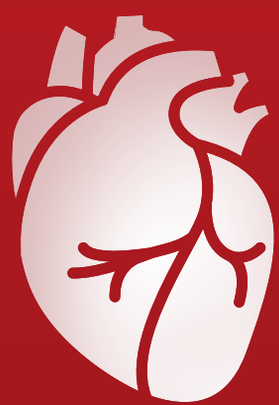
BGI RANDOX

CARDIOLOGY & LIPID TESTING

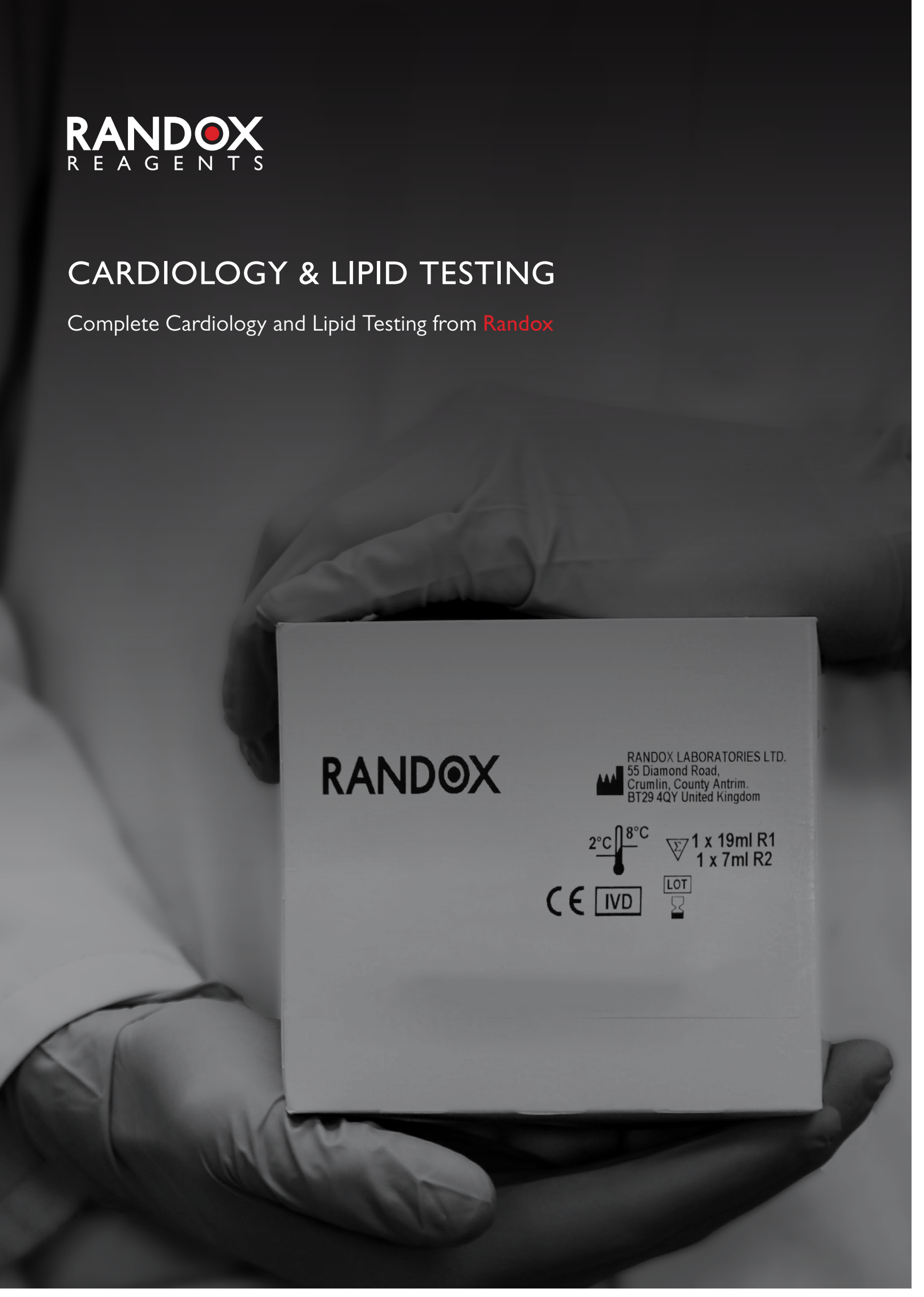


COMPLETE CARDIOLOGY & LIPID TESTING FROM RANDOX

RANDOX
REAGENTS

CARDIOLOGY & LIPID TESTING

Complete Cardiology and Lipid Testing from Randox



KEY

NP

NICHE PRODUCT

When you see this symbol you will know that Randox have one of the only **automated biochemistry assays available on the market**

UF

UNIQUE FEATURE

When you see this symbol you will know that this feature is **unique to the Randox product**

BENEFITS OF RANDOX REAGENTS

Randox offers an extensive range of third party diagnostic reagents which are internationally recognised as being of the highest quality; producing accurate and precise results.

We have a considerable test menu of over 100 assays, covering over 100 disease markers including: antioxidants, diabetes, drugs of abuse testing, lipids, specific proteins, therapeutic drug monitoring and veterinary testing.

A wide range of formats and methods are available providing greater flexibility and choice for any laboratory size.

In addition to flexible pack sizes and a comprehensive list of analyser applications, we can also provide dedicated reagent packs (Randox Easy Read and Easy Fit regents) for a wide range of chemistry analysers providing you with freedom of choice from an independent manufacturer.

EXPAND YOUR TEST MENU WITHOUT EXPANDING YOUR LAB

There is no need to buy any extra equipment in order to expand your test menu. Our reagents can be programmed onto the majority of the most common biochemistry analysers.

EXPAND ROUTINE TESTING

With speciality assays for 195 of the most common clinical chemistry analysers; assays which usually require dedicated equipment (or was previously only available as an ELISA) can now be run on automated biochemistry analysers, allowing your laboratory to expand its routine test menu. E.g. TxBCardio™, H-FABP, adiponectin, and many more.

REDUCE COSTS

The excellent quality and stability associated with Randox reagents helps to reduce costs by keeping waste and costly re-runs to a minimum.

BRING TESTING IN-HOUSE

The availability of flexible pack sizes ensures suitability for laboratories of all sizes and means tests can easily be brought in-house without the worry of increased waste.

REDUCE LABOUR

Reduce time spent running tests through liquid ready-to-use reagents, automated methods (compared to the traditional laborious ELISA methods used for tests such as cystatin C or adiponectin); and our easy-fit options.

REDUCE THE RISK OF ERRORS AND HAVE CONFIDENCE IN PATIENT RESULTS

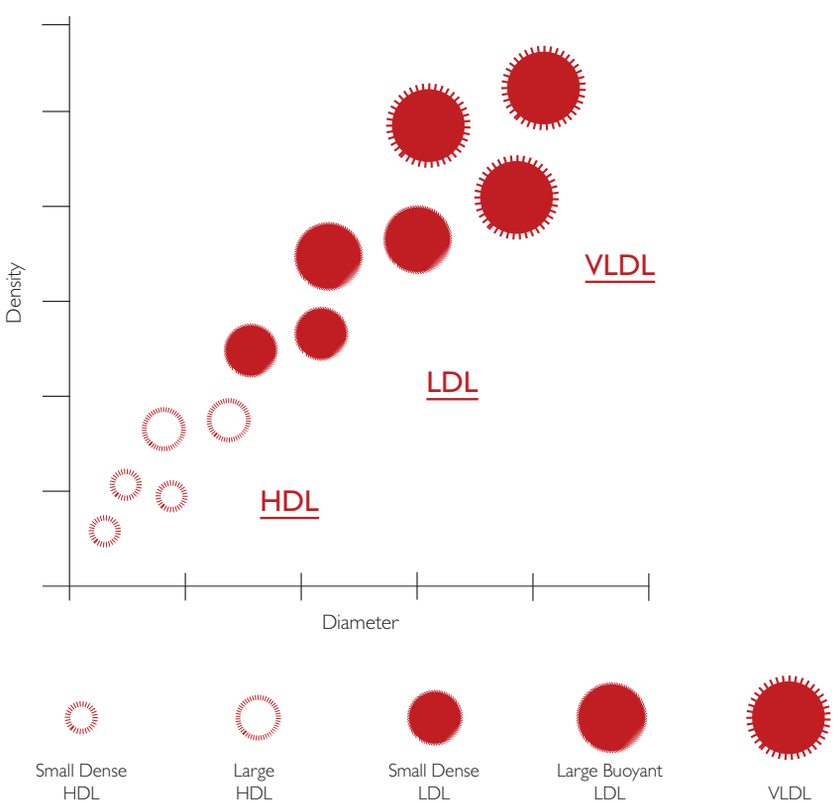
Our traceability of material and extremely tight manufacturing tolerances ensure uniformity across reagent batches reducing lot-to-lot variability. All our assays are validated against gold-standard methods; increasing confidence in patient test results.

