Therapeutic drug monitoring

Siemens Healthineers provides a comprehensive portfolio of therapeutic drug monitoring (TDM) solutions to provide clinicians with essential tools to establish safe and effective drug treatments for every patient. Our wide range of TDM testing solutions help healthcare professionals determine and maintain appropriate drug concentrations for personalized therapy and enhanced patient care.

siemens-healthineers.com/TDM

SIEMENS Healthineers

Therapeutic drug monitoring

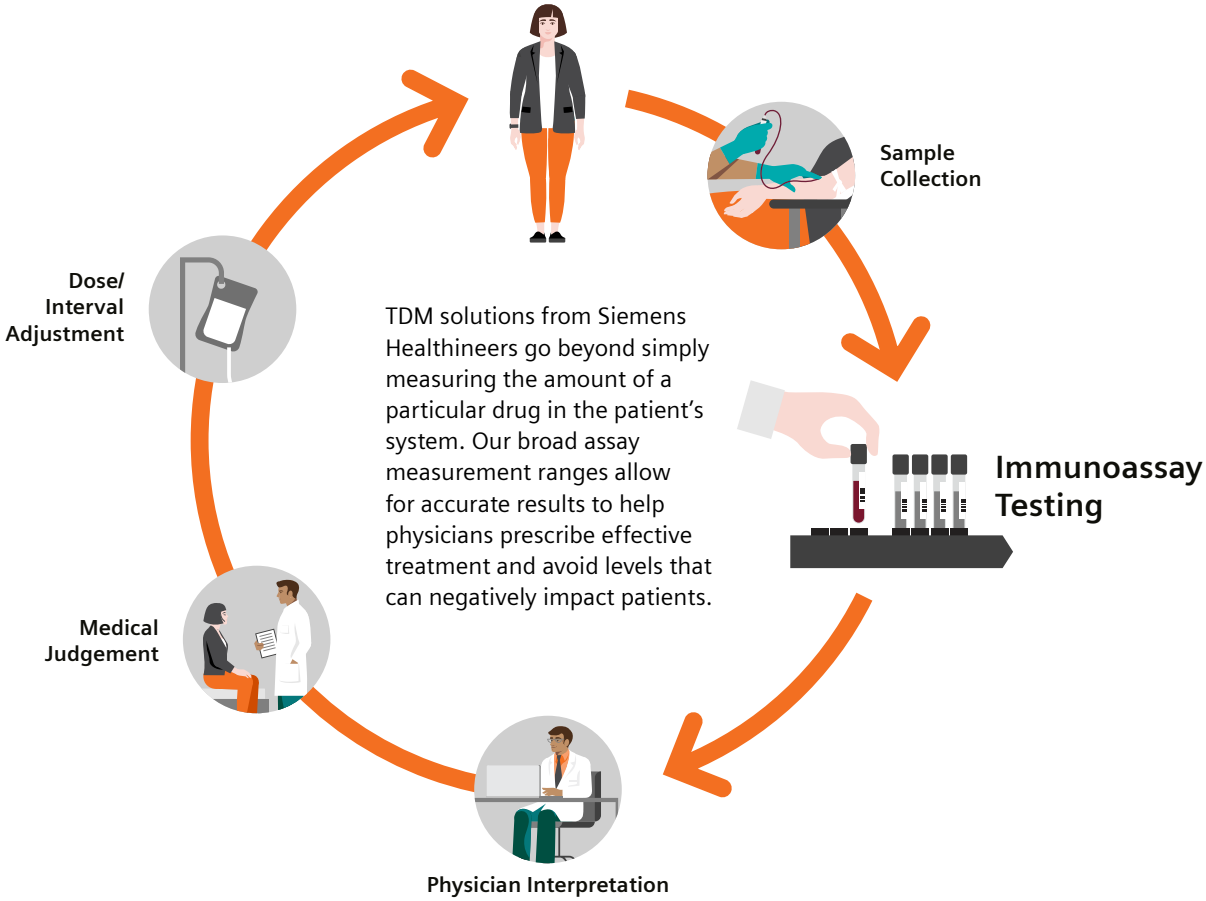
Personalized care starts with a test

Therapeutic drugs help millions of people manage numerous illnesses, disorders, conditions, and diseases. Therapeutic drug monitoring (TDM) helps physicians determine the best dosages for certain "hard-to-dose" medicines and enables long-term monitoring of therapeutic drug use. Further, it helps physicians to determine if changes in health, aging, or illness might require changes in dosing to keep a patient at an ideal dosage or "therapeutic dose level" and to avoid potential drug toxicity.

Accurate TDM testing is vital to successful patient outcomes by enabling:

- Maintenance of appropriate drug concentrations
- Identification of non-compliance
- Assessment of drug interactions
- Personalized dosage

The common classes of drugs used to monitor and ensure correct blood concentration include antiepileptics, antiarrhythmics, antimicrobials, antineoplastics, bronchodilators, and immunosuppressant drugs.



