiepileptic	Eslicarbazepine Acetate	DAG-WZ001A	Eslicarbazepine Acetate [BSA]	
	Lacosamide	DAG-WZ004A	Lacosamide [BSA]	
	Lamotrigine	DAG-WZ005A	Lamotrigine [BSA]	
	Oxcarbazepine	DAG-WZ007A	Oxcarbazepine [BSA]	
	Rufinamide	DAG-WZ010A	Rufinamide [BSA]	
	Tiagabine	DAG-WZ011A	Tiagabine [BSA]	
	Carbamazepine		DAG-WZ3100O	Carbamazepine [OVA]
			DAG1166	Carbamazepine [HRP]
			DAGA-347B	Carbamazepine [BSA]
			DAGA-347K	Carbamazepine [KLH]
			DMABT-54912MC	Anti-Carbamazepine monoclonal antibody, clone DB2
			DMAB3100	Anti-Carbamazepine monoclonal antibody, clone C3213M
			CABT-L2305	Anti-Carbamazepine monoclonal antibody, clone H42345N
		DPAB27690	Sheep Anti-Carbamazepine polyclonal antibody	
	Clonazepam		DAG-WZ102O	Clonazepam [OVA]
			DAG2976	Clonazepam [BSA]
			DAGA-080H	Clonazepam [HRP]
			DAGA-098K	Clonazepam [KLH]
			HMABPY102	RHA™ anti-Clonazepam monoclonal antibody, clone CZP
			DPAB-WZ0011	Sheep Anti-Clonazepam polyclonal antibody
	Phenytoin		DAG-WZ4036O	Phenytoin [OVA]
			DAGA-356B	Phenytoin [BSA]
			DAGA-356H	Phenytoin [HRP]
		DAGA-356K	Phenytoin [KLH]	
		DMAB4063	Anti-Phenytoin monoclonal antibody, clone A303	
		DMAB4065	Anti-Phenytoin monoclonal antibody, clone A305	
		DMABT-54917MP	Anti-Phenytoin monoclonal antibody, clone QIZ2	
		DMABT-54918MP	Anti-Phenytoin monoclonal antibody, clone QIZ3	
		DMABT-Z60355	Anti-Phenytoin monoclonal antibody, clone3R3J4	
		DMABT-Z60465	Anti-Phenytoin monoclonal antibody, clone 35-404.3	
		DMABT-Z60466	Anti-Phenytoin monoclonal antibody, clone 37-602.3	
		DPATB-H82984	Rabbit Anti-Phenytoin polyclonal antibody	
		DPATB-H83000	Duck Anti-Phenytoin polyclonal antibody	
	DPABY-948	Sheep Anti-Phenytoin polyclonal antibody		

Drug Function	Drug	Cat. No.	Product Name
Antiepileptic	Valproic acid	DAG-WZ4990O	Valproic acid [OVA]
		DAGA-361K	Valproic acid [KLH]
		DAG3422	Valproic acid [BSA]
		DADA-361H	Valproic acid [HRP]
		DMAB4490	Anti-VPA monoclonal antibody, clone A802
		DMAB4491	Anti-VPA monoclonal antibody, clone A803
		DMAB4492	Anti-VPA monoclonal antibody, clone A804
		DMAB4496	Anti-VPA monoclonal antibody, clone A805
		DMAB4494	Anti-VPA monoclonal antibody, clone A806
		DPATB-H83276	Rabbit Anti-VPA polyclonal antibody
DAPT B-H83262	Rat Anti-VPA polyclonal antibody		
Analgesics	Acetaminophen	DAG-WZ3071O	Acetaminophen [OVA]
		DAG2957	Acetaminophen [BSA]
		DAGA-218K	Acetaminophen [KLH]
		DAGA-218H	Acetaminophen [HRP]
		DMAB-WZ0001	Anti-Acetaminophen monoclonal antibody
	DPBT-68240SA	Sheep Anti-Acetaminophen polyclonal antibody	
	Acetyl Salicylic Acid	DAG-WZ3990O	Acetyl Salicylic Acid [OVA]
		DAG3275	Acetyl Salicylic Acid [BSA]
		DAGA-219K	Acetyl Salicylic Acid [KLH]
		DMAB-WZ0002	Anti-Acetyl Salicylic Acid monoclonal antibody
DPAB-DC3947		Rat Anti-Acetyl Salicylic Acid polyclonal antibody	
DPAB3990	Rabbit Anti-Acetyl Salicylic Acid polyclonal antibody		
Analgesics	Morphine	DAG-WZ3925O	Morphine [OVA]
		DAGA-303B	Morphine [BSA]
		DAGA-303K	Morphine [KLH]
		DAG3140	Morphine [BTG]
		DAG1243	Morphine [HRP]
		DMAB3925	Anti-Morphine monoclonal antibody, clone CDI264
		DMAB3926	Anti-Morphine monoclonal antibody, clone CDI298
		DMAB3927	Anti-Morphine monoclonal antibody, clone CDI919
		DMABT-54866MM	Anti-Morphine monoclonal antibody, clone 005-20045
		DMAB7248	Anti-Morphine monoclonal antibody, clone C2811N
		DMABT-Z60416	Anti-Morphine monoclonal antibody, clone DFK375
		DCABY-626	Anti-Morphine monoclonal antibody, clone NP4B3
		DCABY-4769	Anti-Morphine monoclonal antibody, clone N2800Nps2
		DCABY-4770	Anti-Morphine monoclonal antibody, clone N2800Nps4
		DCABY-4771	Anti-Morphine monoclonal antibody, clone N2800Nps3
CABT-L1964	Anti-Morphine monoclonal antibody, clone C2679N		
DPBT-68280SM	Sheep Anti-Morphine (C-terminal) polyclonal antibody		
DPATB-H83407	Rabbit Anti-Morphine polyclonal antibody		
DPATB-H83005	Goat Anti-Morphine polyclonal antibody		

