

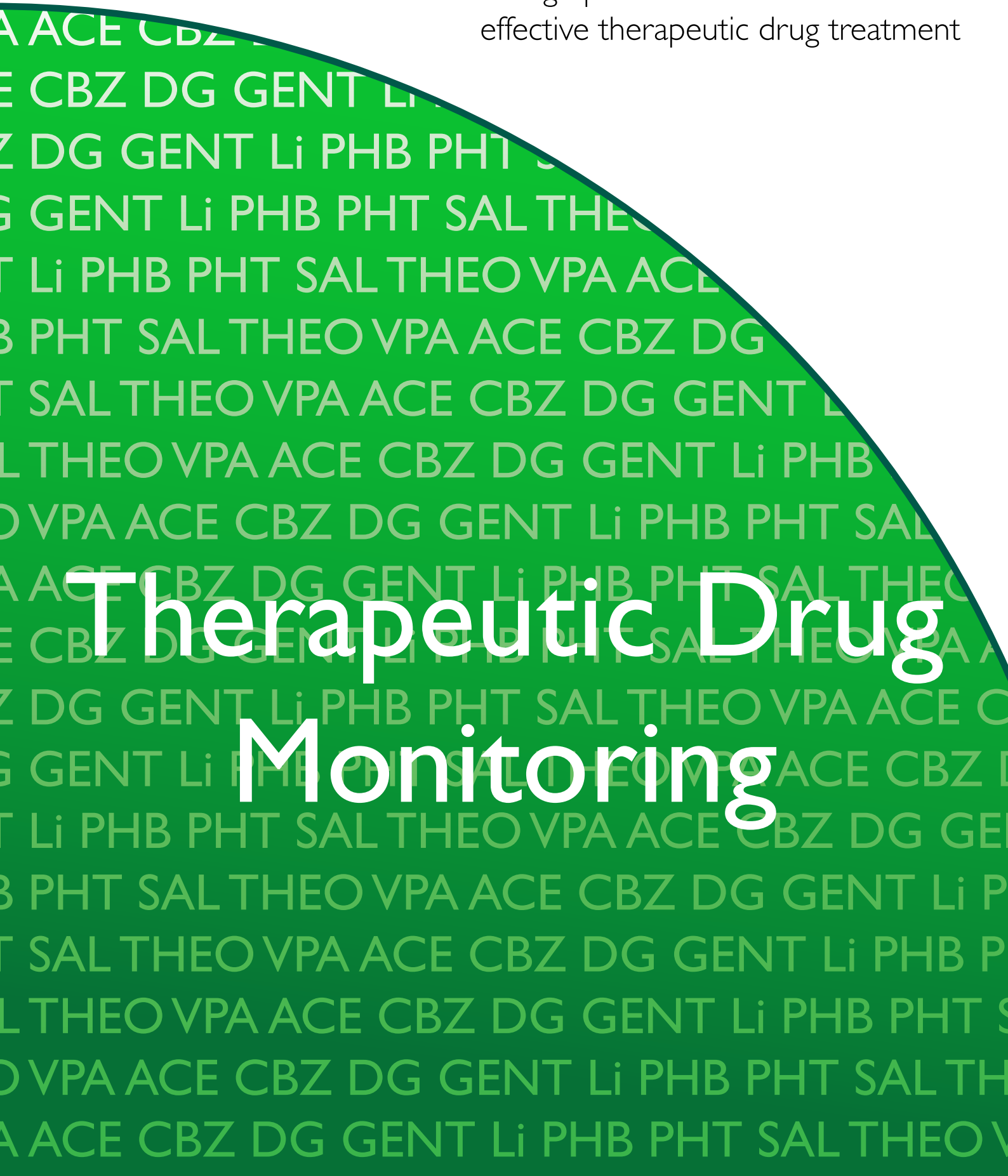


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RANDOX

Therapeutic Drug Monitoring

High performance tests to ensure effective therapeutic drug treatment



Therapeutic Drug Monitoring

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In order for therapeutic treatment to be successful, a constant concentration of the required medication must be maintained. Many medicinal drugs have a narrow therapeutic range, meaning there is little difference between the dosage required for effective treatment and a dosage that will cause severe side effects and even toxicity.