INTRODUCTION TO RANDOX CARDIOLOGY AND LIPID TESTING

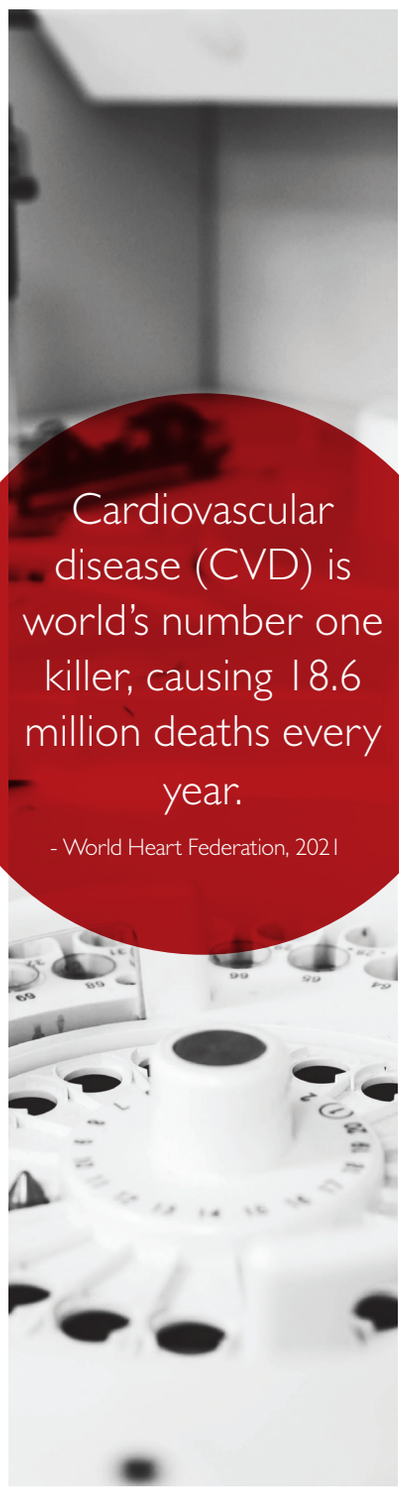
International bodies, including the National Lipid Association and the European Guidelines on Cardiovascular Disease (CVD) Prevention in Clinical Practice advocate measuring lipids to truly identify CVD risk. However, the traditional lipid panel of cholesterol, HDL-C, triglycerides and LDL-C only detect approximately 20% of all coronary artery disease (CAD) patients. Advanced lipid testing is recommended to optimise patient treatment, both in primary and secondary risk categories and as such provide the necessary tools to prevent and reduce the risks. Randox offers a comprehensive cardiology product profile which includes superior performing reagents for the detection of conventional risk factors, as well as emerging biomarkers associated with further risk.

LIPOPROTEIN SUBFRACTIONS

Fig. 1 The changes in density and diameter of the lipoprotein subfractions.[1]



Please note this is a visual representation and is not drawn to scale.



HDL CHOLESTEROL

Key Features of the Randox HDL Cholesterol Assay

UF **Superior direct clearance methodology** ensuring truly accurate results even with abnormal samples

- **Liquid ready-to-use reagents** for convenience and ease of use
- **Extensive measuring range** of 0.189 - 3.73mmol/L
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox HDL Cholesterol (HDL-C) assay on a wide range of clinical chemistry analysers

UF Benefits of the Randox Direct Clearance Method

Although many direct methods of HDL-C measurement perform well with normal samples, they show reduced specificity and often underestimate the concentration of HDL-C in samples containing abnormal lipoproteins, for example, samples from patients with elevated triglyceride levels or liver damage. The Randox direct clearance method offers superior performance to these methods and works by completely removing all non-HDL-C components resulting in a high degree of accuracy and specificity with HL samples.

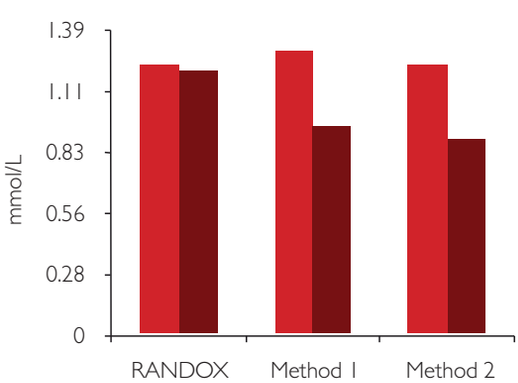
Clinical Significance

High-density lipoproteins (HDL) are one of the major classes of plasma lipoproteins. HDL-C is often referred to as 'good cholesterol' as it transports from the tissues to the liver for removal from the body. High levels of HDL-C can lower the risk of developing heart disease.

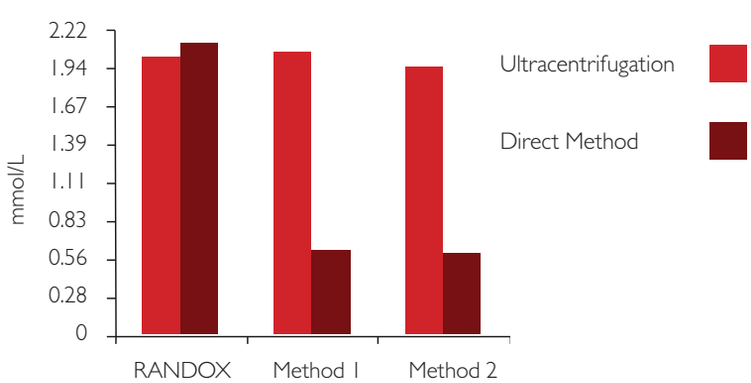
Performance in discrepant patient samples

Fig. 2 below compares the performance of the Randox direct clearance method and two other direct masking methods with the ultracentrifugation reference method in two abnormal samples. The Randox direct clearance method correlates well with the ultracentrifugation method; however the two other commercially available direct masking methods seriously underestimate the concentration of HDL-C.

Fig. 2 Randox Direct Clearance Method vs Direct Masking Methods.[2]

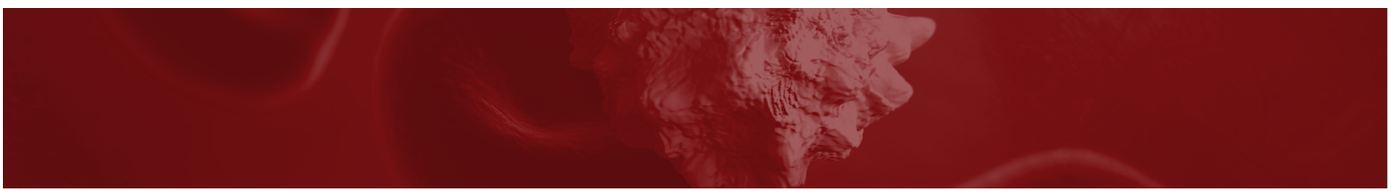


SAMPLE 1



SAMPLE 2

All ordering information can be found on *Page 20-21*



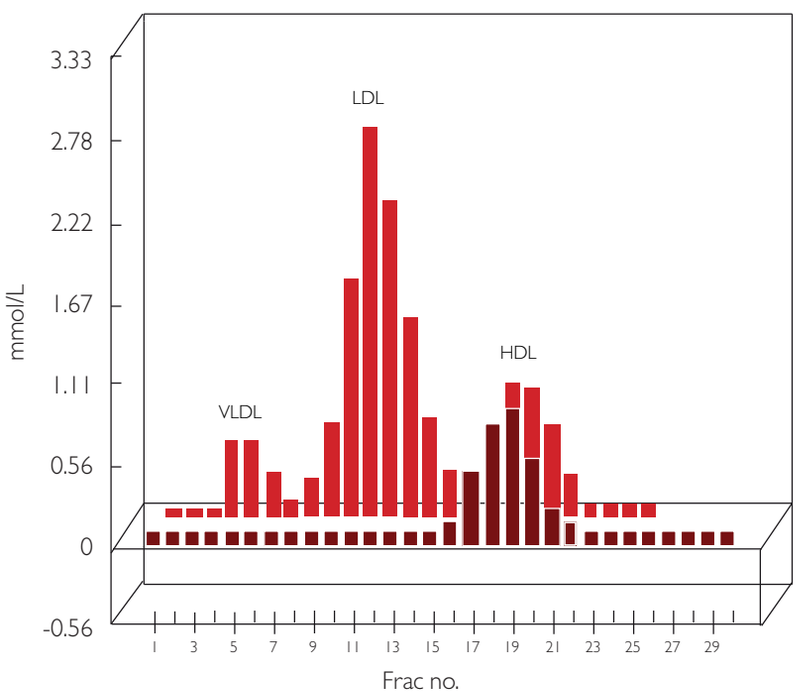


Fig. 3 Specificity of Randox Direct Clearance Assay for HDL Cholesterol

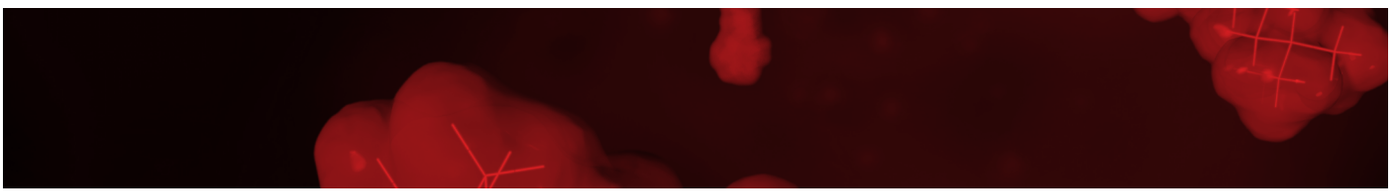
Specificity of the Randox direct clearance HDL-C assay was verified against gel filtration. Fig. 3 indicates how specific the Randox direct clearance method is for HDL-C. Our kit was found to only react with the HDL-C fractions separated by gel filtration.

