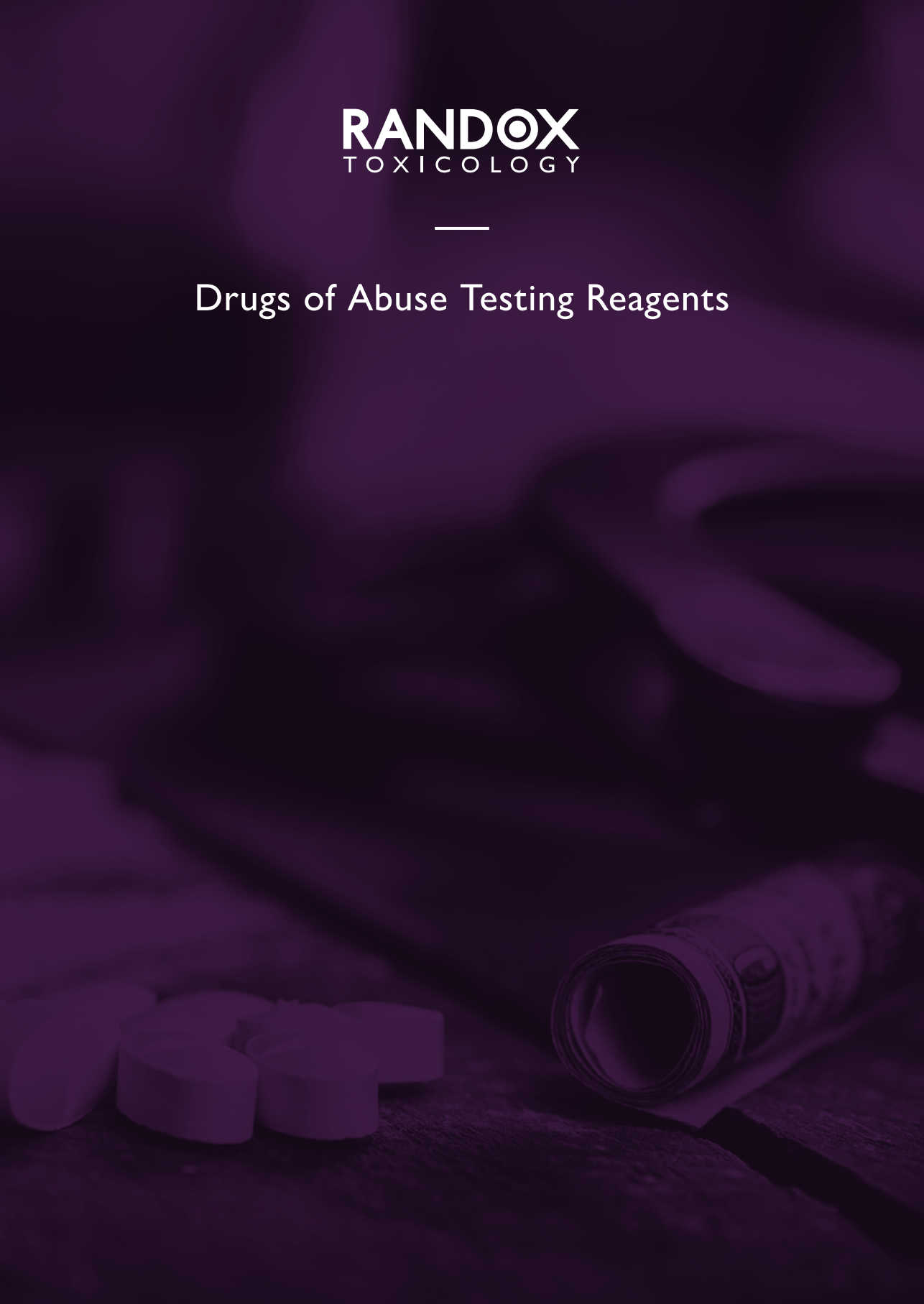


RANDOX
TOXICOLOGY

Drugs of Abuse Testing Reagents



Drugs of Abuse Testing

The abuse of alcohol and drugs is a growing problem for today's society which has wide reaching effects on the user, their family, the workplace and for a country's health system. In order to help deal with this problem high quality, accurate drug screening tests are essential. Randox Toxicology provides a comprehensive range of eleven drugs of abuse assays which offer a range of benefits.