Individuals absorb, metabolise and make use of drugs at different rates meaning a standard dose cannot be prescribed for every patient. It is therefore extremely important to monitor therapeutic drug treatment to ensure therapy compliance, efficacy and to prevent drug induced toxicity.

Randox provides a comprehensive range of ten therapeutic drug monitoring assays which offer a range of benefits:

- **High performance methods** - the majority of Randox therapeutic drug monitoring assays utilise a latex enhanced immunoturbidimetric (LEI) method. Acetaminophen and salicylate are both enzymatic assays and the lithium test uses a colorimetric method
- **Liquid, ready-to-use reagents** - for convenience and ease of use
- **Extensive measuring ranges** - ensuring accurate detection of both therapeutic and toxic drug concentrations
- **Applications available** - with instrument specific settings for a wide range of clinical chemistry analysers
- **Multi-analyte controls and calibrator available** - facilitating QC consolidation

Randox Therapeutic Drug Monitoring Reagents

Acetaminophen

Cat. No: ACE4023 R1 2x11ml
R2 2x6.5ml

Acetaminophen, commonly known as paracetamol, is a frequently used pain-relieving drug whose consumption is not normally associated with any adverse effects. However, long-term treatment and prolonged use of acetaminophen can cause liver and kidney damage. Overdose is also a risk factor and this can lead to hepatic failure if left untreated.

Key Features

- Enzymatic method
- Wide measuring range- 4.89-652mg/l. The therapeutic range of acetaminophen is 10-30mg/l
- Liquid, ready-to-use standard included in the kit
- On-board stability of seven days at approximately +10°C
- Limited interference from Bilirubin, Hemolysis, Intralipid® and Triglycerides

Carbamazepine

Cat. No: TD3416 R1 2x12ml
R2 2x5ml

Carbamazepine is an anti-epileptic drug used in the treatment of seizures which may also prove effective in the long-term treatment of manic-depressive illnesses. The side effects of an incorrect carbamazepine dosage can include breathing difficulties, seizures and drowsiness.

Key Features

- LEI method
- Wide measuring range- 1.02-19µg/ml. The therapeutic range of carbamazepine is 4-12µg/ml
- Stable to expiry date when stored at +2 to +8°C
- Limited interference from Bilirubin, Haemoglobin, Intralipid® and Triglycerides

Digoxin

Cat. No: TD3410 R1 2x8ml
R2 2x6ml

Digoxin is a cardiovascular drug used to treat heart conditions such as arrhythmias and heart failure. Digoxin toxicity can be associated with a number of health problems such as changes in heart rate and rhythm, gastrointestinal problems and fatigue.

Key Features

- LEI method
- Wide measuring range- 0.371-5.46ng/ml. The therapeutic range of digoxin is 0.8-2ng/ml
- Stable to expiry date when stored at +2 to +8°C
- Limited interference from Bilirubin, Intralipid® and Triglycerides

Gentamicin

Cat. No: TD3413 R1 2x15ml
R2 2x6ml

Gentamicin is an antibiotic drug used to treat a wide range of bacterial infections. Within the therapeutic range most individuals will respond well to gentamicin treatment and will not experience any side effects. However, the most common complications associated with gentamicin toxicity are ear and hearing problems as well as kidney damage.

Lithium

Cat. No: LM4005 R1 2x18.3ml, R2 2x6.5ml
LM8053 R1 2x18.3ml, R2 2x6.5ml

Lithium is used in the treatment of the manic phase of affective disorders, mania and manic-depression, however there is a narrow range between the therapeutic range and a toxic dose of lithium. Early symptoms of lithium toxicity include lethargy, irregular tremors, speech problems and ataxia.

Phenobarbital

Cat. No: TD3408 R1 2x17ml
R2 2x6ml

Phenobarbital is an anti-epileptic and sedative-hypnotic drug. The side effects associated with an incorrect phenobarbital prescription can include drowsiness, depression, headaches and dizziness.

Phenytoin

Cat. No: TD3409 R1 2x17ml
R2 2x6ml

Phenytoin is an anti-epileptic drug used for the control of generalised seizures, however incorrect doses can prove toxic. The effects of incorrect phenytoin treatment can include insomnia, nausea, confusion and fatigue.