Total Cholesterol Reagent

Randox HDL Cholesterol Reagent

"THE DIAGRAM ABOVE SHOWS HOW **SPECIFIC** THE **RANDOX** DIRECT CLEARANCE METHOD IS"

All ordering information can be found on *Page 20-21*



LDL CHOLESTEROL

Key Features of the Randox LDL Cholesterol Assay

- **Superior direct clearance methodology** ensuring truly accurate results are delivered
- **Liquid ready-to-use reagents** for convenience and ease-of-use
- **Extensive measuring range** of 0.189 – 22.2mmol/L for the measurement of clinically significant levels

UF **Applications available** detailing instrument-specific settings for the convenient use of the Randox LDL Cholesterol (LDL-C) assay on a wide range of clinical chemistry analysers

UF Benefits of the Randox Direct Clearance Method

The Randox direct clearance method eliminates sample pre-treatment, displaying an excellent correlation to both the ultracentrifugation and precipitation methods. The detergents and buffering systems used by most commercially available direct clearance LDL-C assays produce varying results, leading to differences in assay performance.

Excellent precision as the Randox LDL-C assay retains its precision even at high levels of triglycerides.

Minimal interferences as the Randox advanced reagent formulation enables rapid clearance of turbidity resulting in minimal interference from patient samples.

Clinical Significance

LDL-C, often referred to as 'bad cholesterol', transports cholesterol to the tissues and is linked to the development of atherosclerotic lesions. The accurate measurement of LDL-C is therefore of vital importance in therapies which focus on lipid reduction to prevent or reduce the progress of atherosclerosis and to avoid plaque rupturing.

The traditional method of measuring LDL-C levels is through the empirical relationship of Friedewald. This equation uses quantitative measurements of total cholesterol, HDL-C and triglycerides to find a value for LDL-C. However, this equation has a number of limitations that have led to inaccuracies. The Randox LDL-C assay eliminates the limitations associated with Friedewald by utilising the direct clearance method, providing a more accurate diagnosis of patient samples.

Fig. 4 Mis-estimation of LDL-C by Calculation Method with Increasing Triglycerides

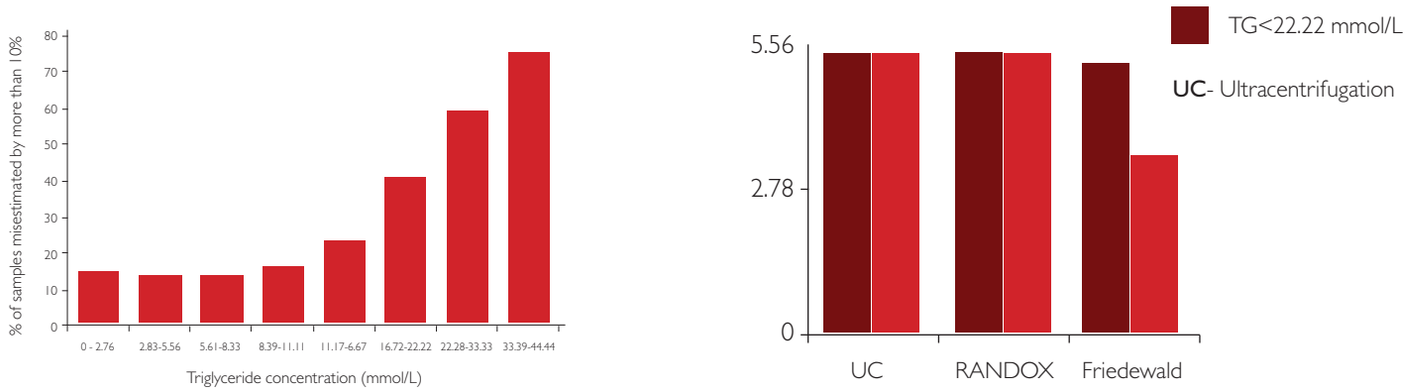
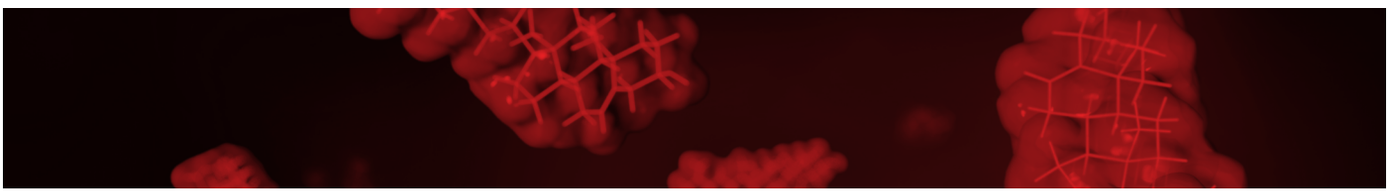


Fig. 4 shows the mis-estimation of LDL-C by the Friedewald equation with increasing triglycerides and how the Randox direct clearance method offers superior performance.

All ordering information can be found on *Page 20-21*



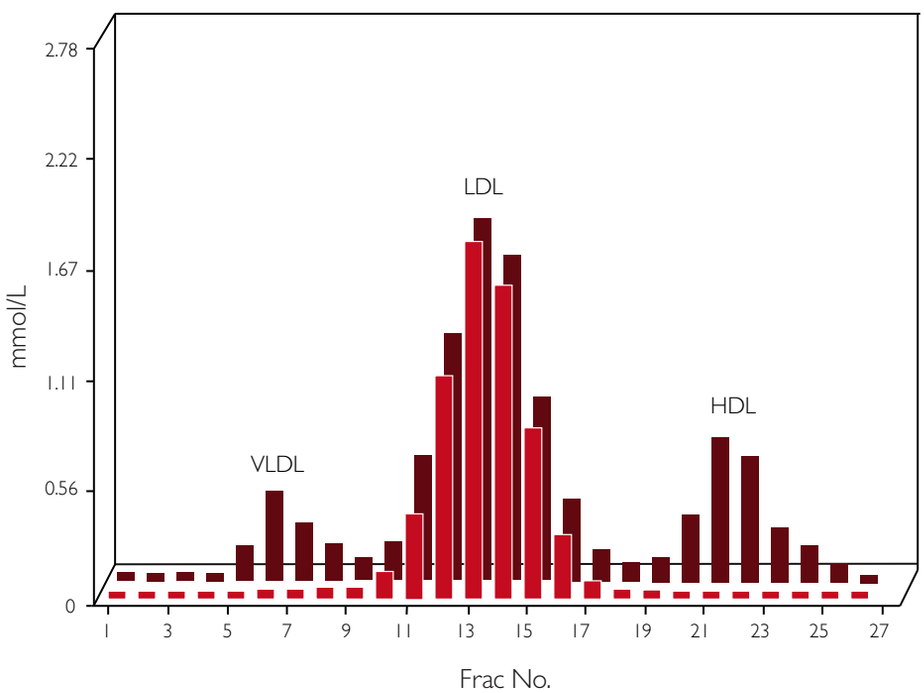


Fig. 5 Specificity of the Randox Direct Clearance Assay for LDL Cholesterol

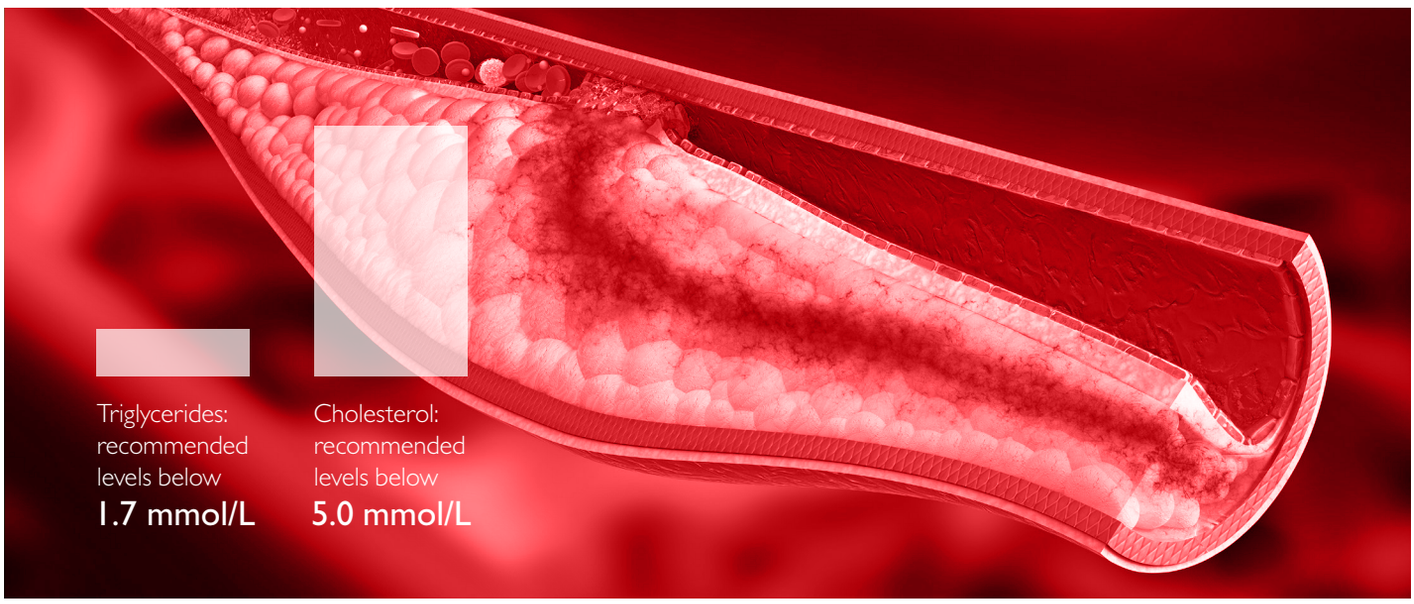
Specificity of the Randox direct clearance LDL-C assay was verified against gel filtration. Fig. 5 indicates how specific the Randox direct clearance method is for LDL-C. Our kit was found to only react with the LDL-C fractions separated by gel filtration.

