Randox

Cardiology & Lipid Testing

Complete Cardiology & Lipid Testing From Randox
CARDIOLOGY & LIPID TESTING

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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 111 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 reagents) 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.

Below the age of 70, CVD is responsible for 39% of all noncommunicable disease deaths.
- World Heart Federation, 2017
HDL CHOLESTEROL

Key Features of the Randox HDL Cholesterol Assay

- 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

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

All ordering information can be found on Page 23-24
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.

"The diagram above shows how specific the Randox direct clearance method is."
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
- 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

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.
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.

The Friedewald formula has been reported to misclassify up to 50% of patients.
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.

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.
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. 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 of 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.

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, and 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 with a lower affinity to the hepatic LDL-C receptor and as such circulates in the blood longer and 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).

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.

Fig. 6 Correlation of Ultracentrifugation and Denka Seiken Methods.

\[
y = 0.95x - 0.38 \\
R = 0.910
\]

64 SAMPLES FROM HEALTHY PEOPLE, CAD & DIABETIC PATIENTS

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

**LOW RISK**

**HEALTHY INDIVIDUAL**

sdLDL-C 20 mg/dL

**HIGHER RISK**

**CAD PATIENT**

sdLDL-C 70 mg/dL

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

• 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.
• 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 23-24
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. 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
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.
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.

Increased Apo A-I Levels = decreased CVD risk

All ordering information can be found on Page 23-24
APOLIPOPROTEINS

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.

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.

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.
Biological significance of HDL3 Cholesterol

HDL-C comprises of several subclass particles, which differ in their sizes, densities and components. These HDL-C subclasses are considered to play different roles in the progression and regression of atherosclerosis. HDL3-C is a smaller and denser subfraction of the HDL-C particle.

Standard tests for cholesterol, HDL-C, LDL-C and triglyceride levels only detect approximately 20% of all CAD patients. The other 80% can only be identified by differentiating subgroups, and carrying out more detailed lipid testing.

Clinical Significance

HDL-C is the scavenger of cholesterol within arterial walls and if HDL3 levels are significantly depleted, the ability to remove this cholesterol is reduced. Therefore it is widely accepted that there is an inverse correlation between HDL3-C and CVD risk, as demonstrated in a number of recent key publications:

1. HDL3-C subclass may be primarily responsible for the inverse association of HDL-C and CVD. (Albers et. al, 2016)

The aims of this secondary analysis were to examine the levels of cholesterol in HDL-C subclasses (HDL2-C and HDL3-C), sdLDL-C, and LDL-TG at baseline, as well as the relationship between these levels and cardiovascular (CV) outcomes. Analyses were performed on 3094 study participants who were already on statin therapy prior to enrollment in the trial.

The results of this secondary analysis of the AIM-HIGH Study indicate that levels of HDL3-C, but not other lipoprotein fractions, are predictive of CV events, suggesting that the HDL3 subclass may be primarily responsible for the inverse association of HDL-C and CVD.

2. In secondary prevention, the increased risk for long-term hard clinical events is associated with low HDL3-C, but not HDL2-C or HDL-C, highlighting the potential value of subclassifying HDL-C. (Martin et. al, 2015)

We collaboratively analysed data from two, complementary prospective cohorts: the TRUMPH study of 2465 AMI patients, and the IHCS study of 2414 patients who underwent coronary angiography.

In secondary prevention, the increased risk for long-term hard clinical events is associated with low HDL3-C, but not HDL2-C or HDL-C, highlighting the potential value of subclassifying HDL-C.

3. Smaller, denser HDL3-C levels are primarily responsible for the inverse association between HDL-C and incident CHD in this diverse group of primary prevention subjects. (Joshi et. al, 2016)

We aimed to clarify the associations of HDL-C subclasses with incident CHD in two large primary prevention cohorts.

We measured cholesterol at baseline from the two major HDL-C subfractions (HDL2 and HDL3) in 4114 African American participants from the Jackson Heart Study and 818 predominantly Caucasian participants from the Framingham Offspring Cohort Study.

Smaller, denser HDL3-C levels are primarily responsible for the inverse association between HDL-C and incident CHD in this diverse group of primary prevention subjects.
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.

• Elevated concentrations of sPLA$_2$-IIA showed a statistically significant increased risk for secondary CVD events independent of a variety of potential cofounders.

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. 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 lysophosphatidylcholine (LPC) which can generate pro-inflammatory actions, accelerating atherosclerosis.

