



COMPLETE CARDIOLOGY
AND LIPID TESTING
FROM RANDOX

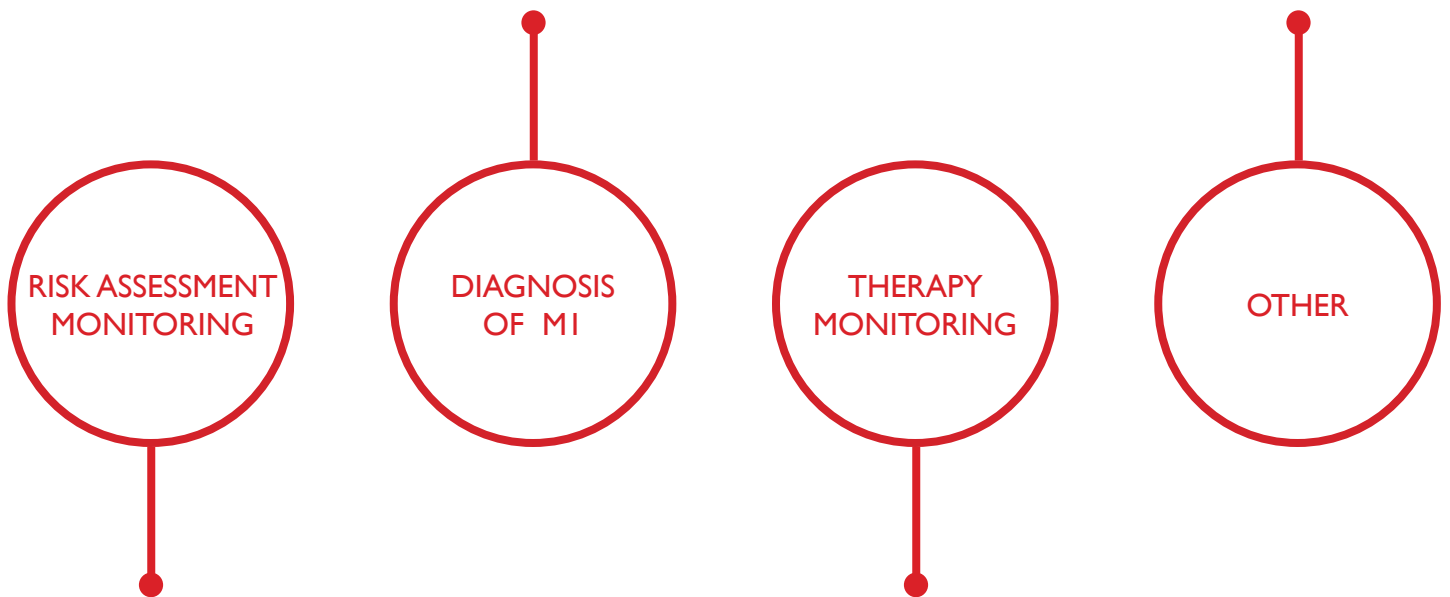
CARDIOLOGY & LIPID TESTING



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KEY



UNIQUE FEATURE

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



NICHE PRODUCT

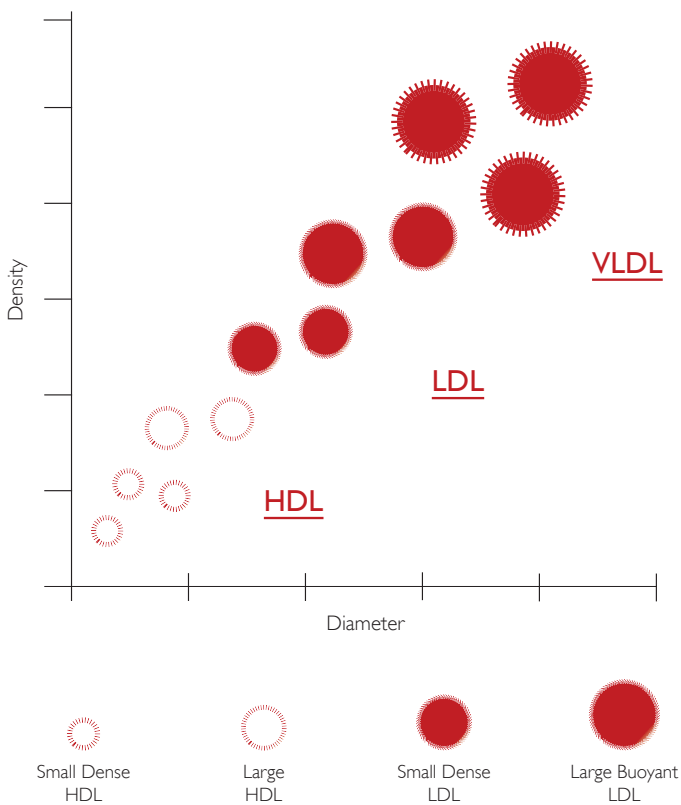
When you see this symbol you will know that Randox have one of the only automated biochemistry assays available on the market