Drug Function	Drug	Cat. No.	Product Name	
Antineoplastic	Busulfan	DAG-WZ3219A	Busulfan [BSA]	
		DAG-WZ3219H	Busulfan [HRP]	
DAG-WZ3219O		Busulfan [OVA]		
CABT-L3219		Anti-Busulfan monoclonal antibody, clone 414		
DPAB-WZ0013		Sheep Anti-Busulfan polyclonal antibody		
Methotrexate	Methotrexate	DAG-WZ3635O	Methotrexate [OVA]	
		DAGB319	Methotrexate [HRP]	
		DAGA-351B	Methotrexate [BSA]	
		DAGA-351K	Methotrexate [KLH]	
		DMAB-WZ0004	Anti-Methotrexate monoclonal antibody	
		DPABY-912	Sheep Anti-Methotrexate polyclonal antibody	
		DPATB-H81809	Goat Anti-Methotrexate polyclonal antibody	
Cardiac Agent	Digoxin	DAG-WZ60352O	Digoxin [OVA]	
		DAG3043	Digoxin [BSA]	
		DAG3044	Digoxin [HRP]	
		DMABT-Z60352	Anti-Digoxin monoclonal antibody, clone 37R3E20	
		DMABT-Z60491	Anti-Digoxin monoclonal antibody, clone FK-34	
		CABT-L2334	Anti-Digoxin monoclonal antibody, clone 214	
		DPBT-68263SD	Sheep Anti-Digoxin polyclonal antibody	
		DPATB-H83095	Duck Anti-Digoxin polyclonal antibody	
		DPATB-H83405	Rabbit Anti-Digoxin polyclonal antibody	
		DPATB-H82992	Magic™ Anti-Digoxin polyclonal antibody	
	Amiodarone	DAG-WZ015A	Amiodarone [BSA]	
	Flecainide	DAG-WZ016A	Flecainide [BSA]	
	Lidocaine	Lidocaine	DAG-WZ60468O	Lidocaine [OVA]
			DAG1215	Lidocaine [HRP]
			DAGA-286B	Lidocaine [BSA]
DAGA-286K			Lidocaine [KLH]	
DMABT-Z60468			Anti-Lidocaine monoclonal antibody, clone 23-334.6	
DPATB-H82894	Sheep Anti-Lidocaine polyclonal antibody			
Immunosuppressive Agents	Ciclosporin	DAG-WZ017A	Ciclosporin [BSA]	
	Sirolimus	DAG-WZ018A	Sirolimus [BSA]	
	Mycophenolic Acid	Mycophenolic Acid	DAG-WZ3638O	Mycophenolic Acid [OVA]
			DAGA-352B	Mycophenolic Acid [BSA]
			DAGB317	Mycophenolic Acid [HRP]
			DAGA-352K	Mycophenolic Acid [KLH]
			DMAB-WZ0003	Anti-Mycophenolic Acid monoclonal antibody
	DPABY-919	Sheep Anti-Mycophenolic Acid polyclonal antibody		
	Tacrolimus	Tacrolimus	DAG-WZ4350O	Tacrolimus [OVA]
			DAGB304	Tacrolimus [HRP]
DMAB4350			Anti-FK-506 monoclonal antibody, clone C247M	
DPAB-DC4807			Sheep Anti-Tacrolimus polyclonal antibody	