Randox LDL Cholesterol

Total Cholesterol

“THE FRIEDEWALD FORMULA HAS BEEN REPORTED TO MISCLASSIFY UP TO 50% OF PATIENTS[3]”

All ordering information can be found on *Page 20-21*



CHOLESTEROL (TOTAL)

Key Features of the Randox Cholesterol Assay

- **Wide range of kits available** ensuring laboratories of all sizes can find a product to suit their needs
- **Liquid ready-to-use reagents** for convenience and ease-of-use
- **Standards included in certain kits** for user convenience (these are for manual and semi-automated use only)
- **Extensive measuring range** of 0.865-16.6 mmol/L for the measurement of clinically significant levels
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Cholesterol assay on a wide range of clinical chemistry analysers
- **CHOD-PAP method**

Clinical Significance

Total Cholesterol measures all lipoprotein sub-classes to assess a patient's overall cholesterol levels. Elevated levels of cholesterol in the blood are associated with atherosclerosis and an increased risk of heart disease. As such Total Cholesterol testing plays a vital role in preventative health care. Both the American National Cholesterol Education Programme (NCEP) and the European Society of Cardiologists (ESC) recommend levels below 5 mmol/L.

TRIGLYCERIDES

Key Features of the Randox Triglycerides Assay

- **Wide range of kit sizes and formats available** offering choice and minimal reagent waste
- **Liquid and lyophilised formats available** for greater choice
- **Standards included in certain kits** for user convenience (these are for manual and semi-automated use only)
- **Extensive measuring range** of 0.134-12.7 mmol/L for the measurement of clinically significant levels
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Triglycerides assay on a wide range of clinical chemistry analysers
- **GPO-PAP method**

Clinical Significance

Elevated triglyceride levels increase the atherogenicity of HDL-C and LDL-C. A triglyceride concentration of less than 1.7 mmol/L is desirable. Levels higher than this are not only associated with an increased risk of heart disease but also type 2 diabetes, kidney disease, hypothyroidism and pancreatitis.

All ordering information can be found on *Page 20-21*

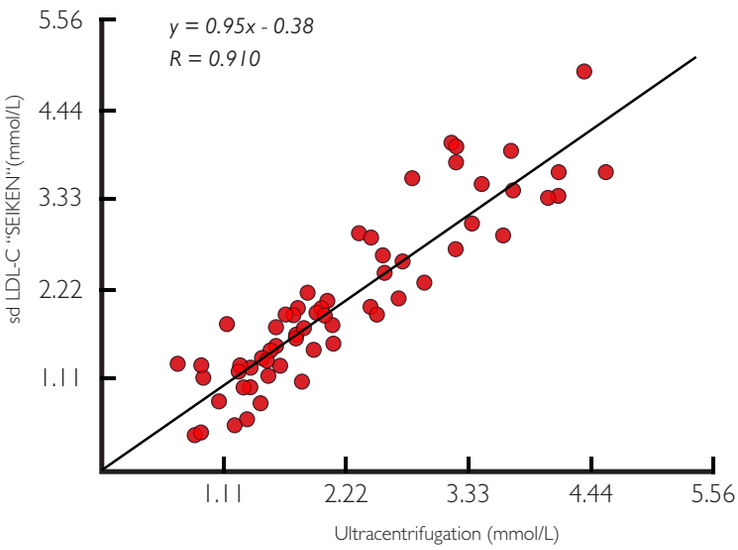
NP SMALL-DENSE LDL CHOLESTEROL (sdLDL-C)

Key Features of the Randox sdLDL Cholesterol Assay

Until recently, the primary methods of assessing a patient's sdLDL-C levels were based on techniques such as ultracentrifugation and electrophoresis both of which are extremely laborious and time-consuming. [4] sdLDL-C can now be assessed in the routine biochemistry laboratory using the Randox Clearance assay.

- **Randox sdLDL-C utilises the clearance method** which produces results in ten minutes. There are two main reaction steps based on the presence of surfactants and enzymes that selectively react with a certain group of lipoproteins
- **The Randox automated sdLDL-C assay correlates extremely well with the gold standard method** ultracentrifugation as shown in Fig. 6
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox sdLDL-C assay on a wide range of clinical chemistry analysers
- **Liquid ready-to-use reagents** for convenience and ease-of-use

Fig. 6 Correlation of Ultracentrifugation and Denka Seiken Methods. [6]



64 SAMPLES FROM HEALTHY PEOPLE, CAD & DIABETIC PATIENTS

Clinical Significance

When measuring LDL-C, you are measuring the cholesterol mass within LDL-C particles. The LDL particle population within LDL is heterogeneous - meaning that size, density & composition of each particle will be different. sdLDL-C is a subfraction of low density lipoprotein (LDL) with smaller particle size and higher density than larger more buoyant LDL-C. They all transport triglycerides and cholesterol to the tissues but their atherogenesis varies according to their size. sdLDL-C will more readily permeate the inner arterial wall has a lower affinity to the hepatic LDL-C receptor and as such circulates in the blood longer and is more is more susceptible to oxidation.

As sdLDL-C is particularly atherogenic, a person with elevated sdLDL-C levels has a 3-fold increased risk of myocardial infarction (MI).[5]

sdLDL-C measurement provides a more comprehensive understanding of the risk of lipoproteins within a patient. sdLDL-C measurement is more comprehensive in detecting cardiovascular risk compared to the traditional LDL-C test. Fig. 7 illustrates the predominance of sdLDL-C particles in comparison to LDL-C particles.[7]

Fig. 7 Predominance of sdLDL-C particles in comparison to LDL-C particles.[7]

Even though the overall LDL-C mass is the same for each patient, by measuring sdLDL-C, there are very different treatment considerations needed.

All ordering information can be found on *Page 20-21*

LIPOPROTEIN (a) (Lp(a))

Traditional challenges of Lp(a) measurement

The widespread use of Lp(a) as an independent risk factor for cardiovascular disease risk has, until recently, been impeded by the lack of internationally accepted standardisation and the fact that many commercial Lp(a) methods suffer from apolipoprotein (a) (apo(a)) size related bias, potentially leading to patient misclassification.

The size heterogeneity of apo(a) affects, to varying degrees the results of many commercially available Lp(a) kits. This may result in an underestimation of Lp(a) in samples containing apo(a) molecules smaller than that used in the assay's calibrator and conversely may overestimate the concentration in samples containing larger apo(a) particles.

Criteria to overcome challenges of Lp(a) measurement

IFCC -
The International Federation of Clinical Chemistry (IFCC) Working Group on Lp(a) recommends that laboratories use assays which do not suffer from apo(a) size-related bias, in order to minimise the potential of risk misclassification of patients for coronary heart disease.

Lipoprotein(a) Foundation -
The Lp(a) Foundation has referenced Marcovina and Albers (2016)[8] as their recommendation for the best Lp(a) test. This study comes to the following conclusions:

- Robust assays based on the Denka method are available, which are reported in nanomoles per litre (nmol/L) and are traceable to WHO/IFCC reference material
- Five point calibrators with accuracy assigned target values will minimise the sensitivity to apo (a) size
- Upon request, manufacturers should provide the certificate of evaluation of the calibrator and reagent lots with the relative expiration dates

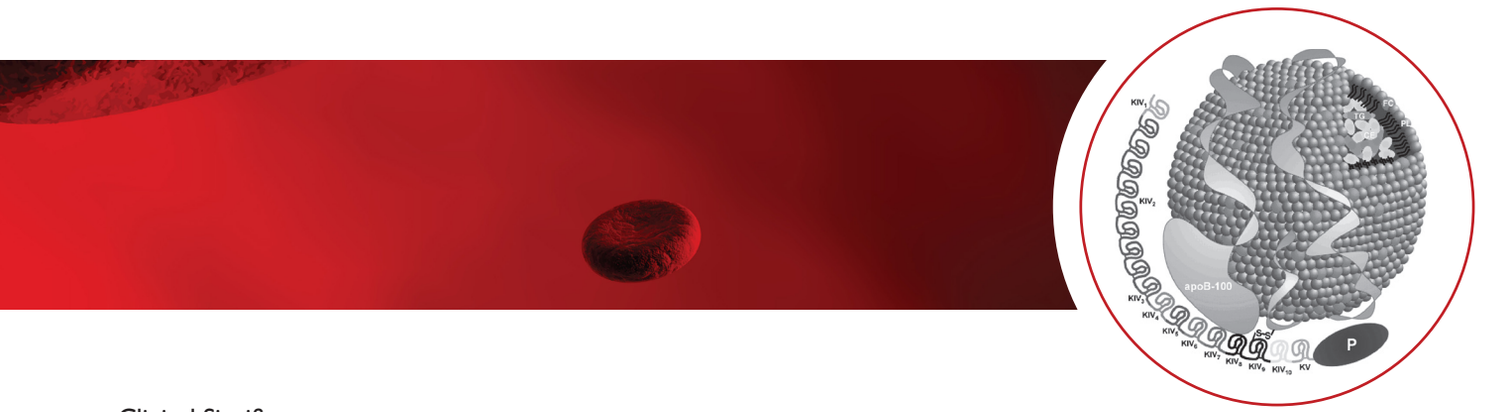
Key Features of the Randox Lp(a) Assay

UF **The Randox Lp(a) assay is one of the only methodologies on the market that detects the non-variable part of the Lp(a) molecule and therefore suffers minimal size related bias** providing more accurate and consistent results. The Randox Lp(a) kit is standardised to the WHO/ IFCC reference material SRM 2B and is closest in terms of agreement to the ELISA reference method.