INTRODUCTION

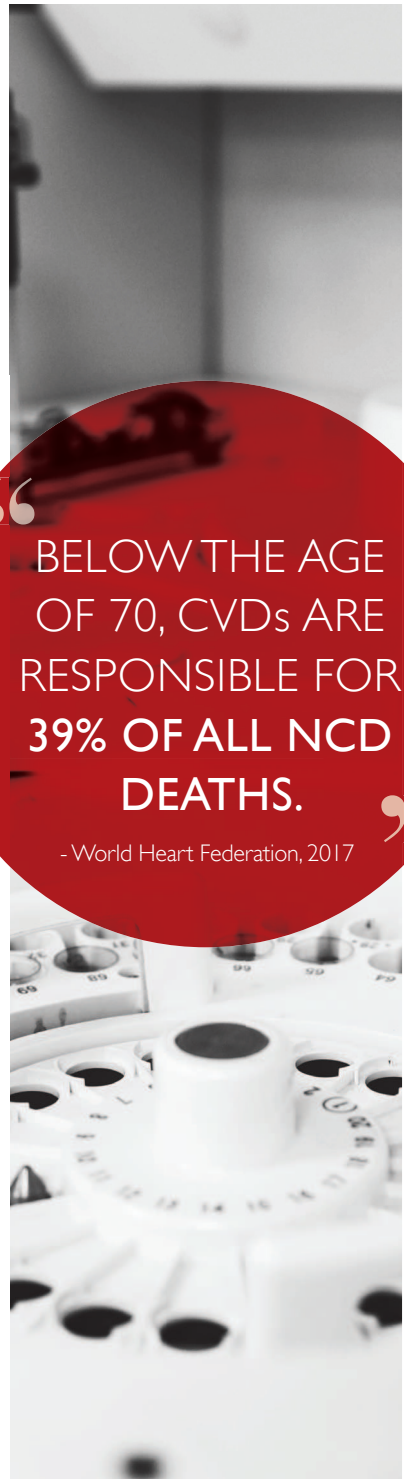
INTRODUCTION TO RANDOX CARDIOLOGY AND LIPID TESTING

The need for a more extensive lipid profiling is on the increase, to truly identify the risk of cardiovascular diseases, both in primary and secondary risk categories; and as such provide the necessary tools to prevent and reduce the risks. Randox offer a comprehensive cardiology product profile which includes high performance reagents for the detection of conventional risk factors, as well as emerging biomarkers associated with further risk.

LIPOPROTEIN SUBFRACTIONS



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





HDL CHOLESTEROL

Key Features of Randox HDL Cholesterol

- 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 for measurement of clinically important results
- Applications available for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox HDL Cholesterol assays on a variety of systems

UF Benefits of the Randox Direct Clearance Method

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

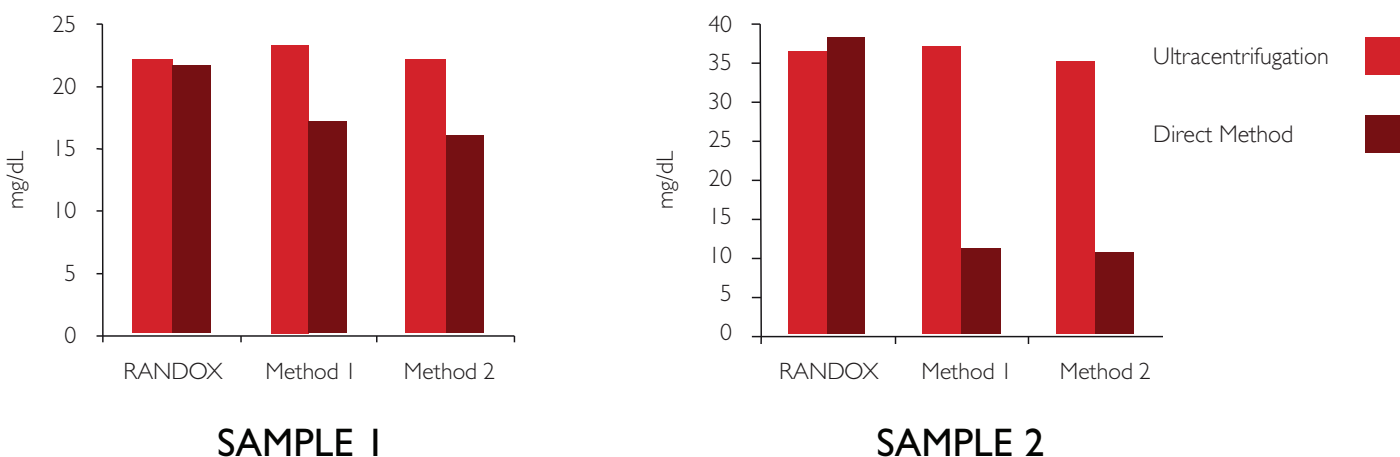
Clinical Significance

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

Performance in discrepant patient samples

Fig.1 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 compares well with the ultracentrifugation method; however the two other commercially available direct masking methods seriously underestimate the concentration of HDL.

Fig.1 Randox Direct Clearance Method vs Direct Masking Methods.¹



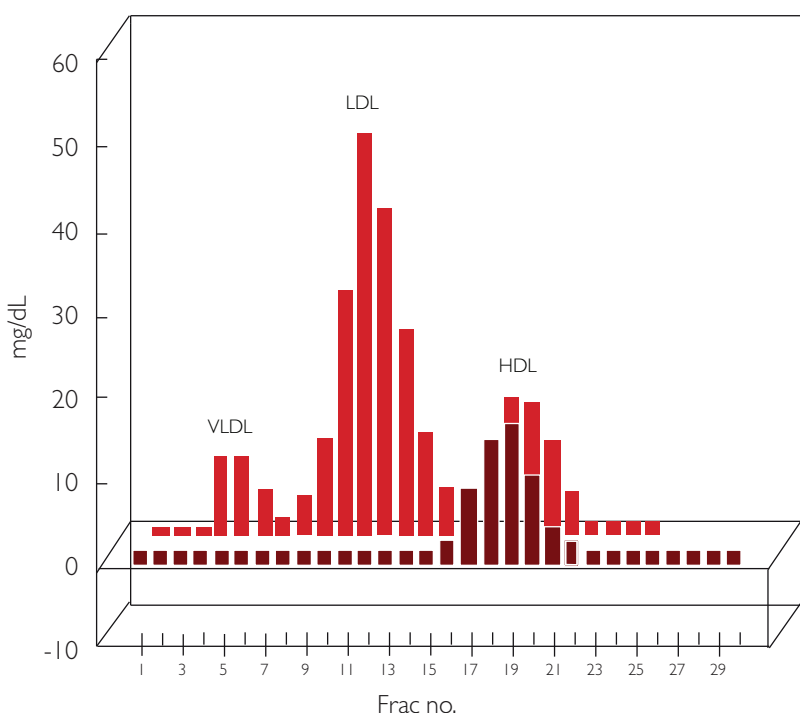


Fig. 2 Specificity of Radox Direct Clearance Assay for HDL Cholesterol

Specificity of the Radox direct clearance HDL assay was verified against gel filtration. Fig. 2 shows just how specific the Radox direct clearance method is for HDL Cholesterol. Our kit was found to only react with the HDL fractions separated by gel filtration.

