

# Therapeutic Drug Monitoring (TDM) Laboratory Solution

**TDM**



Therapeutic drug monitoring is the use of modern advanced in vivo drug analysis technology, by monitoring the concentration of drugs and active metabolites in the patient's biological fluids, including whole blood, serum, plasma or urine. It can guide the formulation and adjustment of clinical rational drug use solution, so as to achieve the best therapeutic effect, ensure the effectiveness and safety of drug treatment, and provide valuable experiments for the diagnosis and treatment of drug overdose poisoning. Based on laboratory evidence, the clinical drug use has been improved from the traditional empirical model to a more scientific level.

- Homogeneous enzyme immuno assay method, suitable for biochemical analyzer, simple and fast determination;
- Comparison of reagent performance and CLIA reagent, good correlation.

### ● Clinical significance

Phenytoin is the first choice for anti-epileptic drugs. It has the best effect on grand mal seizures and is the first choice for grand seizures; it is second for simple or complex partial seizures. In addition, phenytoin can also be used to treat peripheral neuralgia and arrhythmia.

### ● Clinical symptoms of high phenytoin concentration

Concentration (µg/mL)	Clinical symptoms
>20	Tremors appear, liver function and kidneys are easily damaged
>30	Dyskinesia
>40	Coma

### ● Accuracy

	Level 1	Level 2
Mean	4.33	17.35
STD	0.08	0.29
CV	1.77%	1.65%
Target Value	4.00	16.00
Recovery	108.36%	108.46%
Bias	8.36%	8.46%

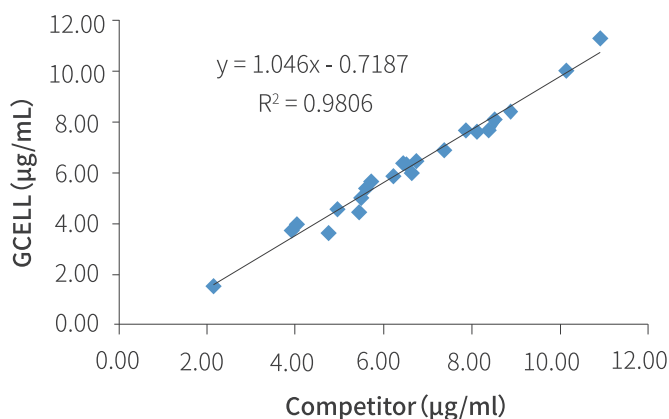
### ● Interference

	Conc. Tested	Bias
Conjugated bilirubin	30 mg/dL	1.91%
Unconjugated bilirubin	66 mg/dL	-1.94%
Hemoglobin	800 mg/dL	0.41%
RF	1166 IU/ml	1.49%
Human serum albumin	5 g/dL	-9.02%
	7.5 g/dL	-12.08%
IgG	12 g/dL	-9.41%
TG	1250 mg/dL	-2.97%

### ● Clinical significance

Carbamazepine is currently one of the most commonly used clinical antiepileptic drugs in pediatrics, and it is the first choice for the treatment of simple and complex partial seizures. Carbamazepine not only has anti-epileptic effects, but also has anti-peripheral neuralgia, anti-diuretic, anti-manic depression, anti-arrhythmia, alcoholic withdrawal syndrome, etc., and has a wide range of clinical applications.

### ● Correlation



### ● Interference

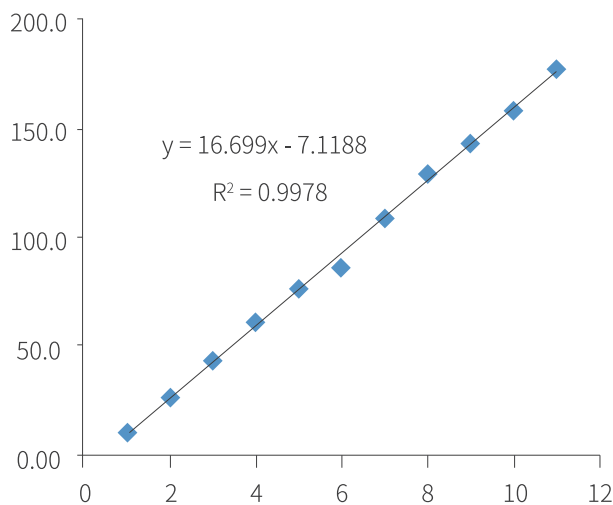
		Level 1	Level 2
Interfering substances	Control	4.17	10.18
		-	-
Human serum albumin	2.5 g/dl	4.12	10.08
	5.0 g/dl	4.17	9.92
	7.5 g/dl	4.25	9.78
	10.0 g/dl	4.23	9.62
RF	250 IU/ml	4.19	10.18
	500 IU/ml	4.26	10.17
	750 IU/ml	4.27	10.01
	1000 IU/ml	4.37	10.07
TG	429 mg/dl	4.15	9.91
	858 mg/dl	4.15	9.82
	1286 mg/dl	4.21	9.74
	1715 mg/dl	4.23	9.59

### ● Clinical significance

Valproic Acid can achieve ideal effects in the treatment of epilepsy, and its effective blood concentration is 50.0-100 µg/ml.