UF **Five point calibrator with accuracy-based assigned target values are provided** which accurately reflect the heterogeneity of isoforms present in the general population

- **Measuring units available in nmol/L upon request**
- **Highly sensitive and specific** method for Lp(a) detection in serum and plasma
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Lp(a) assay on a wide range of clinical chemistry analysers
- **Liquid ready-to-use reagents** for convenience and ease-of-use

All ordering information can be found on *Page 20-21*



Clinical Significance

The determination of Lp(a) levels is intended for use in conjunction with the clinical evaluation, patient risk assessment and other lipid tests to evaluate disorders of lipid metabolism and to assess coronary heart disease in specific populations.

The size of the apo(a) protein is genetically determined and varies widely. As such, the **levels of Lp(a) can vary up to 1000-fold between individuals**.[9] Recent years have seen major scientific advances in the understanding of Lp(a) and its causal role in premature cardiovascular disease (CVD).

Elevated Lp(a) levels are associated robustly and specifically with an increased CVD risk.

Additional Risks

- Along with other tests, Lp(a) can provide additional information on a patient's risk factor of developing CVD
- It is particularly useful for determining the risk of CVD in specific populations due to ethnic variations
- The predictive value of Lp(a) is independent of LDL, non-HDL and the presence of other CVD risk factors
- Lp(a) levels, like elevated LDL, is causally related to the premature development of atherosclerosis and CVD

Guidelines for Clinical Significance

European Guidelines for Management of Dyslipidaemia
Lp(a) should be measured in individuals considered at high risk of CVD or with a strong family history of premature CVD. The guidelines recommend aiming for Lp(a) ~<50mg/dL as a treatment priority, after maximal therapeutic management of LDL cholesterol.

European Atherosclerotic Society [10]
The European Atherosclerotic Society suggest that Lp(a) should be measured once in all subjects at intermediate or high risk of CVD/CHD who present with:

I. Premature CVD
II. Family hypercholesterolaemia
III. A family history of premature CVD and/or elevated Lp(a)
IV. Recurrent CVD despite statin treatment
V. ≥ 3% 10-year risk of fatal CVD according to the European guidelines
VI. ≥ 10% 10-year risk of fatal and/or non-fatal CHD according to the US guidelines

Repeat measurement is only necessary if treatment for high Lp(a) levels is initiated in order to evaluate a therapeutic response.

EAS Consensus Panel
The evidence clearly supports Lp(a) as a priority for reducing cardiovascular risk, beyond that associated with LDL cholesterol. Clinicians should consider screening statin-treated patients with recurrent heart disease, in addition to those considered at moderate to high risk of heart disease.

International Classification of Diseases, 10th Edition, Clinical Modification/Procedure Coding System (ICD-10)

In October 2018, new diagnostic codes were released for Lp(a):

- E78.41 aids in identifying asymptomatic patients with elevated Lp(a) levels
- Z83.430 aids in identifying those with a family history of elevated Lp(a) levels

These codes were generated because previously clinicians did not have a way to document elevated Lp(a) levels, except using a genetic hypercholesterolemia code. Due to the lack of ICD-10 codes for Lp(a) limits research on Lp(a) using electronic health records. These new codes will aid in diagnosing elevated Lp(a) levels before the first signs of the disease (heart attack or stroke) become visible enabling timely and effective treatment methods to be implemented. These codes will further assist in the testing of the hypothesis that elevated Lp(a) levels correlates with an increased risk of CVD.[11]

APOLIPOPROTEIN A-I

Key Features of the Randox Apolipoprotein A-I Assay

- **Liquid ready-to-use reagents** for convenience and ease-of-use
- **Wide measuring range** of 6.50-233 mg/dL for the measurement of clinically important results
- **Limited interference** from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Apolipoprotein A-I assay on a wide range of clinical chemistry analysers

Clinical Significance

Apolipoprotein A-I is one of the main protein forms found in High Density Lipoproteins (HDL). The chief role of Apolipoprotein A-I is in the activation of lecithin cholesterol acyl transferase (LCAT) and the capture and removal of free cholesterol from extrahepatic tissues. This process is called reverse cholesterol transport. Apolipoprotein A-I may therefore be described as non-atherogenic, showing an inverse relationship to cardiovascular risk.

Studies have shown that there is an inverse relationship between Apolipoprotein A-I and coronary artery disease (CAD), whereas Apolipoprotein B has a direct relationship with CAD. Patients with CAD generally display reduced levels of Apolipoprotein A-I and increased levels of Apolipoprotein B.

APOLIPOPROTEIN A-II

Key Features of the Randox Apolipoprotein A-II Assay

- **Liquid ready-to-use reagents** for convenience and ease-of-use
- **Wide measuring range** of 6.75-61.1 mg/dL for the measurement of clinically important results
- **Limited interference** from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Apolipoprotein A-II assay on a wide range of clinical chemistry analysers

Clinical Significance

Apolipoprotein A-II is a major constituent of HDL-C particles and plays an important role in the processes of reverse cholesterol transport and lipid metabolism. The increased production of Apolipoprotein A-II promotes atherosclerosis by decreasing the proportion of anti-atherogenic HDL-C containing Apolipoprotein A-I.

APOLIPOPROTEIN B

Key Features of the Randox Apolipoprotein B Assay

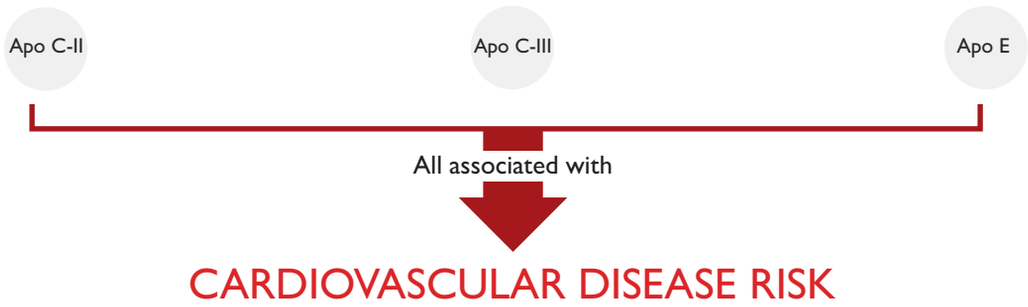
- **Liquid ready-to-use reagents** for convenience and ease of use
- **Extensive measuring range** of 11.2-184 mg/dL for the measurement of clinically important results
- **Limited interference** from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Apolipoprotein B assay on a wide range of clinical chemistry analysers

Clinical Significance

Apolipoprotein B is the main form of protein found in Low Density Lipoproteins (LDL). Apolipoprotein B shows atherogenic signs and is therefore useful in the evaluation of coronary risk. Elevated levels of Apolipoprotein B indicate increased cardiovascular risk even when total and LDL cholesterol levels are shown to be within the normal range, making this an important risk marker.

Apolipoprotein B is often tested alongside Apolipoprotein A-I to determine the Apolipoprotein B / Apolipoprotein A ratio which can be used as an alternative to the Total Cholesterol /HDL Cholesterol ratio when determining cardiovascular risk.

All ordering information can be found on *Page 20-21*



NP APOLIPOPROTEIN C-II

Key Features of the Randox Apolipoprotein C-II Assay

- **Liquid ready-to-use reagents** for convenience and ease-of-use
- **Excellent sensitivity** of 1.48 mg/dL, ensuring depleted levels of Apo C-II are detected
- **Limited interference** from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Apolipoprotein C-II assay on a wide range of clinical chemistry analysers

Clinical Significance

Apolipoprotein C-II deficiency can lead to hypertriglyceridemia in patients; therefore measuring Apolipoprotein C-II can be used as an aid in assessing CVD risk. Apolipoprotein C-II deficient patients present with chylomicronemia, xanthomas, and recurrent pancreatitis.

NP APOLIPOPROTEIN C-III

Key Features of the Randox Apolipoprotein C-III Assay

- **Liquid ready-to-use reagents** offering optimum convenience and ease-of-use
- **Excellent linearity** of 21.7 mg/dL. The approximate normal upper limit for Apo C-III is 9.5 mg/dL, therefore the Randox assay will comfortably detect elevated, potentially harmful levels of Apo C-III
- **Limited interference** from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Apolipoprotein C-III assay on a wide range of clinical chemistry analysers

Clinical Significance

Apolipoprotein C-III modulates the uptake of triglyceride-rich lipoproteins by the LDL receptor related protein through inhibition of lipoprotein lipase. Elevated levels of Apolipoprotein C-III are associated with both primary and secondary hypertriglyceridemia.