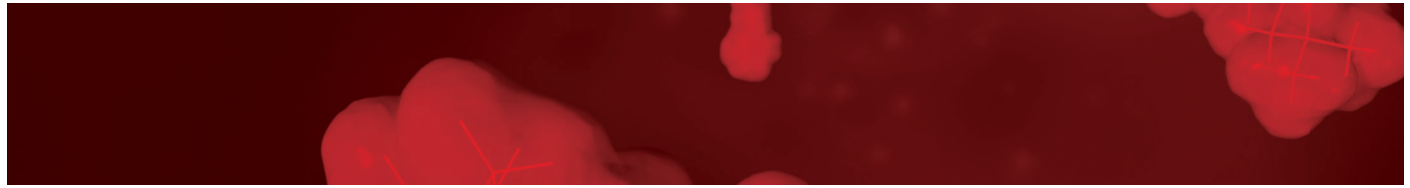
Total Cholesterol Reagent



Radox HDL Cholesterol Reagent



“
THE DIAGRAM ABOVE
SHOWS HOW SPECIFIC
THE RANDOX DIRECT
CLEARANCE METHOD IS
”



LDL CHOLESTEROL

Key Features of Randox LDL Cholesterol

- **Superior direct clearance methodology** - ensuring truly accurate results are delivered
 - **Liquid ready-to-use reagents** - convenience and ease-of-use
 - **Extensive measuring range** - of 0.189 – 22.2mmol/l for measurement of clinically important results
- UF** Applications available for an **extensive range of biochemistry analysers** which detail instrument-specific settings for the convenient use of Randox LDL Cholesterol assays on a variety of systems

UF **Benefits of the Randox Direct Clearance Method**

Requires no sample pre-treatment - The detergents and buffering systems used by most commercially available direct clearance LDL assays produce varying results, leading to differences in assay performance. The Randox direct LDL cholesterol assay requires no sample pre-treatment and displays excellent correlation to both the ultracentrifugation and precipitation methods.

Excellent precision - Our LDL assay retains its precision even at high levels of triglycerides.

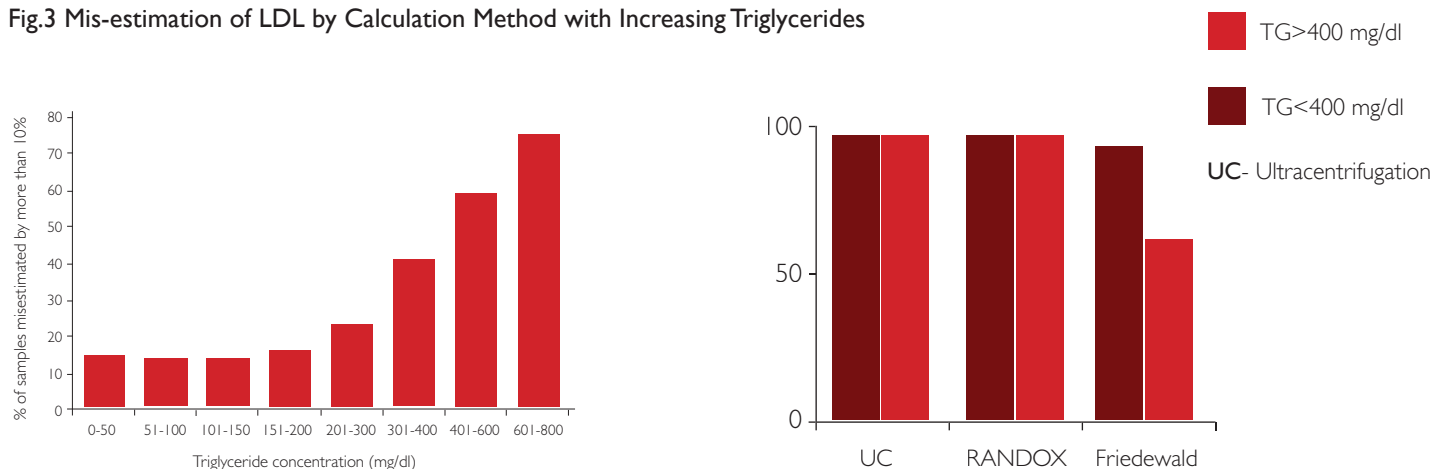
Minimal interference - Our advanced reagent formulation enables rapid clearance of turbidity resulting in minimal interference from patient samples.

Does not suffer from inaccuracy of the Friedewald Equation - which is only accurate if triglyceride levels are <400mg/dl, chylomicrons are not present and the sample does not contain beta-VLDL.

Clinical Significance

LDL Cholesterol, often referred to as 'bad cholesterol', transports cholesterol to the tissues and is linked to the development of atherosclerotic lesions. Accurate measurement of LDL cholesterol 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.

Fig.3 Mis-estimation of LDL by Calculation Method with Increasing Triglycerides



This shows the mis-estimation of LDL cholesterol by the Friedewald equation with increasing triglycerides and how the Randox direct clearance method offers better performance.