Salicylate

Cat. No: SAL4024 R1 2x11ml
R2 2x3.8ml

Salicylate, commonly known as aspirin, has pain-relieving and anti-inflammatory properties and is frequently used due to the lack of serious side effects at normal therapeutic doses. Over dosage of salicylate however can cause metabolic acidosis, gastrointestinal and central nervous systems disturbances and even renal failure.

Key Features

- LEI method
- Wide measuring range- 0.847-11 µg/ml. The therapeutic range of gentamicin is 5-10 µg/ml
- Stable to expiry date when stored at +2 to +8°C
- Limited interference from Haemoglobin, Intralipid® and Triglycerides

Key Features

- Colorimetric method
- Wide measuring range- 0.218-3mmol/l. The therapeutic range of lithium is 1-1.20mmol/l
- Stable to expiry date when stored at +2 to +8°C
- Limited interference from Bilirubin, Haemoglobin, Intralipid® and Triglycerides

Key Features

- LEI method
- Wide measuring range- 2.55-87.7 µg/ml. The therapeutic range of phenobarbital is 15-40 µg/ml
- Stable to expiry date when stored at +2 to +8°C
- Limited interference from Bilirubin, Haemoglobin, Intralipid® and Triglycerides

Key Features

- LEI method
- Wide measuring range- 2.9-44.5 µg/ml. The therapeutic range of phenytoin is 10-20 µg/ml
- Stable to expiry date when stored at +2 to +8°C
- Limited interference from Bilirubin, Haemoglobin, Intralipid® and Triglycerides

Key Features

- Enzymatic method
- Wide measuring range- 24.8-1079mg/l. The therapeutic range of salicylate is 150-300mg/l
- Liquid, ready-to-use standard included in the kit
- On-board stability of 28 days at approximately +10°C
- Limited interference from Bilirubin, Hemolysis, Intralipid® and Triglycerides

Theophylline

Cat. No: TD3412 R1 2x17ml
R2 2x5ml

Theophylline is used to stimulate muscles in the cardiovascular, respiratory and central nervous systems. It is a bronchodilator commonly used to treat asthma and other airway diseases. The side effects of incorrect theophylline dosage can include increased heart rate, central nervous system effects and seizures.

Key Features

- LEI method
- Wide measuring range- 1.64-42.7µg/ml. The therapeutic range of theophylline is 10-20µg/ml
- Stable to expiry date when stored at +2 to +8°C
- Limited interference from Bilirubin, Haemoglobin, Intralipid® and Triglycerides

Valproic Acid

Cat. No: TD3414 R1 2x12ml
R2 2x5ml

Valproic acid is a widely used anti-epileptic drug. Within the therapeutic range most individuals will respond well to valproic acid treatment however; the side effects associated with toxicity of this drug can include tremors, gastrointestinal problems, dizziness and vision problems.

Key Features

- LEI method
- Wide measuring range- 11.3-159µg/ml. The therapeutic range of valproic acid is 50-100µg/ml
- Stable to expiry date when stored at +2 to +8°C
- Limited interference from Bilirubin, Haemoglobin, Intralipid® and Triglycerides

Please note all performance information was achieved using the Randox RX series of clinical analysers. Results may vary depending on the analyser used.

Therapeutic Drug Monitoring Controls and Calibrator

Controls

- Assayed target values and ranges are supplied for 18 analytes including commonly used antibiotics, anti-convulsant and anti-inflammatory drugs
- 100% human serum
- Reconstituted stability of four weeks at +2 - 8°C

Calibrator

- Accurately assigned values provided for seven therapeutic drugs
- 100% human serum
- Reconstituted stability of four weeks at +2 - 8°C

Product	Size	Cat. No.
Therapeutic Drug Calibrator Series	6 x 3ml	TD3417
Therapeutic Drug Control Level 1	20 x 5ml	HD1667
Therapeutic Drug Control Level 2	20 x 5ml	HD1668
Therapeutic Drug Control Level 3	20 x 5ml	HD1669
Clinical Chemistry Calibration Serum Level 3	20 x 5ml	CAL2351*

* **Please note** CAL2351 is required for calibration of Randox Lithium

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