### ● Linearity

Linearity is [10, 150.0] µg/mL.



### ● Interference

	Replicate 1	Replicate 2	Mean	bias%
0.1M NaOH control	78.6	80.1	79.4	-1.6%
20 mg/dl Bilirubin	78.4	77.8	78.1	
0.1M NaOH control	78.7	77.3	78.0	-0.9%
30 mg/dl Bilirubin	76.7	77.9	77.3	
Water control	80.4	82.4	81.4	-2.3%
20 mg/dl Bilirubin unconjugated	79.7	79.4	79.6	
Water control	77.7	79.9	78.8	-1.7%
30 mg/dl Bilirubin unconjugated	76.8	78.1	77.5	
Water control	78.4	81.4	79.9	1.7%
800 mg/dl Hemoglobin	81.6	80.9	81.3	4.9%
1000 mg/dl Hemoglobin	83.4	84.2	83.8	
Water control	79.2	81.3	80.3	-3.7%
1000 mg/dl Intralipid	74.9	79.7	77.3	
Water control	76.3	75.5	75.9	-1.8%
2000 mg/dl Intralipid	75.4	73.6	74.5	

### ● Clinical significance

Cortisol plays an important role in the regulation of many important physiological processes, including energy metabolism, maintaining electrolyte and blood pressure balance, immune regulation, stress response, cell proliferation and differentiation, memory regulation and cognitive function

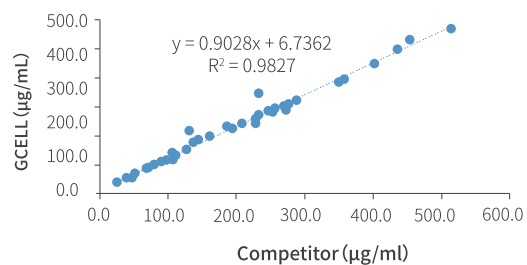
### ● Linearity

Linearity is [20, 750.0] ng/mL.

### ● Correlation

The correlation of a well-known brand(x) and Gcell(Y) is  $y = 0.9028x + 6.7362$ ,

$R^2 = 0.9827$ .



### ● Interference

Analyte	Concentration
Intralipid	0.5%
DBIL	20 mg/dL
Hemoglobin	500mg/dl
RF	500 IU/mL

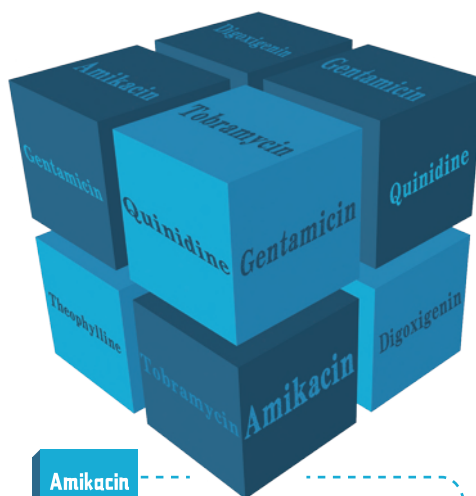
### Quinidine

Clinically, continuous oral quinidine can be used to treat and prevent atrioventricular arrhythmia. The drug has a narrow safety range and is prone to toxic reactions. Therefore, it is of great significance to monitor the blood concentration of this drug.

**The TDM List of biochemical platform (Homogeneous Enzyme Immunoassay Method) developed by BSBE is suitable for all kinds of biochemical analyzers to meet the needs of different customers.**

### Theophylline

Theophylline is mainly used for the prevention and treatment of bronchial asthma, apnea of premature infants, etc. Theophylline is one of the most frequently used drugs for TDM because the therapeutic effect and toxicity of theophylline are dependent on plasma concentration.



### Gentamicin and tobramycin

Gentamicin and tobramycin have a wide range of antibacterials, and have good clinical effects on infections caused by Gram-negative bacteria. Regular monitoring of blood concentrations can effectively prevent gentamicin and tobramycin. Ototoxicity and nephrotoxicity of tobramycin.

### Amikacin

It has a strong anti-G bacteria effect. Regular monitoring of blood drug concentration and individualized administration can effectively prevent amikacin's ototoxicity and nephrotoxicity.

### Digoxigenin

The main and most basic function of digitalis drugs is to enhance the contractility of the myocardium. It is a commonly used inotrope in clinical practice. It has a narrow therapeutic window and large individual differences. Its concentration monitoring plays a very important role in preventing drug poisoning. big effect.

## BSBE TDM Menu

Type	Description
Cardiac glycosides	● Digoxin, ■ Digoxigenin
Antiarrhythmic	■ Quinidine
Anti-epileptic	▲ Phenytoin, ● Phenobarbital, ▲ Valproic Acid, ▲ Carbamazepine
Immunosuppressant	■ Cyclosporine, ■ Tacrolimus, ■ Rapamycin, ■ Mycophenolic Acid
Asthma/Asthma	■ Theophylline
Antibiotic	■ Vancomycin, ■ Gentamicin, ■ Amikacin, ■ Tobramycin
Anti-cancer	● Methotrexate
Hormone	▲ Cortisol

Note: ▲ On sell ● Coming soon ■ Developing