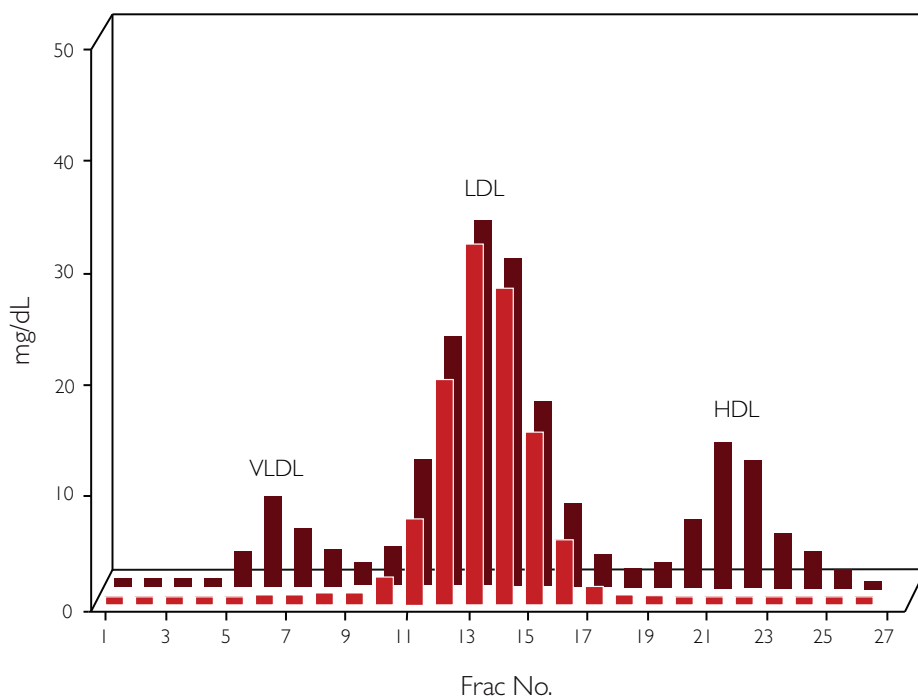
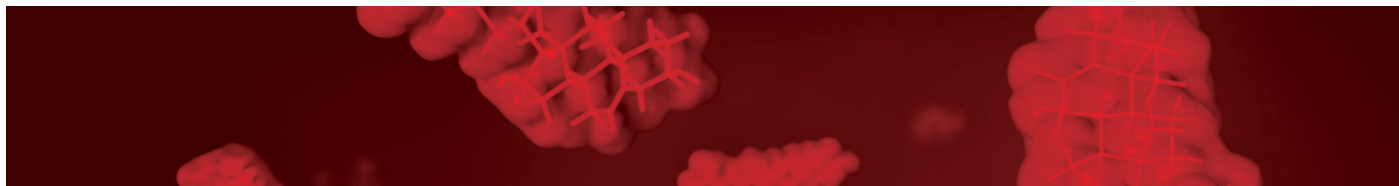




Fig. 4 Specificity of Randox Direct Clearance Assay for LDL Cholesterol

Specificity of the Randox direct clearance LDL assay was verified against gel filtration. Fig. 4 shows just how specific the Randox direct clearance method is for LDL Cholesterol. Our kit was found to only react with the LDL fractions separated by gel filtration.

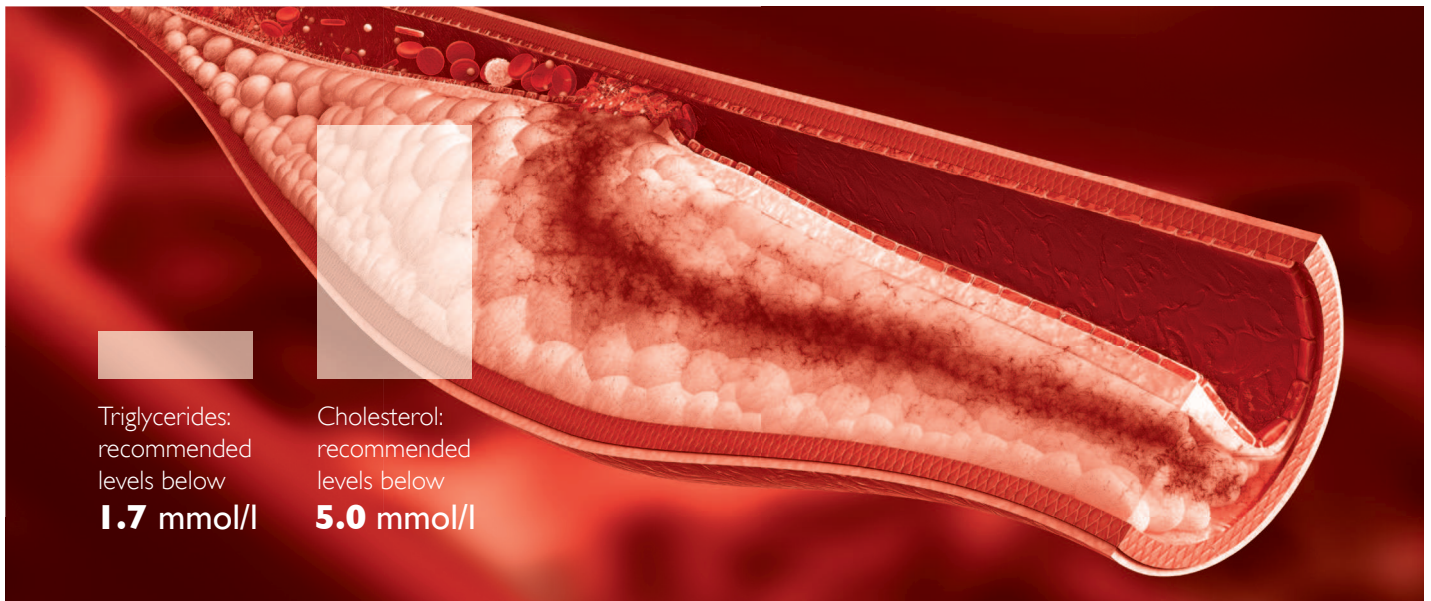
 Randox LDL Cholesterol
 Total Cholesterol