**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. 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.

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

**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.**

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All ordering information can be found on Page 23-24
HOMOCYSTEINE

Key Features of the Randox Homocysteine Assay

- **Two shot, liquid ready-to-use reagent kit** for optimum convenience
- **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

Low Risk <1mg/L  Average Risk 1 – 3 mg/L  High Risk >3mg/L

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.
Key Features of the Randox Adiponectin Assay

- **Automated assay** removes the inconvenience and time consumption associated with traditional ELISA based testing
- **Liquid ready-to-use reagents** for convenience and ease-of-use
- **Latex Enhanced Immunoturbidimetric method** delivering high performance and producing results in as little as 10 minutes
- **Extensive measuring range** of 0.32 - 23.8μg/ml for the comfortable detection of clinically important results
- **Dedicated adiponectin controls and 6-point calibrator available** offering a complete testing package
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox Adiponectin assay on a wide range of clinical chemistry analysers

Clinical Significance

Adiponectin is solely secreted by adipocytes and is a protein hormone with anti-inflammatory and insulin-sensitising properties. It plays an important role in a number of metabolic processes such as glucose regulation and fatty acid oxidation.

Adiponectin levels are inversely correlated with abdominal visceral fat (AVF) levels, which have proven to be a strong predictor of several pathologies including: metabolic syndrome, type 2 diabetes, cancer and CVD. Body mass index (BMI) (weight kg / height m^2) is common method of determining patients that may be classed as overweight or obese, however this has limitations, based on age, sex, and race. As such adiponectin levels are a much more reliable indicator of at-risk patients.

Key references

- Adiponectin levels are an independent predictor of coronary heart disease (CHD) in caucasian men initially free of CHD. Raising plasma adiponectin levels is highly protective of future CHD events in men.\(^2\)
- Low plasma adiponectin concentrations are associated with MI in individuals below the age of 60, and this remains significant after adjustment for history of hypertension HDL-C, smoking and BMI.\(^2\)
- Low levels of adiponectin are associated with an increased risk of new-onset hypertension in men and postmenopausal women.\(^2\)
- In children, serum levels of adiponectin are inversely related to hypertension. Low values of adiponectin in both obese and normal weight children are associated with a higher probability of hypertension.\(^2\)

Fig 11 illustrates the proposed salutary effects of adiponectin\(^2\)
HEART - TYPE FATTY ACID BINDING PROTEIN (H-FABP)

Key Features of the Randox H-FABP Assay

- The only CE-marked automated biochemistry assay available on the market for the routine assessment of Heart-type Fatty Acid Binding Protein
- Results are returned rapidly typically within 14 minutes
- Liquid ready-to-use reagents for convenience and ease-of-use
- Applications available detailing instrument-specific settings for the convenient use of the Randox H-FABP assay on a wide range of clinical chemistry analysers

Biological significance of H-FABP

- H-FABP is an unbound, low molecular weight protein, located in the cytoplasm of cardiac myocytes.
- The molecular weight is only 15kDa smaller than Myoglobin (18kDa), Troponin I (22kDa), Troponin T (37kDa) and CK-MB (86kDa).
- The function of H-FABP is in the intracellular uptake of long chain fatty acids in the myocardium.

Fig. 12 Compares the release of H-FABP and Troponin after MI.
H-FABP

Prognostic Value in Acute Coronary Syndrome (ACS)

- Elevated H-FABP is a significant predictor of death or MI up to 1 year. 28
- H-FABP provides additional prognostic information, independent of Troponin T, ECG and clinical examination. 29

H-FABP and Troponin - the optimum biomarker strategy

- In the early hours after chest pain onset (CPO), H-FABP offered superior diagnostic sensitivity for AMI than Troponin.30
- The optimal combination of biomarkers across all time points was Troponin I and H-FABP.30
- Even based on samples taken immediately after hospital admission (<24h after CPO), the combination of H-FABP & Troponin I was superior to the triple marker strategy across the measures of sensitivity, specificity, PPV & NPV.29

Fig. 13 Comparison of the release kinetics of H-FABP against CK-MB, cTnT, cTnI and Myo.

Diagnostic Value in ACS

- Using the combination approach consistently improved the NPV, negative likelihood ratio and the risk ratio.28
- Measurement of plasma h-FABP and high sensitivity troponin T together on admission appears to be more precise predictor of ACS rather than either high sensitivity troponin T or H-FABP alone.31

Release Kinetics

- H-FABP is highly specific to the heart, approximately 15-20 times more specific than Myoglobin.32
- The normal serum/plasma value is also much lower, compared to Myoglobin.33
- Due to the low molecular weight & cytoplasmic location of H-FABP, it is released extremely quickly after an ischemic episode – detectable as early as 30 minutes afterwards.34,35

H-FABP in reinfarction

- Furthermore, the rapid return to baseline within 24 hours, offers significant potential utility in patients with suspected reinfarction, instead of CK-MB.34
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

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

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.
Key Features of the Randox TxBCardio™ Assay

• A highly accurate method for the evaluation of aspirin therapy effectiveness. The primary target of aspirin therapy is TxA₂; however, this has a very short half-life making accurate measurement difficult. When TxA₂ degrades it is converted into a number of metabolites, the most abundant of which is 11dhTxB₂. Randox TxBCardio™ specifically measures 11dhTxB₂ offering a highly accurate method for TxA₂ production analysis in patients.

• Automated latex-enhanced immunoturbidimetric assay facilitating aspirin therapy testing on automated biochemistry analysers and eliminating the need for dedicated equipment.