Renowned methodology

All of the Randox Toxicology drugs of abuse tests are homogenous enzyme immunoassays, with the exception of ethanol which is an enzymatic assay



Excellent correlation

Excellent correlation with Gas Chromatography/ Mass Spectrometry (GC/MS) methodology



Ready-to-use

Liquid ready-to-use reagents for convenience and ease of use



Extensive measuring ranges

Extensive measuring ranges enabling accurate drug detection



Liquid calibrators and controls

Multianalyte liquid calibrators and controls available for selected tests

Barbiturates

Cat No: DA4008

Method: Homogenous Enzyme
Immunoassay

R1: 2x16.9ml

R2: 2x8ml

Barbiturates are central nervous system depressants which are used therapeutically as sedatives and anticonvulsants. There are a number of risks associated with the recreational consumption of barbiturates including lowered blood pressure, fatigue, impaired judgement and respiratory depression.

- 93.3% correlation with GC/MS values
- Included in Randox multi-analyte drugs of abuse control and calibrator products
- Stable to expiry date at +2 to +8°C
- Multiple analyser applications available

Benzodiazepines

Cat No: DA4009

Method: Homogenous Enzyme
Immunoassay

R1: 2x16.9ml

R2: 2x8ml

Benzodiazepines have a range of physio-chemical and pharmacological properties. When benzodiazepines are used recreationally the effects can be sedating and intoxicating, however the consumption of these drugs can lead to a number of problems such as physical and psychological dependence, depression, anxiety and insomnia.

- 93.7% correlation with GC/MS values
- Dedicated benzodiazepines controls and calibrator available
- On-board stability of 28 days at approximately +10°C
- Multiple analyser applications available

Cannabinoids

Cat No: DA4010

Method: Homogenous Enzyme
Immunoassay

R1: 2x16.9ml

R2: 2x8ml

Cannabinoids are the compounds that produce the effects associated with marijuana consumption. Marijuana abuse produces mixed calming and stimulating effects but the consequences associated with the use of this drug can include memory and concentration problems and increased heart rate. The chronic use of marijuana may cause psychological damage.

- 93.3% correlation with GC/MS values
- Dedicated cannabinoids controls and calibrator available
- On-board stability 28 days at approximately +10°C
- Multiple analyser applications available

Cocaine Metabolite

Cat No: DA4011

Method: Homogenous Enzyme
Immunoassay

R1: 2x16.9ml

R2: 2x8ml

Cocaine is a central nervous system stimulant whose consumption can have effects such as euphoria, alertness and hyperactivity. However, cocaine abuse can also produce numerous undesirable side effects including cardiac toxicity and behavioural responses such as paranoia, hallucinations and severe psychosis.

- 99.3% correlation with GC/MS values
- Included in Randox multi-analyte drugs of abuse control and calibrator products
- On-board stability of 28 days at approximately +10°C
- Multiple analyser applications available

Ecstasy

Cat No: DA4014

Method: Homogenous Enzyme
Immunoassay

R1: 2x16.9ml

R2: 2x8ml

Ecstasy drugs are a group of amphetamine derivatives, including MDMA, MDA and MDEA. Ecstasy drugs are frequently abused for their mood altering effects which can create feelings of euphoria. However, ecstasy can also cause the user to experience hallucinations, depression, cardiac arrhythmias and sleep disorders.

- 93.8% correlation with GC/MS values
- Dedicated ecstasy controls and calibrator available
- Stable to expiry date when stored at +2 to +8°C
- On-board stability of 28 days at approximately +10°C
- Multiple analyser applications available

EDDP

Cat No: DA4013

Method: Homogenous Enzyme
Immunoassay

R1: 2x16.9ml

R2: 2x8ml

EDDP is a methadone metabolite. Methadone is a prescribed opioid which is used to relieve chronic pain, as well as for the detoxification and treatment of narcotic or heroin addiction. EDDP testing is commonly carried out to assess whether individuals receiving methadone therapy are complying with their treatment. Methadone abuse can have side effects such as hallucinations and changes in the user's personality.

- 95.0% correlation with GC/MS values
- Dedicated EDDP controls and calibrator available
- Stable up to the expiry date when stored at +2 to +8°C
- Multiple analyser applications available

Ethanol

Cat No: DA4015

Method: Enzymatic assay using NAD
and alcohol dehydrogenase

R1: 2x16.9ml

R2: 2x8ml

Ethyl alcohol is found in high concentrations in alcoholic beverages. Many people consume alcohol responsibly; however abuse of alcohol can lead to a loss of alertness, stupor, coma and over the long term, could lead to addiction. Furthermore, drinking alcohol during pregnancy carries a heavy risk of permanent mental and physical defects in the child, known as foetal alcohol syndrome.