Drug Function	Drug	Cat. No.	Product Name
Psychoactive Agents	Clozapine	DAG-WZ019A	Clozapine [BSA]
	Fluoxetine	DAG-WZ020A	Fluoxetine [BSA]
	Amitriptyline	DAG-WZ59178	Amitriptyline [OVA]
		DAG1019	Amitriptyline [HRP]
		DAGA-224B	Amitriptyline [BSA]
		DAGA-224K	Amitriptyline [KLH]
		DMABT-Z59177	Anti-Amitriptyline monoclonal antibody, clone 304
		DMABT-Z59178	Anti-Amitriptyline monoclonal antibody, clone 23-320.3
		DMABT-Z59179	Anti-Amitriptyline monoclonal antibody, clone 9.H.20
	DPABY-794	Sheep Anti-Amitriptyline polyclonal antibody	
	Haloperidol	DAG-WZ8647O	Haloperidol [OVA]
		DAG1164	Haloperidol [HRP]
		DAGA-271B	Haloperidol [BSA]
		DAGA-271K	Haloperidol [KLH]
DMAB8647		Anti-Haloperidol monoclonal antibody, clone G58U58	
DPAB27791		Sheep Anti-Haloperidol polyclonal antibody	
DPABY-053		Rabbit Anti-Haloperidol polyclonal antibody	
Analeptic	Theophylline	DAG-WZ4380O	Theophylline [OVA]
		DAG426	Theophylline [BSA]
		DAG3030	Theophylline [HRP]
		DAGA-360K	Theophylline [KLH]
		DMAB4380	Anti-Theophylline monoclonal antibody, clone C874M
		DMAB2217	Anti-Theophylline monoclonal antibody, clone A057-14003
		DMAB4381	Anti-Theophylline monoclonal antibody, clone A202
		DPAB27989	Sheep Anti-Theophylline polyclonal antibody
	DPBT-68291RT	Rabbit Anti-Theophylline polyclonal antibody	
	Caffeine	DAG-WZ3079O	Caffeine [OVA]
		DAG2971	Caffeine [BSA]
		DAG2972	Caffeine [HRP]
		DAG2973	Caffeine [HSA]
		DMAB3079	Anti-Caffeine monoclonal antibody, clone A9402
DMAB6135		Anti-Caffeine monoclonal antibody, clone N94129	
DMABT-Z59342	Anti-Caffeine monoclonal antibody, clone H3-R4D3I3		
CABT-B9001	Anti-Caffeine monoclonal antibody, clone IN576		
DPAB-WZ0012	Sheep Anti-Caffeine polyclonal antibody		

Drug Function	Drug	Cat. No.	Product Name
Addiction Therapeutics	Buprenorphine	DAG-WZ3069O	Buprenorphine [OVA]
		DAGF-179	Buprenorphine [BSA]
		DAGF-180	Buprenorphine [BTG]
		DAGA-232K	Buprenorphine [KLH]
		DAG419	Buprenorphine [HRP]
		DMAB3069	Anti-Buprenorphine monoclonal antibody, clone C2702N
		DMAB7623	Anti-Buprenorphine monoclonal antibody, cloneD54H56
		DCABY-4687	Anti-Buprenorphine monoclonal antibody, cloneN2800Cv2
		DPAB27686	Sheep Anti-Buprenorphine polyclonal antibody
	Methadone	DAG-WZ3910O	Methadone [OVA]
		DAG1229	Methadone [HRP]
		DAG3000	Methadone [BSA]
		DAGA-296K	Methadone [KLH]
		DCABY-4756	Anti-Methadone monoclonal antibody, clone N2800Ne2
		DCABY-4757	Anti-Methadone monoclonal antibody, clone N2800Ne3
		DMAB3910	Anti-Methadone monoclonal antibody, clone C2791N
		DMABT-54862MM	Anti-Methadone monoclonal antibody, clone NE2
		DMABT-54863MM	Anti-Methadone monoclonal antibody, clone Nfu 3B8
		DMAB7677	Anti-Methadone monoclonal antibody, clone D62H64
DPABY-903	Sheep Anti-MTD polyclonal antibody		
Antiretroviral	Amantadine	DAGA-031B	Amantadine [BSA]
		DAGA-034K	Amantadine [KLH]
		DAGA-027H	Amantadine [HRP]
		HMABPY034	RHA™ anti-Amantadine monoclonal antibody
	Ribavirin	DAGA-030B	Ribavirin [BSA]
		DAGA-026H	Ribavirin [HRP]
		DAGA-033K	Ribavirin [KLH]
		HMABPY033	RHA™ anti-Ribavirin monoclonal antibody, clone RBV
Antibiotics	Amikacin	DAG-P2530	Amikacin [BSA]
		DAG1018	Amikacin [HRP]
		CABT-L2530	Anti-Amikacin monoclonal antibody, clone AMK
		DCABY-630	Anti-Amikacin monoclonal antibody, clone BN2
		DPABY-792	Sheep Anti-Amikacin polyclonal antibody