• Rapid analysis with an assay time of as little as ten minutes for more efficient results.

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

• Applications available detailing instrument-specific settings for the convenient use of the Randox TxBCardio™ (small TM) and a wide range of clinical chemistry analysers.

Clinical Significance

Aspirin is the foundation of antiplatelet therapy and is widely prescribed in the primary and secondary prevention of cardiovascular disease. However, not all patients receiving aspirin therapy respond in the same way, with many suffering from a lack of aspirin effect, also known as aspirin resistance.

Clinical research has shown that patients who have a sub-optimum response to their aspirin therapy are over three times more likely to die from a heart attack or stroke than those who respond positively to such therapy.

Up to 30% of patients on low dose aspirin therapy are affected by aspirin “resistance”.

The identification of these patients can be significantly improved through the use of the Randox TxBCardio™ assay. Results generated by the Randox TxBCardio™ assay can be used to enable timely intervention by clinicians with patients deemed to be at increased risk. Patient management can then be altered via improved patient compliance, increased aspirin dosage levels and/or combination therapies with other drugs.

Aspirin effect correlates to low urinary 11dhTxB₂

Lack of Aspirin effect correlates to high urinary 11dhTxB₂
**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 (DTRs); a different antibody/oligonucleotide is immobilised at each spatially distinct DTR. Up to 49 individual DTRs 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.

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**Familial Hypercholesterolaemia (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 23-24
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 algorithm 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
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* Precipitant for use with CH200, CH201 and CH202

† Indicates liquid option available

(S) Indicates standard included in kit

(U) USA Only

Not all products are available for diagnostic use in USA. Please contact your local representative for further information.

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


Body, R., McDowell, G., Carley, S., Wibberley, C., Ferguson, J. and Mackway-Jones, K. A FAB-ulous 'rule out' strategy? Heart fatty acid binding protein and troponin for rapid exclusion of acute


Glatz, J.F.,C., van Bilsen, M., Paulussen, R.J.A., Veerkamp, J., van der Vusse, G.J. and Reneman, R.S.. Release of fatty acid-binding protein from isolated rat heart subjected to ischemia and reperfusion or

Menzaghi, C., Trischitta, V. and Doria, A. Genetic Influences of Adiponectin on Insulin Resistance, Type 2 Diabetes, and Cardiovascular Disease. Perspectives in Diabetes, vol. 56, p. 1198-1209


# A-Z Portfolio of Reagents

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<tr>
<td>Apolipoprotein C-III</td>
<td>Ferritin</td>
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<tr>
<td>Apolipoprotein E</td>
<td>Fructosamine</td>
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<tr>
<td>Aspartate Aminotransferase (AST)</td>
<td>G6PDH</td>
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<tr>
<td>Barbiturates</td>
<td>Gamma GT</td>
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<tr>
<td>Benzodiazepines</td>
<td>Gentamicin</td>
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<tr>
<td>β2 Microglobulin</td>
<td>GLDH</td>
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<tr>
<td>Bile Acids</td>
<td>Glucose</td>
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<tr>
<td>Bilirubin (Direct)</td>
<td>Glutamate</td>
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<tr>
<td>Bilirubin (Total)</td>
<td>Glutamine</td>
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<tr>
<td>Calcium</td>
<td>Glutathione Peroxidase (Ransel)</td>
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<tr>
<td>Cannabinoids</td>
<td>Glutathione Reductase</td>
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<tr>
<td>Carbamazepine</td>
<td>Glycerol</td>
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<td>Ceruloplasmin</td>
<td>Haemoglobin</td>
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<td>Chloride</td>
<td>Haptoglobin</td>
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<tr>
<td>Cholesterol (Total)</td>
<td>HbA1c</td>
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<tr>
<td>Cholesterol (HDL)</td>
<td>HbA1c II</td>
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<td>Cholesterol (HDL3)</td>
<td>H-FABP</td>
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<td>Cholesterol (LDL)</td>
<td>Homocysteine</td>
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<td>Cholesterol (sdlDL)</td>
<td>D-3-Hydroxybutyrate (Ranbut)</td>
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<td>Cholinesterase</td>
<td>IgA</td>
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<tr>
<td>CK-MB</td>
<td>IgE</td>
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<tr>
<td>CK-NAC</td>
<td>IgG</td>
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<td>CO₂ Total</td>
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<td>Iron/UIBC</td>
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<td>Lactate Dehydrogenase L-P</td>
<td>Lipase</td>
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<td>Lactate Dehydrogenase P-L</td>
<td>Lipase (a)</td>
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<td>NEFA (Non-Esterified Fatty Acids)</td>
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<td>Soluble Transferrin Receptor (sTTR)</td>
<td>Superoxide Dismutase (Ransod)</td>
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<tr>
<td>Superoxide Dismutase (Ransod)</td>
<td>Syphilis</td>
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<tr>
<td>Total Iron Binding Capacity (TIBC)</td>
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<td>Total Antioxidant Status (TAS)</td>
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