TDM solutions from Siemens Healthineers go beyond simply measuring the amount of a particular drug in the patient's system. Our broad assay measurement ranges allow for accurate results to help physicians prescribe effective treatment and avoid levels that can negatively impact patients.

Enhanced patient care through effective and safe drug therapy

Extensive TDM menu

Supports evolving needs of labs and testing facilities of all sizes.

Trusted EMIT technology

Allows for accurate results to support confident clinical decision-making.

Wide assay range

Provides fast, reliable analysis to achieve therapeutic efficacy for every patient.

Therapeutic Drug Monitoring menu		
Amikacin	Levetiracetam*	Sirolimus
Caffeine	Lidocaine	Tacrolimus
Carbamazepine	Methotrexate†	Theophylline
Cyclosporine	Mycophenolic Acid (MPA)‡	Tobramycin
Digoxin	N-Acetylprocainamide (NAPA)	Topiramate*
Disopyramide	Phenobarbital	Valproic Acid
Ethosuximide	Phenytoin	Vancomycin
Gabapentin*	Primidone	Voriconazole*
Gentamicin	Procainamide	Zonisamide*
Lamotrigine*	Quinidine	

**User-defined method*
†Available as user-defined method and EMIT assay.
‡Not available in the U.S.
Product availability may vary from country to country and is subject to local regulatory requirements.

Trusted EMIT technology

TDM assays from Siemens Healthineers combine the specificity and sensitivity of immunoassay with the convenient speed and reproducibility of enzyme measurements.

Our EMIT TDM assays utilize a homogenous enzyme immunoassay method. The assay is based on competition between the drug in the sample and the drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites.

Enzyme activity decreases upon binding to the antibody, so the drug concentration is measured in terms of enzyme activity. Enzyme activity converts nicotinamide adenine dinucleotide (NAD) to NADH—the reduced form of NAD—resulting in an absorbance change that is measured spectrophotometrically. Endogenous G6PDH does not interfere, because the coenzyme NAD functions only with the bacterial (i.e., Leuconostoc mesenteroides) enzyme employed in the assay.

Semiquantitative results are calculated through the use of multiple calibrator levels to provide an approximate cumulative concentration of the drugs and metabolites detected by the reagent. The semiquantitation of positive results enables the laboratory to determine an appropriate dilution of the specimen for confirmation by GC/MS. Semiquantitation also permits the laboratory to establish quality control procedures and assess control performance.

Therapeutic drug monitoring

Quick-reference guide to commonly prescribed drugs

Medication	Therapeutic range	When to sample after dose	Pharmacokinetics
Anti-arrhythmic/Cardioactive Drugs			
Digoxin (oral, injection)	0.9–2.0 ng/mL, >2.0 ng/mL (toxic)	30 minutes	Half-life: 35 hours
Disopyramide (oral)	2–5 µg/mL, 7 µg/mL (toxic)	2–3 hours	Half-life: 4.5–9 hours
Lidocaine (oral, injection, ocular, topical)	1.2–6.0 mcg/mL	12 hours initially, every 24 hours thereafter	Half-life: 70–200 minutes Steady state: 5–10 hours
Procainamide (injection, oral)	4–12 µg/mL,10–30 µg/mL (+NAPA), >30 µg/mL (+NAPA, toxic)	IV: 2 hours after start of infusion Oral: before next dose/>24 hours after initial dose	Half-life: 3–5 hours
N-acetylprocainamide (NAPA) (oral, injection)			Half-life: 6–10 hours (kidney disease prolongs half-life)
Quinidine (oral, injection)	2–5 µg/mL	Quinidine sulfate: 1 hour Quinidine gluconate salt: 5 hours	Half-life: 6–7 hours Steady state: 2 days Protein binding: 80–90%
Antiasthmatic Drugs			
Caffeine (oral)	8–20 µg/mL, >50 µg/mL (toxic)	2 hours	Half-life: 1.5–9.5 hours Steady state: 2 weeks
Theophylline (oral)	10–20 µg/mL	30–90 minutes	Half-life: 3.5 hours (children), 8–9 hours (adults)
Antiepileptic Drugs			
Carbamazepine (oral, injection)	4–12 mg/L	2–9 hours	Steady state: 2–4 days Half-life: 8–20 hours Active 10,11 epoxide metabolite contributes to clinical effects 75% serum protein binding
Ethosuximide (oral)	40–100 mg/L	1–4 hours	Steady state: 7–10 days Half-life: 40–60 hours 0% serum protein binding
Gabapentin (oral)	2–20 mg/L	2–3 hours	Steady state: 2–4 days Half-life: 5–9 hours 0% serum protein binding
Lamotrigine (oral)	2.5–15 mg/L	1–3 hours	Steady state: 3–6 days, 5–15 days with valproic acid comedication Half-life: 5–35 hours, 30–90 hours with valproic acid comedication 55% serum protein binding
Levetiracetam (oral, injection)	12–46 mg/L	1 hour	Steady state: 1–2 days Half-life: 6–8 hours 0% serum protein binding
Phenobarbital (oral, injection)	10–40 mg/L	0.5–4 hours	Steady state: 12–24 days Half-life: 70–140 hours 55% serum protein binding
Phenytoin (oral, injection)	10–20 mg/L	1–12 hours	Steady state: 5–17 days Half-life: 30–100 hours 90% serum protein binding
Primidone (oral)	5–10 mg/L	2–5 hours	Steady state: 2–4 days Half-life: 7–22 hours Metabolically derived phenobarbital contributes largely to clinical effects 10% serum protein binding
Topiramate (oral)	5–20 mg/L	2–4 hours	Steady state: 4–5 days Half-life: 20–30 hours 15% serum protein binding
Valproic acid (oral)	50–100 mg/L	3–6 hours	Steady state: 2–4 days Half-life: 11–20 hours 90% serum protein binding
Zonisamide (oral)	10–40 mg/L	2–5 hours	Steady state: 9–12 days Half-life: 50–70 hours 50% serum protein binding