Genetically determined Apolipoprotein C-III deficiency has shown to increase the rate of triglyceride clearance from the plasma **up to 7-fold**. Apolipoprotein C-III levels have been reported higher in many conditions including type 2 diabetes, hyperbilirubinemia, kidney deficiency and decreased thyroid function. Factors that can influence Apolipoprotein C-III levels include gender, age, menopause and genetic polymorphisms in the Apolipoprotein C-III gene.

NP APOLIPOPROTEIN E

Key Features of the Randox Apolipoprotein E Assay

- **Liquid ready-to-use reagents** for convenience and ease-of-use
- **Extensive measuring range** of 1.04-12.3 mg/dL for measurement of clinically important results
- **Limited interference** from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Apolipoprotein E (Apo E) assay on a wide range of clinical chemistry analysers

Clinical Significance

Apo E is an amino acid which has many functions including the transport of triglycerides to the liver tissue and distribution of cholesterol between cells.

A deficiency in Apo E gives rise to high serum cholesterol and triglyceride levels and as a result, leads to premature atherosclerosis. A number of factors can affect Apo E concentrations including: the genetic polymorphism, oral contraceptive intake, puberty, BMI and age.

All ordering information can be found on *Page 20-21*

NP sPLA$_2$-IIA

FOR RESEARCH USE ONLY

Biological Significance of sPLA$_2$-IIA

The secretory phospholipase A$_2$ family comprises of a large range of enzymes whose main function is to hydrolyse phospholipids from the cell membrane surface and lipoproteins.[15] sPLA$_2$-IIA is thought to be the most highly expressed of the enzymes and observational studies have indicated that higher circulating sPLA$_2$-IIA mass is associated with increased risk of incident and major vascular event (MVE).[15]

Clinical Significance

sPLA$_2$-IIA is a cardiovascular biomarker, which aids in prediction of coronary risk and in the prognosis of patients across different cardiac risk groups. It is a strong predictor of adverse outcomes, including CVD, myocardial infarction (MI), stroke and heart failure.[16] Key observations through research have found that sPLA$_2$-mediated modification of lipoproteins plays a role in the development of atherosclerosis. The surface of both LDL-C and HDL-C is surrounded by phosphatidylcholine (PC) a type of phospholipid which has been scientifically proven to serve as a good extracellular target for several isoforms of sPLA$_2$-IIA. sPLA$_2$-IIA works by hydrolysing these phospholipids resulting in the production of free fatty acids and lysophophatidylcholine (LPC) which can generate pro-inflammatory actions, accelerating atherosclerosis.[17] Fig 8 is an illustration of the proposed role sPLA$_2$-IIA in the development of atherosclerosis. The diagram highlights the role sPLA$_2$-IIA has in the hydrolysis of LDL-C into the more atherogenic sdLDL-C.

Lp-PLA$_2$ vs sPLA$_2$-IIA

Lp-PLA$_2$ is a cardiac biomarker, sharing similarities with sPLA$_2$-IIA as it too is a member of the phospholipase A$_2$ enzyme family. Both sPLA$_2$-IIA and Lp-PLA$_2$ have associations with LDL-C.

Though involved in similar mechanisms, research has found that among biomarkers of inflammation, sPLA$_2$-IIA mass improved identification of patients with an increased risk of major adverse cardiovascular event.[18] Although Lp-PLA$_2$ mass has been associated with some cardiovascular diseases, researchers question whether Lp-PLA$_2$ has clinical utility and its role as a risk prediction biomarker.[19]

Findings from Key Publications:

- High levels of sPLA$_2$ -IIA can also be associated with other diseases providing more areas for testing. The risk factors associated with elevated sPLA$_2$-IIA are diabetes, mellitus, hypertension, HDL and LDL-cholesterol.[20]
- Elevated concentrations of sPLA$_2$-IIA showed a statistically significant increased risk for secondary CVD events independent of a variety of potential cofounders.[21]

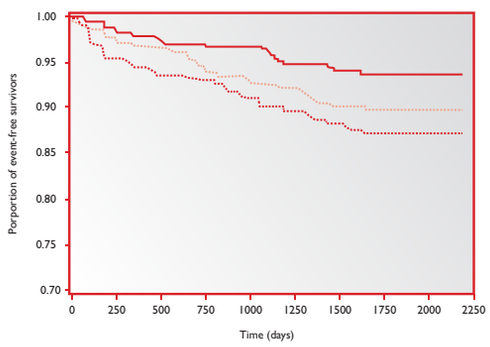
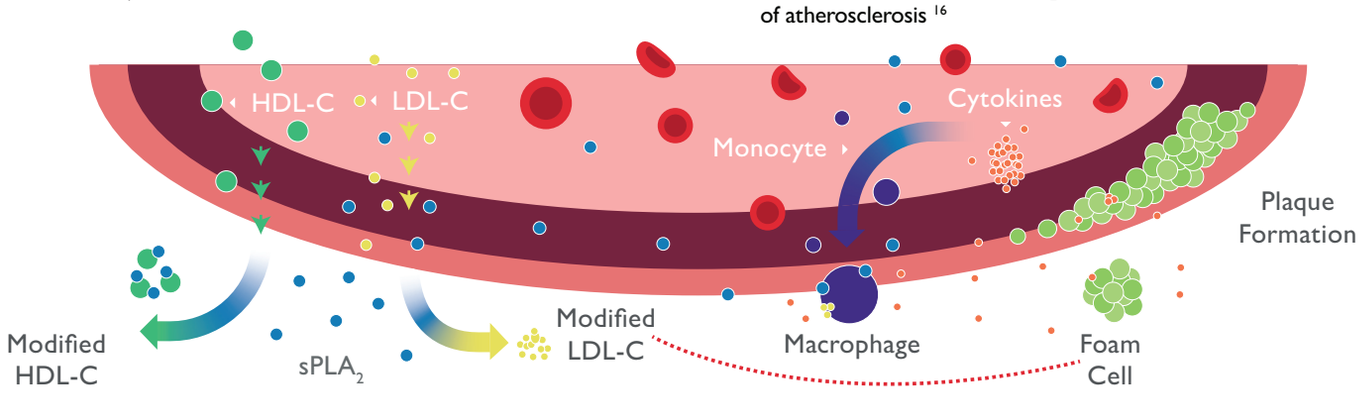


Fig. 9 Kaplan-Meier estimates of secondary fatal and non-fatal CVD events during follow-up according to tertiles of sPLA$_2$ mass at baseline. [21]

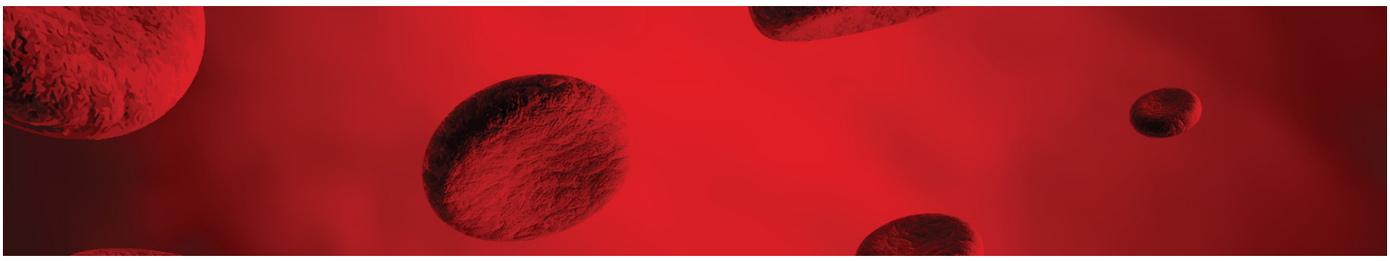
Key Features of the Randox sPLA$_2$-IIA assay

- **A niche product from Randox** meaning that we are one of the only manufacturers to provide the sPLA$_2$-IIA test in an automated chemistry form
- **Automated assay** which removes the inconvenience and time consumption associated with traditional ELISA based testing
- **Applications available** for a wide range of automated biochemistry analysers to ensure ease of programming and confidence in results
- **Liquid ready-to-use** reagents for convenience and ease-of-use
- **Latex Enhanced Immunoturbidimetric method** delivering high performance
- **Controls and calibrators available** offering a complete testing package

Fig. 8 A proposed role of sPLA$_2$-IIA in the development of atherosclerosis [16]



All ordering information can be found on *Page 20-21*



HOMOCYSTEINE

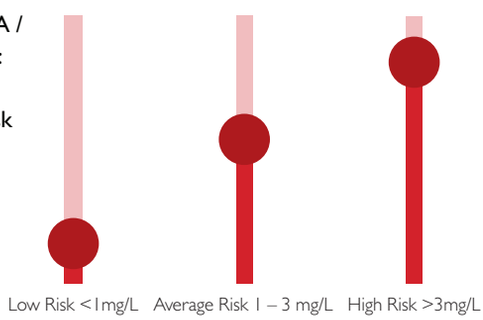
Key Features of the Randox Homocysteine Assay

- UF **Two shot, liquid ready-to-use reagent kit** for optimum convenience
- UF **Limited interference** from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Calibrator is included in the kit** offering a complete testing package
- **Wide measuring range** of 1.7 - 47.9 µmol/L. The normal range for homocysteine is approximately 5-20 µmol/L therefore the Randox assay can detect abnormal levels of homocysteine within a sample
- **Excellent stability** of 28 days on-board the analyser when stored at +10°C, minimising reagent waste
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Homocysteine assay on a wide range of clinical chemistry analysers

Clinical Significance

Elevated levels of homocysteine have been shown to damage the endothelial cell wall of arteries. Damage and the associated inflammation at these sites, coupled with elevated lipoproteins can place an individual at higher risk of developing CVD through atherosclerosis. Hyperhomocysteinemia, elevated levels of homocysteine, can be associated with an increased risk of CVD. Patients with chronic renal disease experience an excess morbidity and mortality due to arteriosclerotic CVD. Elevated concentrations of homocysteine is a frequently observed finding in the blood of these patients.