- Suitable for use with both urine and serum samples
- Dedicated ethanol calibrator and control set available
- Stable to expiry date when stored at +2 to +8°C
- Measuring range 3-500 mg/dl
- Multiple analyser applications available

Ethyl Glucuronide (EtG)

Cat No: ETG10072

Method: Latex Enhanced
Immunoturbidimetric

R1: 2x13ml

R2: 2x13ml

EtG can be detected in body fluids for an extended period of time after the elimination of alcohol from the body. In extreme cases the window of detection in urine could be up to 80 hours. EtG has been proposed as a marker of recent ethanol intake in a variety of clinical and legal settings, for example in detecting recent drinking in cases of a negative ethanol test or to confirm abstinence from alcohol.

- 98.0% correlation with LCMS/MS values
- No cross-reactivity with EtS
- Low false negatives - 100% agreement based on a Cut Off of 500 ng/mL
- On-board stability of 14 days

Cat No: ETG10073

Method: Latex Enhanced
Immunoturbidimetric

R1: 2x100ml

R2: 2x100ml

Methadone

Cat No: DA4016

Method: Homogenous Enzyme
Immunoassay

R1: 2x16.9ml

R2: 2x8ml

As highlighted previously, the primary medical application of methadone is in the detoxification and treatment of narcotic or heroin addiction. Illicit methadone consumption can have a number of side effects. The user may experience problems such as chronic fatigue, hallucinations, mood changes and insomnia.

- 90.9% correlation with GC/MS values
- Included in Randox multi-analyte drugs of abuse control and calibrator products
- Stable to expiry date when stored at +2 to +8°C
- Multiple analyser applications available

Methamphetamine

Cat No: DA4007

Method: Homogenous Enzyme
Immunoassay

R1: 2x16.9ml

R2: 2x8ml

Amphetamines act as stimulants for the central nervous system and can induce feelings of euphoria, alertness and a sense of increased energy. However, the side effects associated with the consumption of these drugs are serious and include hypertension, insomnia, paranoia and anxiety.

- 97.5% correlation with GC/MS values
- Included in Randox multi-analyte drugs of abuse control and calibrator products
- Stable to expiry date when stored at +2 to +8°C. Once opened the reagent is stable on-board the analyser for 28 days at approximately +10°C
- Multiple analyser applications available

Opiates

Cat No: DA4012

Method: Homogenous Enzyme
Immunoassay

R1: 2x16.9ml

R2: 2x8ml

Common opiates include morphine, codeine and heroin. Morphine and codeine are legal painkillers however they are frequently abused for their central nervous system effects. Recreational use of these drugs can have a number of negative side effects including seizures, insomnia and respiratory depression. The risks associated with heroin consumption are great. Heroin is highly addictive and when administered intravenously with non-sterile needles, there is the risk of contracting diseases such as HIV or hepatitis.

- 91.9% correlation with GC/MS values
- Included in Randox multi-analyte drugs of abuse control and calibrator products
- Stable to expiry date when stored at +2 to +8°C. Once opened the reagent is stable on-board the analyser for 28 days at approximately +10°C
- Multiple analyser applications available

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.	Product	Cat No.
Benzodiazepines Control Level 1 5 x 5mL	DA3130	Multi-drug Control Level 1 5 x 5mL	DA3121
Benzodiazepines Control Level 2 5 x 5mL	DA3131	Multi-drug Control Level 2 5 x 5mL	DA3122
Cannabinoid Control Level 1 5 x 3mL	DA3127	Benzodiazepines Calibrator set 5 x 10mL	DA3129
Cannabinoid Control Level 2 5 x 3mL	DA3128	Cannabinoid Calibrator set 5 x 3mL	DA2700
Ecstasy Control Level 1 5 x 5mL	DA3125	Ecstasy Calibrator set 5 x 10mL	DA2701
Ecstasy Control Level 2 5 x 5mL	DA3126	EDDP Calibrator set 5 x 10mL	DA2702
EDDP Control Level 1 5 x 5mL	DA3123	Multi-drug Calibrator set 5 x 10mL	DA2704
EDDP Control Level 2 5 x 5mL	DA3124	Ethanol Calibrator / Control Set 5 x 10mL	DA2703

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.

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Advancing the Future of Toxicology