“

THE FRIEDEWALD FORMULA HAS BEEN REPORTED TO MISCLASSIFY UP TO 50% OF PATIENTS²

”



CHOLESTEROL (TOTAL)

Key Features of Randox Cholesterol

- **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 manual kits** - for user convenience (these are for manual and semi-automated use only)
- **Extensive measuring range** - of 0.865-16.6 mmol/l for measurement of clinically important results
- **Applications available for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox Cholesterol assays on a variety of systems
- **CHOD-PAP method**

Clinical Significance

Total Cholesterol measures all lipoprotein sub-classes to assess a patient's overall cholesterol level. High 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 Randox Triglycerides

- **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 manual kits** - for user convenience (these are for manual and semi-automated use only)
- **Extensive measuring range** - of 0.134-12.7 mmol/l for measurement of clinically important results
- **Applications available for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox Triglyceride assays on a variety of systems
- **GPO-PAP method**

Clinical Significance

High triglyceride levels increase the atherogenicity of HDL and LDL cholesterol. 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.



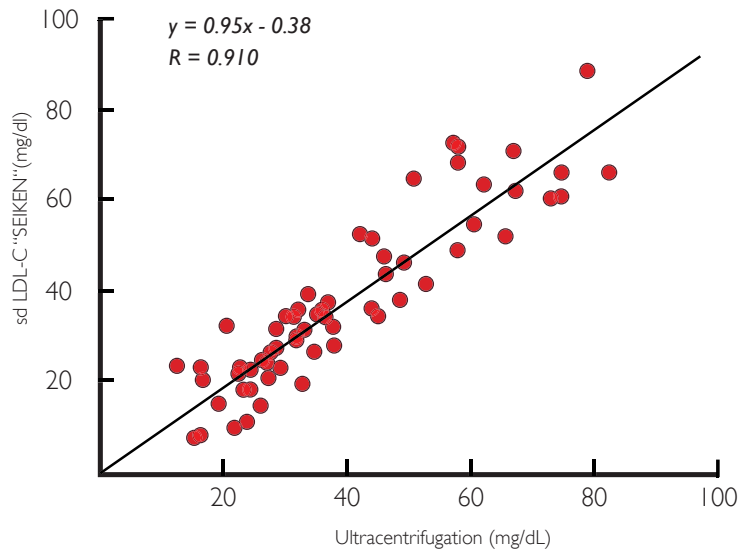
(NP) SMALL-DENSE LDL (sLDL) CHOLESTEROL

Key Features of Randox sLDL Cholesterol

Until recently, the primary methods of assessing a patient's sLDL were based on techniques such as ultracentrifugation and electrophoresis both of which are extremely laborious and time-consuming. ³sLDL can now be assessed in the routine biochemistry laboratory using the Randox immunoturbidimetric assay.

- **Randox sLDL utilises the “Denka Seiken” 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 sLDL assay correlates extremely well with the gold standard method** - ultracentrifugation shown in Fig. 5
- **Applications are available for a wide range of automated biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox sLDL on a variety of systems
- **Liquid ready-to-use reagents** - for convenience and ease-of-use

Fig. 5 Correlation of Ultracentrifugation and Seiken Methods⁵



64 SAMPLES FROM HEALTHY PEOPLE, CAD & DIABETIC PATIENTS

Clinical Significance

Small-dense LDL is a subtype of LDL cholesterol. There are two main types of LDL which vary in size through genetic determination and dietary lipid intake, ranging from small and dense to large and buoyant LDL. All LDLs transport triglycerides and cholesterol to the tissues but their atherogenesis varies according to size. Smaller particles such as sLDL more readily permeate the inner arterial wall and are more susceptible to oxidation.

Research has shown individuals with a predominance of sLDL **have a 3-fold increased risk of myocardial infarction (MI)**.⁴ Elevated levels of sLDL are caused by sedentary lifestyle, a diet high in saturated fat, insulin resistance, pre-diabetes and genetic disposition. Measurement of sLDL allows the clinician to get a more comprehensive picture of lipid risk factors and tailor treatment accordingly.

Fig. 6 Types of patients where sLDL should be requested

- ABDOMINAL OBESITY
- PATIENTS ON STATIN THERAPY
- CVD RISK EQUIVALENT
- PREDIABETES OR METABOLIC SYNDROME
- HYPERTENSION
- HIGH TRIGLYCERIDES
- TYPE 2 DIABETES
- LOW HDL-C

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 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.