Fig. 10 2006 AHA / CDC Guidelines: hsCRP Levels vs Heart Attack Risk



HIGH SENSITIVITY CRP

Key Features of the Randox High Sensitivity CRP Assay

- **Liquid ready-to-use reagents** for optimum convenience and ease-of-use
- **Latex Enhanced Immunoturbidimetric methodology** delivering high performance
- **Wide measuring range** of 0.477-10 mg/L for measurement of clinically important results
- **Limited interference** from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox hsCRP assay on a wide range of clinical chemistry analysers

Clinical Significance

Risk Assessment - High Sensitivity CRP (hsCRP) in addition to lipid evaluation and risk scoring systems aids in the assessment of cardiovascular disease (CVD) risk. Approximately half of all heart attacks occur in patients who have a normal lipid profile and are classified **as low risk based on traditional methods** of risk estimation. The measurement of hsCRP can help clinicians to identify these individuals earlier. Healthy individuals with CRP levels higher than 3mg/l are 2 to 4 times more likely to have a heart attack or stroke. It can also be used to evaluate the risk of a **recurrent cardiac event.**

Prognosis - In high risk groups there have been indications that CRP could be used as a prognostic tool.

Guidelines - The American Heart Association (AHA) and Centre for Disease Control and Prevention (CDC) recommend the use of hsCRP as a more sensitive marker of CVD risk compared to traditional CRP assays, and suggest the risk guidelines, shown in Figure 10.

All ordering information can be found on *Page 20-21*

CK-MB

Key Features of Randox CK-MB

- **Wide range of kits sizes and formats available** offering choice and minimal reagent waste
- **Liquid and lyophilised options available** to satisfy individual user requirements
- **Randox Easy Fit reagents available** which directly fit on to a wide range of analysers, including Hitachi 717, Abbott Architect and Beckman Coulter AU Series machines and are used in conjunction with validated analyser applications to ensure ease of programming
- **Randox Easy Read reagents available for Hitachi analysers** which these reagents are packaged in dedicated bottles and are barcoded for use, removing the need for any additional steps to be completed
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox CK-MB assay on a wide range of clinical chemistry analysers

MYOGLOBIN

Key Features of Randox Myoglobin

- **Latex Enhanced Immunoturbidimetric methodology** offering superior performance
- **Liquid ready-to-use reagents** for convenience and ease-of-use
- **Wide measuring range of 20.1 - 725 ng/ml** with normal levels of myoglobin being < 85 ng/ml
- **Applications available** detailing instrument specific settings for the convenient use of the Randox Myoglobin assay on a wide range of clinical chemistry analysers

DIGOXIN

Key Features of the Randox Digoxin Assay

- **Latex Enhanced Immunoturbidimetric methodology** offering superior performance
- **Liquid ready-to-use reagents** for convenience and ease-of-use
- **Excellent stability** of 21 days on-board the analyser at +2 to +8°C, minimising reagent waste
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Digoxin assay on a wide range of clinical chemistry analysers

Clinical Significance

Digoxin is a drug commonly used to treat patients with heart failure and arrhythmias. It increases the strength of the heart's contraction. A stronger heartbeat means that the heart will circulate more blood and helps to reduce the symptoms of heart failure. Digoxin can also regulate, and slow the heart rate, and is therefore useful in certain heart rhythm disorders.

As these conditions are generally chronic, monitoring Digoxin levels is useful in managing the patient's condition.

All ordering information can be found on *Page 20-21*

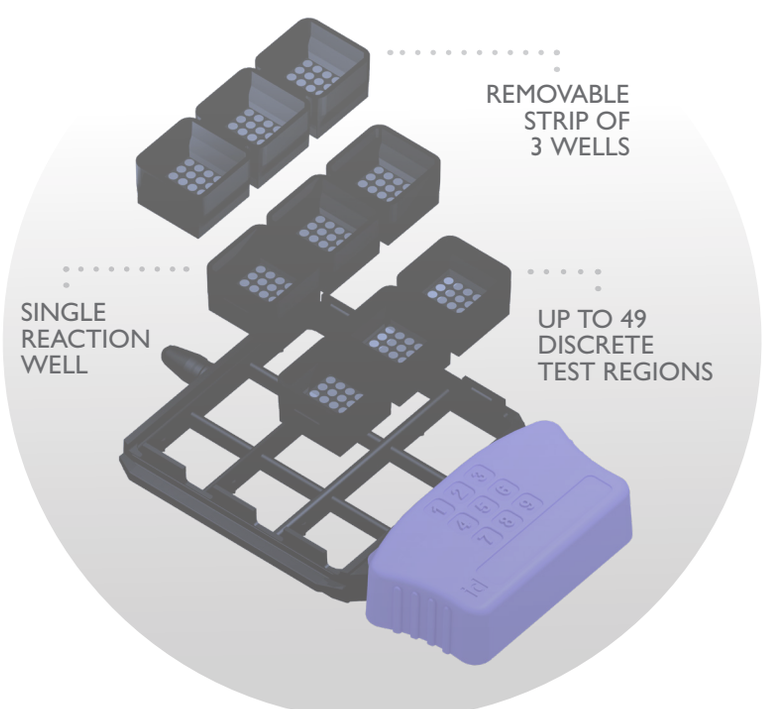
RANDOX MULTIPLEX BIOCHIP ARRAY TECHNOLOGY

Randox offer diagnostic and research solutions utilising our innovative Biochip Array Technology (BAT). BAT enables multi-analyte testing of biological samples to provide a complete patient profile from a single sample for rapid and accurate diagnosis.

The biochip acts as a solid phase reaction vessel, where biochips are pre-fabricated with discrete test regions (DTR's); a different antibody/ oligonucleotide is immobilised at each spatially distinct DTR. Up to 49 individual DTR's can be arrayed on to a single biochip with one biochip per sample used to generate multiple results simultaneously.

The biochip detection is based on a chemiluminescent signal emitting light, without heat, as a result of a chemical reaction. The light emitted is detected and quantified using a CCD camera.

Biochip Array Technology operates via the Evidence series of analysers designed to deliver efficient high-quality testing and significant time and cost savings.



FAMILIAL HYPER CHOLESTEROLAEMIA (FH) ARRAYS I & II

Key Features

- Rapid turnaround time of ~3 hours from extracted genomic DNA to result
- Samples can be assessed in low batches (3 biochips) with only 20ng of genomic DNA required per array
- Ideal protocol for rapid, cost effective cascade testing in family members of FH index patient

Patient

- Rapid mutational test to diagnose FH, the most commonly inherited lipid disease
- Mutational status can be determined rapidly from a single test, with a reduced need for confirmatory testing with NGS
- Genetic analysis for FH mutations gives a definitive diagnosis compared to lipid profiling

Laboratory

- CE - marked IVD product.
- The array tests for 40 specific FH-causing mutations with ~78% coverage in the UK and Ireland, providing a targeted, cost-effective assay for FH testing. Rapid turnaround time allows results to be reported same day, compared to lengthy NGS screening which can take several weeks
- The array consists of 2 mutation panels, allowing for single panel testing in cases of cascade screening of known mutations for further laboratory cost savings

All ordering information can be found on *Page 20-21*

CARDIAC RISK PREDICTION ARRAY

Key features

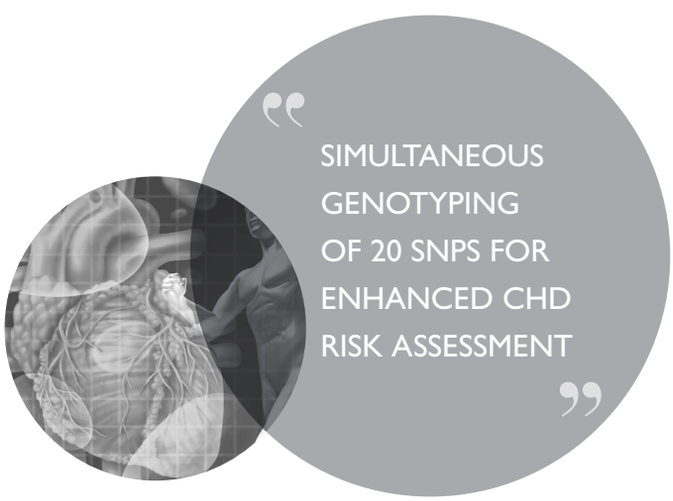
- Same day genotyping of 20 GWAS - identified SNPs
- 36 patient samples can be processed per kit
- Easy to interpret results using the Randox Evidence Investigator dedicated software

Patient

- Enhanced CHD risk assessment allows for early intervention therapeutic treatment and/or lifestyle changes to improve cardiovascular health and reduce the risk of CHD
- Genetic profiling identifies those patients predisposed to statin-induced myopathy, allowing clinicians to make more informed decisions when prescribing lipid lowering therapies

Laboratory

- Developed with key opinion leaders in cardiovascular genetics to identify SNPs associated with CHD risk
- Uniquely combines SNP genotyping and patient questionnaire data with an algorithim to generate an easy to interpret cardiac risk score



CARDIAC PROTEIN ARRAY

The Cardiac Array simultaneously detects up to four cardiac markers from a single patient sample, providing highly accurate quantitative results. Suitable for use within both a clinical and research setting.