Medication	Therapeutic range	When to sample after dose	Pharmacokinetics
Antifungal Drugs			
Voriconazole (oral, injection)	1.0–5.5 mcg/mL	N/A	N/A
Antimicrobial Drugs			
Amikacin (injection)	25–35 mcg/mL	30–60 minutes	Half-life: 0.5–2.5 hours (children), 0.5–15 hours (adults)
Gentamicin (injection, ocular, topical)	4–8 µg/mL (peak), <2 µg/mL (trough), >10 µg/mL (toxic), >2 µg/mL for >10 days (toxic)	30–60 minutes	Half-life: 1.5–15 hours (adults >30 years), 0.5–3 hours (adults <30 years), 0.5–2.5 hours (children), 2–9 hours (neonates)
Tobramycin (inhalation, injection, ocular)	4–10 µg/mL (peak), 2 µg/mL (trough, toxic)	30–60 minutes	Half-life: 1.5–15 hours (adults >30 years), 0.5–3 hours (adults <30 years), 0.5–2.5 hours (children), 2–9 hours (neonates)
Vancomycin (oral, injection)	18–26 µg/mL (2 hours drawn), 25–40 µg/mL (1 hour drawn), 30–40 µg/mL (30 minutes drawn), 5–10 µg/mL (trough)	15–30 minutes	Half-life: 4–10 hours Protein binding: 55%
Antineoplastic Drugs			
Methotrexate (oral, injection)	5.0 µmol/L (toxic @ 24 hours), 0.5 µmol/L (toxic @ 48 hours), 0.05 µmol/L (toxic @ 72 hours)	Dose-dependent	Half-life: 2–4 hours (initial), 8–15 hours (terminal) Elimination: renal excretion of 70–90% unchanged drug Metabolite: 7-hydroxymethotrexate Protein binding: 50–60% @ 1–1000 µmol/L
Immunosuppressive Drugs			
Cyclosporine (CsA) (oral, injection, ocular)	100–500 ng/mL (trough), highly variable	3–5 hours after oral	Half-life: 1.2 hours (alpha), 27 hours (beta) Protein binding: 90%
Mycophenolate acid (MPA) (oral, injection)	>1.3 µg/mL (trough), >1.9 µg/mL (+CsA)	1–2 hours, 6–12 hours	Binding to albumin: 97-98% Peak: 1–2 hours Peak #2: 6 or 1–12 hours
Sirolimus (oral)	Highly variable, 9 ng/mL (trough 2 mg/day dose), 17 ng/mL (trough 5 mg/day dose)	Immediately prior to next dose	Half-life: 35–95 hours Steady state: 1 day
Tacrolimus (oral, injection, topical)	Highly variable	Immediately prior to next dose	Half-life: 3.5 hours (alpha), 11.7 hours (beta) Protein binding: 75–99%

For more information about therapeutic drug monitoring solutions, visit siemens-healthineers.com/TDM

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. Sustainably. As a leader in medical technology, we want to advance a world in which breakthroughs in healthcare create new possibilities with a minimal impact on our planet. By consistently bringing innovations to the market, we enable healthcare professionals to innovate personalized care, achieve operational excellence, and transform the system of care.

Our portfolio, spanning in vitro and in vivo diagnostics to image-guided therapy and cancer care, is crucial for clinical decision-making and treatment pathways. With the unique combination of our strengths in patient twinning,* precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the greatest challenges in healthcare. We will continue to build on these strengths to help overcome the world's most threatening diseases, enable efficient operations, and expand access to care.

We are a team of more than 72,000 Healthineers in over 70 countries passionately pushing the boundaries of what is possible in healthcare to help improve the lives of people around the world.

**Personalization of diagnosis, therapy selection and monitoring, aftercare, and managing health.*

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