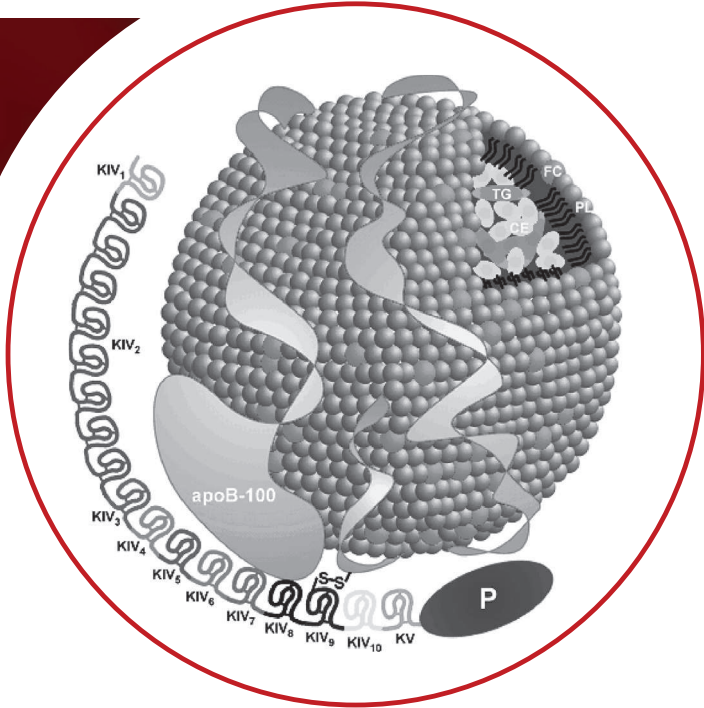
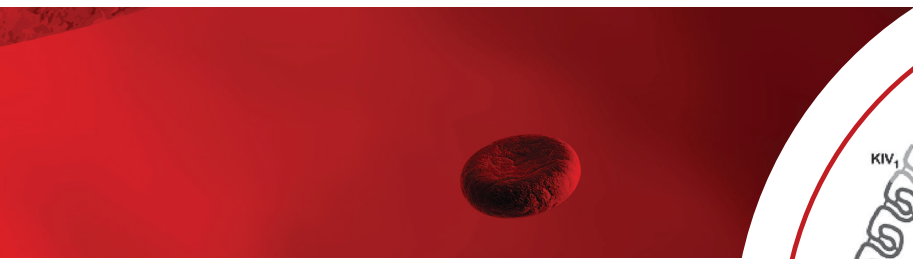
Lipoprotein(a) Foundation -

The Lp(a) Foundation has referenced Marcovina and Albers (2016)⁶ 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

Randox Lp(a)

- 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 calibrators 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 are available for a wide range of biochemistry analysers - which detail instrument-specific settings for the convenient use of Randox Lp(a) on a variety of systems
 - Liquid ready-to-use reagents - for convenience and ease-of-use



Clinical Significance

The size of the apo(a) protein is genetically determined and varies widely hence, **levels of Lp(a) can vary up to 1000-fold between individuals.**⁷ Recent years have seen major scientific advances in the understanding of Lp(a) and its causal role in premature CVD.

Elevated Lp(a) levels associate robustly and specifically with increased CVD risk.

Additional Risks

- Along with other tests, Lp(a) can provide additional information on a patient's risk factor of developing cardiovascular disease
- It is particularly useful for determining the risk of cardiovascular disease (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 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 recommended aiming for Lp(a) \sim <50mg/dl as a treatment priority, after maximal therapeutic management of LDL cholesterol.

European Atherosclerotic Society⁸

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. \geq 3% 10-year risk of fatal CVD according to the European guidelines
- VI. \geq 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 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.

APOLIPOPROTEIN A-I

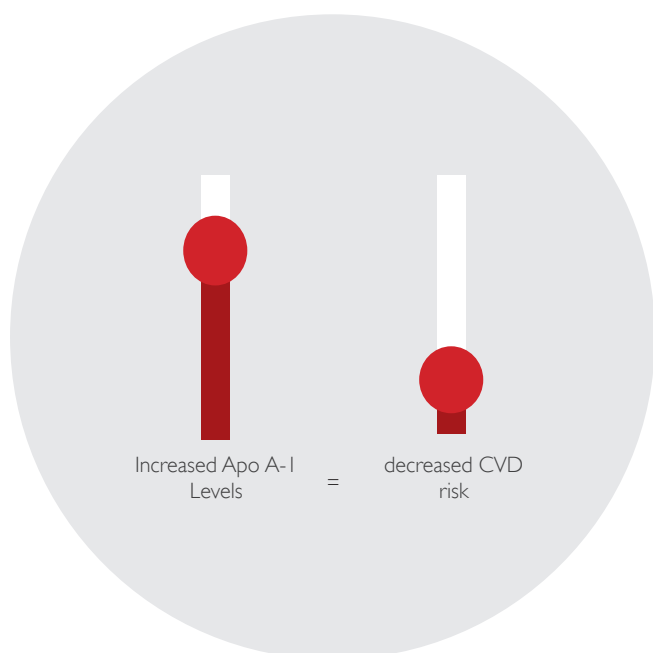
Key Features of Randox Apolipoprotein A-I

- **Liquid ready-to-use reagents** - for convenience and ease-of-use
- **Wide measuring range** - of 6.50-233 mg/dl for measurement of clinically important results
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox Apolipoprotein A-I assays on a variety of systems

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 extra hepatic 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 Randox Apolipoprotein A-II

- **Liquid ready-to-use reagents** - for convenience and ease-of-use
- **Wide measuring range** - of 6.75-61.1 mg/dl for measurement of clinically important results
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available for an extensive range of biochemistry analysers** - which detail instrument specific settings for the convenient use of Randox Apolipoprotein A-II on a variety of systems

Clinical Significance

Apolipoprotein A-II is a major constituent of High Density Lipoprotein (HDL) particles and plays an important role in the processes of reverse cholesterol transport and lipid metabolism. Increased production of Apolipoprotein A-II promotes atherosclerosis by decreasing the proportion of anti-atherogenic HDL containing Apolipoprotein A-I.

APOLIPOPROTEIN B

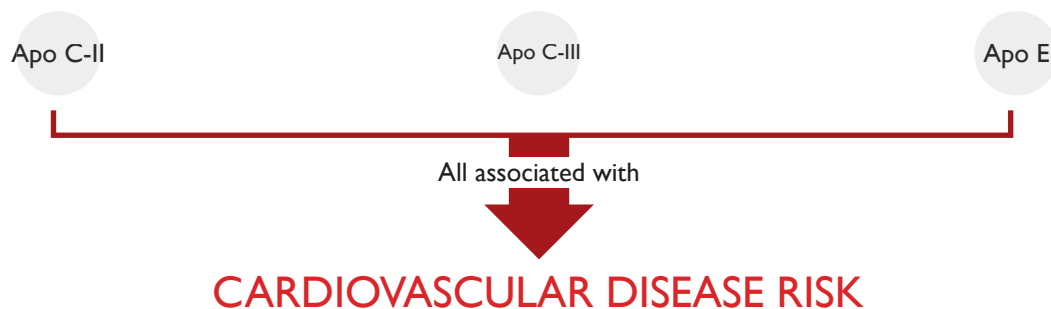
Key Features of Randox Apolipoprotein B

- **Liquid ready-to-use reagents** - for convenience and ease of use
- **Extensive measuring range** - of 11.2-184mg/dl for measurement of clinically important results
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox Apolipoprotein B assays on a variety of systems

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-I ratio which can be used as an alternative to the Total Cholesterol /HDL Cholesterol ratio when determining cardiovascular risk.