ACS refers to a range of acute myocardial states, ranging from unstable angina pectoris to acute myocardial infarction (AMI) with or without ST-segment elevation. Diagnosis and risk stratification (from low risk to high risk) are closely linked in ACS.

Biochemical markers in serum are used as analytical tools for the diagnosis in conjunction with physical examination, clinical history, electrocardiogram and imaging investigations. The Randox Cardiac Array enables the simultaneous determination of four cardiac markers (including late and early markers) from a single sample thus increasing the test result output to facilitate early detection , diagnosis and therapeutic monitoring. Corresponding tri-level QC material available.

Cardiac Array

- Creatine-Kinase Muscle Brain (CK-MB)
- Heart-Type Fatty Acid Binding Protein (H-FABP)
- Myoglobin (MYO)
- Troponin I (cTnI)

Key benefits of Randox Cardiac Array

- Multiplex testing from a single sample
- Suitable for human serum samples
- Small sample volume

Available on Evidence Investigator analyser

- Increased analytical information
- Improved risk stratification of patients with suspected ACS

DESCRIPTION	METHOD	SIZE	CAT. NO. AB362
Apolipoprotein A-I ♦	Immunoturbidimetric	R1 4 x 40ml, R2 4 x 17ml (S)	LP2116
Apolipoprotein A-I ♦	Immunoturbidimetric	R1 2 x 8.6ml, R2 2 x 4.8ml	LP8007
Apolipoprotein A-I ♦	Immunoturbidimetric	R1 4 x 30ml, R2 4 x 12ml	LP3838
Apolipoprotein A-II ♦	Immunoturbidimetric	R1 2 x 11ml, R2 2 x 5ml	LP3867
Apolipoprotein B ♦	Immunoturbidimetric	R1 4 x 50ml, R2 4 x 9ml (S)	LP2117
Apolipoprotein B ♦	Immunoturbidimetric	R1 2 x 8.7ml, R2 3 x 3.9ml	LP8008
Apolipoprotein B ♦	Immunoturbidimetric	R1 4 x 20ml, R2 4 x 6ml	LP3839
Apolipoprotein C-II ♦	Immunoturbidimetric	R1 2 x 11ml, R2 2 x 5ml	LP3866
Apolipoprotein C-III ♦	Immunoturbidimetric	R1 2 x 11ml, R2 2 x 5ml	LP3865
Apolipoprotein E ♦	Immunoturbidimetric	R1 2 x 11ml, R2 2 x 5ml	LP3864
CK-MB	Immunoinhibition (UV)	19 x 2.5ml	CK1296
CK-MB	Immunoinhibition (UV)	R1 4 x 20ml, R2 4 x 6ml	CK3813
CK-MB ♦	Immunoinhibition (UV)	R1 4 x 20ml, R2 4 x 6ml	CK4043
CK-MB	Immunoinhibition (UV)	R1 4 x 20ml, R2 4 x 8ml	CK8148
FH Arrays I & II	Biochip	54 biochip kit	EV3825/ EV3917A1B
Digoxin ♦	L.E.I.	R1 2 x 8ml, R2 2 x 6ml	TD3410
HDL Cholesterol ♦	Direct Clearance	R1 3 x 2.5L, R2 1 x 2.5L	CH1383
HDL Cholesterol ♦	Direct Clearance	R1 6 x 78ml, R2 3 x 52ml	CH2655
HDL Cholesterol ♦	Direct Clearance	R1 3 x 51ml, R2 3 x 20ml	CH3811
HDL Cholesterol ♦	Direct Clearance	R1 4 x 38.2ml, R2 4 x 18.2ml	CH8033
HDL Cholesterol ♦	Direct Clearance	R1 4 x 20ml, R2 4 x 9ml	CH8311
HDL Cholesterol Precipitant ♦	Phosphotungstic Acid	4 x 80ml	CH203*
High Sensitivity CRP ♦	L.E.I.	R1 2 x 11ml, R2 2 x 11ml	CP3885
Homocysteine ♦	Enzymatic	R1 2 x 21.7ml, R2 2 x 4.6ml (S)	HY4036
LDL Cholesterol ♦	Direct Clearance	R1 6 x 78ml, R2 3 x 52ml	CH2656
LDL Cholesterol ♦	Direct Clearance	R1 6 x 30ml, R2 3 x 20ml	CH2657
LDL Cholesterol ♦	Direct Clearance	R1 3 x 51ml, R2 3 x 20ml	CH3841
LDL Cholesterol ♦	Direct Clearance	R1 4 x 19.2ml, R2 4 x 10.1ml	CH8032
LDL Cholesterol ♦	Direct Clearance	R1 4 x 20ml, R2 4 x 9ml	CH8312
Lipoprotein(a) ♦	L.E.I.	R1 1 x 30 ml, R2 1 x 15 ml	LP2757
Lipoprotein(a) ♦	L.E.I.	R1 1 x 10 ml, R2 1 x 6 ml	LP3403
Lipoprotein(a) ♦	L.E.I.	R1 2 x 8.7ml, R2 2 x 5.8ml	LP8054
Myoglobin ♦	L.E.I.	R1 1 x 9.5ml, R2 1 x 4.5ml	MY2127
sdLDL Cholesterol ♦	Direct Clearance	R1 1 x 16.2 ml, R2 1 x 8.2 ml	CH8153

DESCRIPTION	METHOD	SIZE	CAT. NO.
			AB362
sdLDL Cholesterol ♦	Direct Clearance	R1 1 x 19.8ml R2 1 x 8.6ml	562616
sdLDL Cholesterol (U) ♦	Direct Clearance	R1 1 x 18ml R2 1 x 7ml	562760
sdLDL Cholesterol (U) ♦	Direct Clearance	R1 5 x 200ml R2 2 x 200ml	562791, 562807
Total Cholesterol ♦	CHOD-PAP	6 x 30ml (S)	CH200
Total Cholesterol ♦	CHOD-PAP	6 x 100ml (S)	CH201
Total Cholesterol ♦	CHOD-PAP	9 x 51ml	CH3810
Total Cholesterol ♦	CHOD-PAP	4 x 68ml	CH8019
Total Cholesterol ♦	CHOD-PAP	4 x 20ml	CH8310
Triglycerides	GPO-PAP	6 x 15ml (S)	TR210
Triglycerides	GPO-PAP	4 x 100T (S)	TR1697
Triglycerides	GPO-PAP	6 x 51ml	TR3823
Triglycerides	GPO-PAP	4 x 58ml	TR8067
Triglycerides ♦	GPO-PAP	8 x 20ml	TR8147
Triglycerides ♦	GPO-PAP	4 x 20ml	TR8332
Triglycerides	GPO-PAP	4 x 60ml	TR9780

* Precipitant for use with CH200, CH201 and CH202

♦ Indicates liquid option available

(S) Indicates standard included in kit

(U) USA Only

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A-Z PORTFOLIO OF REAGENTS

Albumin
Aldolase
Alkaline Phosphatase
Alanine Aminotransferase (ALT)
Ammonia
Amylase (Pancreatic)
Anti-Streptolysin O (ASO)
Apolipoprotein A-I
Apolipoprotein A-II
Apolipoprotein B
Apolipoprotein C-II
Apolipoprotein C-III
Apolipoprotein E
Aspartate Aminotransferase (AST)
ß2 Microglobulin
Bile Acids
Bilirubin (Direct)
Bilirubin (Total)
Calcium
Carbamazepine
Cholesterol (Total)
Cholesterol (HDL)
Cholesterol (LDL)
Cholesterol (sdLDL)
Cholinesterase
CK-MB
CK-NAC
CO_2 Total
Complement C3
Complement C4
Copper
Creatinine
CRP
CRP (Canine)
CRP (Full Range)
CRP (High Sensitivity)
Cystatin C
Digoxin
Ethanol
Ferritin
Fructosamine
G6PDH
Gamma GT
GLDH
Glucose
Glutamate
Glutamine
Glutathione Peroxidase (Ransel)
Glutathione Reductase
Glycerol
Haemoglobin
Haptoglobin
HbA1c
HbA1c II
Homocysteine
D-3-Hydroxybutyrate (Ranbut)
IgA
IgE
IgG
IgM
Iron
L-Lactate
Lactate Dehydrogenase L-P
Lactate Dehydrogenase P-L
Lipase
Lipoprotein (a)
Magnesium
Microalbumin
Myoglobin
NEFA (Non-Esterified Fatty Acids)
Phenobarbital
Phenytoin
Phosphorus
Potassium
Rheumatoid Factor (RF)
Sodium
$sPLA_2$-IIA
Soluble Transferrin Receptor (sTfR)
Superoxide Dismutase (Ransod)
Syphilis
Total Iron Binding Capacity (TIBC)
Total Antioxidant Status (TAS)
Total Protein
Transferrin
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Urinary Protein
Valproic Acid
Zinc

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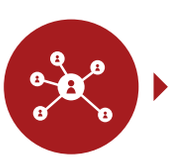

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