RANDOX
TOXICOLOGY

# Therapeutic Drug Monitoring Reagents

# Therapeutic Drug Monitoring

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 Toxicology provides a comprehensive range of nine therapeutic drug monitoring assays which offer a range of benefits.

## Benefits at a Glance

### High performance methods

The majority of Randox Toxicology 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

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

Applications available - with instrument specific settings for a wide range of clinical chemistry analysers

### Multi-analyte controls and calibrators available

Multi-analyte controls and calibrators available – facilitating QC consolidation

## Acetaminophen
*(Paracetamol)*

**Cat No:** ACE4023
**Method:** Colorimetric
**R1:** 2x11ml (C)
**R2:** 2x6.5ml

(C) inidcates calibrator included in kit

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.

- Wide measuring range- 4.89-652 mg/l. The therapeutic range of acetaminophen is 10-30 mg/l
- On-board stability of seven days at approximately +10°C
- Limited interference from Bilirubin, Hemolysis, Intralipid® and Triglycerides

## Carbamazepine

**Cat No:** TD3416
**Method:** Latex Enhanced Immunoturbidimetric
**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.

- Stable to expiry date when stored at +2 to +8°C
- Measuring range 1.02–19.0 µg/ml

## Digoxin

**Cat No:** TD3410
**Method:** Latex Enhanced Immunoturbidimetric
**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.

- Stable to expiry date when stored at +2 to +8°C
- Measuring range 0.371-5.46 ng/ml

## Gentamicin

**Cat No:** TD3413
**Method**: Latex Enhanced Immunoturbidimetric
**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.

- Stable to expiry date when stored at +2 to +8°C
- Measuring range 0.847–11.0 µg/ml

## Lithium

**Cat No:** LM4005
**Method:** Colorimetric
**R1:** 2x18.3ml
**R2:** 2x6.5ml

**Cat No:** LM8053
**Method:** Colorimetric
**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.

- Stable to expiry date at +2 to +8°C
- Measuring range 0.218 - 3.0 mmol/L

## Phenobarbital

**Cat No:** TD3408
**Method:** Latex Enhanced Immunoturbidimetric
**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.

- Stable to expiry date when stored at +2 to +8°C
- Measuring range 2.55-87.7 µg/ml

## Phenytoin

**Cat No:** TD3409
**Method:** Latex Enhanced Immunoturbidimetric
**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.

- Liquid and ready to use
- Stable to expiry date when stored at +2 to +8°C
- Measuring range 2.9– 44.5 µg/ml

## Salicylate
*(Aspirin)*

**Cat No:** SAL4024
**Method:** Enzymatic
**R1:** 2x11ml (C)
**R2:** 2x3.8ml

(C) inidcates calibrator included in kit

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.

- Liquid and ready to use
- Stable to expiry date when stored at +2 to +8°C and on-board stability of 28 days at approximately +10°C
- Measuring range 24.8-1079 mg/L

## Valproic Acid

**Cat No:** TD3414
**Method:** Latex Enhanced Immunoturbidimetric
**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.

- Liquid and ready to use
- Stable to expiry date when stored at +2 to +8°C
- Measuring range 11.3–159 µg/ml

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

## Controls and Calibrators

| Product | Cat No. |
|---|---|
| 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 |
| Therapeutic Drug Calibrator Series 6 x 3mL | TD3417 |

# Commitment to Quality

Randox Toxicology is committed to quality at every stage of the production process from research and development to customer support. This commitment has been recognised through accreditation and approval to the international ISO standard and national bodies such as FDA.

Accreditation to international standards ensures confidence in the quality and consistency of the products and services provided by Randox Toxicology and demonstrates compliance to internationally agreed standards.

## FDA

Many of our products are FDA cleared and therefore appropriate for sale in the USA. In order for an IVD to be approved for sale in the USA it must not only be safe for use and effective but it must also satisfy the requirements set out in part 820 title 21 of the Code of Federal Regulations published by the FDA.

## CFDA

The China Food and Drug Administration (CFDA) have the responsibility to "draft law and regulations on administration of medical devices and supervise their enforcement; take charge of registration and regulation of medical devices; draft relevant national standards, draw up and revise professional standards of medical devices, manufacturing practice and supervise their implementation".

## Health Canada

Many Randox products are licensed for use in Canada. Before an IVD can be sold in Canada it must meet the requirements set out in the Therapeutic Products Directorate. Health Canada review all medical devices to assess their safety, effectiveness and quality before they are authorised for sale.

## CE Mark

CE marking on a product indicates that the product complies with and has satisfied the essential requirements set out by the In Vitro Diagnostic (IVD) Medical Devices Directive 98/79/EC, it also demonstrates the fact the product is fit for its intended purpose.

The CE mark is also a declaration from the manufacturer that the product has met all legislation in relation to health and safety and where required has been assessed in accordance with this legislation.

CE marking is essential for products to be placed on the market and sold in the European Union (EU). It also ensures the free movement of product within the EFTA and EU.

Proud sponsors of


# Advancing the Future of Toxicology

Randox Tox

LT719TOX NOV17