Drug Function	Drug	Cat. No.	Product Name
Antibiotics	Gentamicin	DAG4468	Gentamicin [BSA]
		DAGA-043K	Gentamicin [KLH]
		DAGA-032H	Gentamicin [HRP]
		DMAB3403	Anti-Gentamicin monoclonal antibody, clone A104
		DMAB3404	Anti-Gentamicin monoclonal antibody, clone A103
		DMAB6614	Anti-Gentamicin monoclonal antibody, clone H5-10
		DMAB6615	Anti-Gentamicin monoclonal antibody, clone H11-18
		DMAB6616	Anti-Gentamicin monoclonal antibody, clone H17-33
		DMABT-54913MG	Anti-Gentamicin monoclonal antibody, clone HF2
		DMABT-54914MG	Anti-Gentamicin monoclonal antibody, clone HF3
		HMABPY043	RHA™ anti-Gentamicin monoclonal antibody, clone GM
	DPBT-68266SG	Sheep Anti-Gentamicin polyclonal antibody	
	Tobramycin	DAG3141	Tobramycin [BSA]
		DAG1317	Tobramycin [HRP]
		DAGA-213K	Tobramycin [KLH]
		DAG3141O	Tobramycin [OVA]
		DMAB4404	Anti-Tobramycin monoclonal antibody, clone A128-10053
		DPABY-999	Sheep Anti-Tobramycin polyclonal antibody
		DPATB-H82199	Goat Anti-Tobramycin polyclonal antibody
	Vancomycin	DAG3035	Vancomycin [BSA]
		DAGA-053K	Vancomycin [KLH]
		DAG3036	Vancomycin [HRP]
		DMABT-54924MV	Anti-Vancomycin monoclonal antibody, clone WBO2
		HMABPY054	RHA™ anti-Vancomycin monoclonal antibody, clone VM
		DMABT-Z60038	Anti-Vancomycin monoclonal antibody, clone 4H22
		CABT-LH054	Anti-Vancomycin monoclonal antibody, clone 30
		DPBT-68294RV	Sheep Anti-Vancomycin polyclonal antibody
DPAB0362	Rabbit Anti-Vancomycin polyclonal antibody		
Antifungals	Natamycin	DAGA-052B	Natamycin [BSA]
		DAGA-057K	Natamycin [KLH]
		DAGA-041H	Natamycin [HRP]
		HMABPY058	RHA™ anti-Natamycin monoclonal antibody

Drugs with unpredictable PK/PD relationship:

The dose of drug producing sub therapeutic response in one patient, yield toxic effect in another patient. The PD indices include plasma lipid level, blood glucose, blood pressure, plasma clotting time etc. which provides relationship between dose and plasma or blood drug concentration and pharmacodynamics effects. There is also wide inter patient variability in PK parameters, such as absorption, distribution, metabolism and excretion. There are differences in PK and PD of most drugs between adults and children. In children, sampling volume is limited. Therefore, highly sensitive analytical methods are required for the drug sample measurements.

Drugs which are toxic or ineffective:

The therapeutic drug used for monitoring could be either toxic or ineffective that can render the patient in a great risk.

Buprenorphine, for instance, is an opioid used to treat opioid addiction, acute pain, and chronic pain. Buprenorphine treatment carries the risk of causing psychological or physical dependence. Therefore, Buprenorphine need to be quantitated in blood or urine to monitor use or abuse, confirm a diagnosis of poisoning, or assist in a medicolegal investigation.

Table 1. Common Small Molecule drugs that need to be monitored

NAPA	Digoxin	Amikacin	Phenytoin
Methotrexate	Gentamicin	Quinidine	Tobramycin
Phenobarbital	Salicylic Acid	Theophylline	Valproic Acid
Acetaminophen	Carbamazepine	Mycophenolic Acid	Procainamide



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Contact Us



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45-1 Ramsey Road, Shirley, NY 11967, USA