(NP) APOLIPOPROTEIN C-II

Key Features of Randox Apolipoprotein C-II

- **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 for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox Apolipoprotein C-II on a variety of systems

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 cardiovascular disease risk. Apolipoprotein C-II deficient patients present with chylomicronemia, xanthomas, and recurrent pancreatitis.

(NP) APOLIPOPROTEIN C-III

Key Features of Randox Apolipoprotein C-III

- **Liquid ready-to-use reagents** - offering optimum convenience and ease-of-use
- **Excellent linearity** - of 21.7mg/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 for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox Apolipoprotein C-III on a variety of systems

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 by 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 Randox Apolipoprotein E

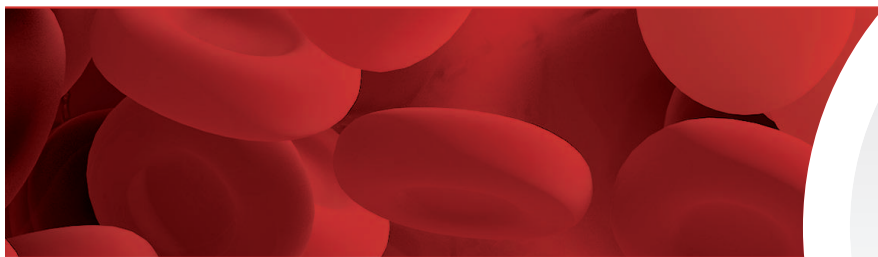
- **Liquid ready-to-use reagents** - for convenience and ease-of-use
- **Extensive measuring range** - of 1.04-12.3mg/dl for measurement of clinically important results
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available for an extensive range of biochemistry analysers** - detailing instrument-specific settings for the convenient use of Randox Apolipoprotein E on a variety of systems

Clinical Significance

Apolipoprotein E is an amino acid which has many functions including 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.





(NP) HDL3 CHOLESTEROL

NEW!

What is HDL3 Cholesterol?

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

Standard tests for cholesterol, HDL, LDL 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 is the scavenger of cholesterol within arterial walls and if HDL3 is in too low numbers 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:

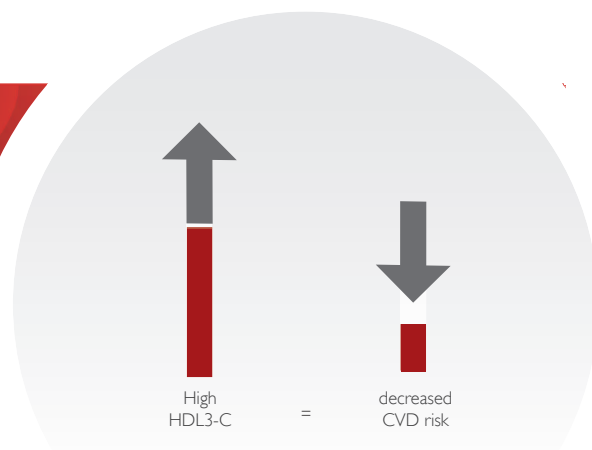
1. HDL3 subclass may be primarily responsible for the inverse association of HDL-C and CV disease. (Albers et. al, 2016)⁹

The aims of this secondary analysis were to examine the levels of cholesterol in HDL subclasses (HDL2-C and HDL3-C), sLDL-C, and LDL-TG at baseline, as well as the relationship between these levels and 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 CV disease.***

2. In secondary prevention, 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)¹⁰

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



In secondary prevention, 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)¹¹

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 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.

Randox HDL3 Cholesterol

- **Liquid ready-to-use reagents** - for convenience and ease-of-use
- **Applications available for an extensive range of biochemistry analysers** – which detail instrument-specific settings for the convenient use of Randox HDL3-C on a variety of systems
- **A 2 step procedure** - based on patented technology from Denka Seiken
- **Open vial stability of 28 days** - when stored at +2 to +8°C
- **HDL3-C controls and calibrators available** - offering the complete testing package
- **Measuring range of 4 - 60mg/dl** - for the measurement of clinically important results
- **Demonstrates a strong correlation with the conventional Ultracentrifugation Method**
- **Allows for quantification of HDL2-C** - by the subtraction of HDL3-C from total HDL-C
- **Measures total HDL3-C**





What is sPLA₂-IIA?

sPLA₂ is a family of pro-inflammatory enzymes linked to the formation and destabilization of atherosclerotic plaques. The sPLA₂ protein expression increases with atherosclerotic lesions development. IIA is the dominant isoform within sPLA₂ activity.

Clinical Significance

sPLA₂-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, stroke and heart failure.

Conclusions from key publications:

- sPLA₂ provides independent prognostic information beyond established risk markers in patients with stable CAD¹²
- Strong association observed between increasing sPLA₂ and risk of heart failure, such that subjects in the highest quartile had nearly a 3-fold higher incidence of heart failure during follow up¹²

- Individuals with sPLA₂ levels in the highest quartile had a 58% higher risk of cardiovascular death, MI or stroke, independent of established risk factors¹²
- sPLA₂ activity but not LpPLA₂ activity was related to atherosclerosis and increased risk of all-cause mortality in a sample of elderly subjects and predicted mortality or recurrent MI in a sample of post-MI patients¹³
- sPLA₂ independently predicts death during a 16 week period after acute coronary syndrome¹⁴
- Elevated concentrations of sPLA₂-IIA mass and activity showed a statistically significant increased risk for secondary CVD events independent of a variety of potential confounders including markers of inflammation, renal function, and haemodynamic stress, and even if considered simultaneously¹⁵

Radox sPLA₂-IIA

- **Liquid ready-to-use reagents** – for convenience and ease-of-use
- **Immunoturbidimetric method**
- **Complementary value-assigned controls and calibrators available** – offering a complete testing package
- **Applications available for an extensive range of biochemistry analysers** – which detail instrument-specific settings for the convenient use of Radox sPLA₂-IIA on a variety of systems

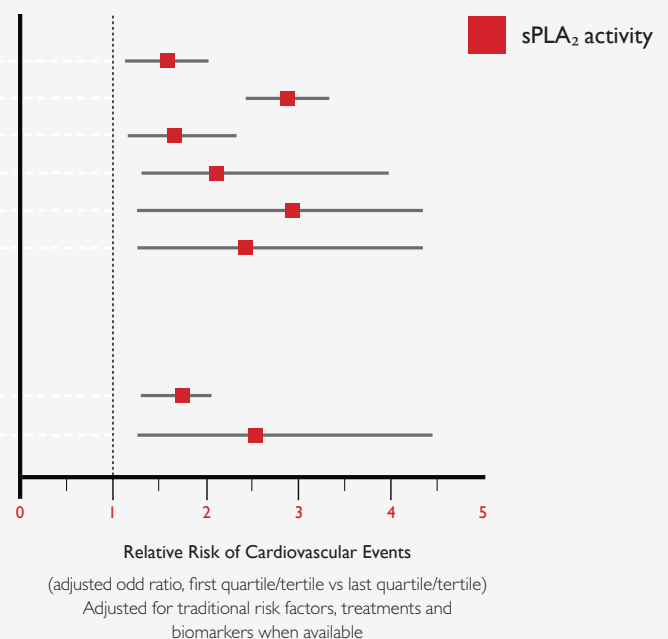
Across 8 publications covering more than 13,200 patients, the significance of sPLA₂ is demonstrated within secondary and primary prevention:

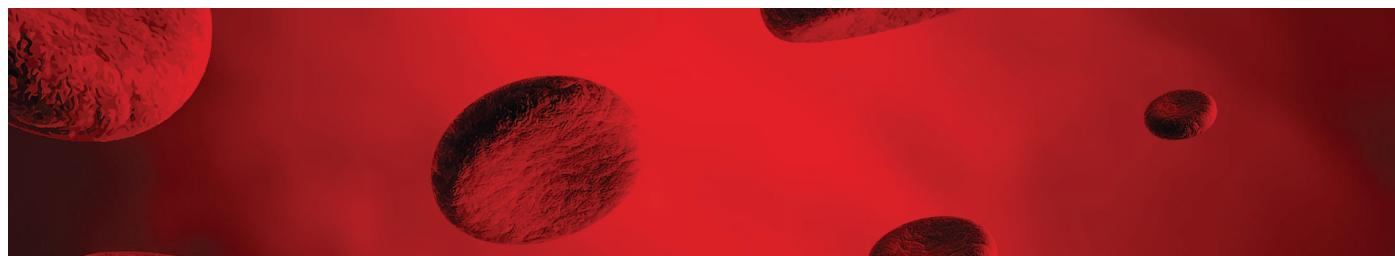
Secondary prevention

- 3738 stable CHD patients PEACE study¹²
- 2587 UA or AMI patients MIRACL study¹⁴
- 1206 CHD patients KAROLA study¹⁵
- 1036 Acute Coronary Events patients FAST-MI study^{16,17}
- 446 Acute CAD patients GRACE study¹⁸
- 419 Emergency patients DIMU-Bichat study¹⁹

Primary prevention

- 2797 asymptomatic patients EPIC-Norfolk study^{20,21}
- 1016 elderly patients PIVUS study¹³





HOMOCYSTEINE

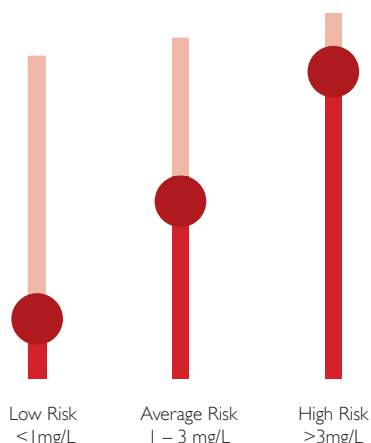
Key Features of Radox Homocysteine

- UF** Two part, 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** - for greater convenience
 - **Wide measuring range** - of 1.7 - 47.9 µmol/L. The normal range for homocysteine is approximately 5-20µmol/L therefore the Radox assay can detect abnormal levels of homocysteine within a sample
 - **Excellent stability** - of 28 days on-board the analyser at +10°C, minimising reagent waste
 - **Applications available for an extensive range of automated biochemistry analysers** - detailing instrument-specific settings for the convenient use of Radox Homocysteine on a variety of systems

Clinical Significance

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 concentration of homocysteine is a frequently observed finding in the blood of these patients.

Fig. 7 2006 AHA / CDC Guidelines: hsCRP Levels vs Heart Attack Risk



HIGH SENSITIVITY CRP

Key Features of Radox High Sensitivity CRP

- **Liquid ready-to-use reagents** - for optimum convenience and ease-of-use
- **Latex Enhanced Immunoturbidimetric methodology** - delivering high performance
- **Wide measuring range** - of 0.477-10mg/l for measurement of clinically important results
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
- **Applications available for an extensive range of automated biochemistry analysers** - which detail instrument-specific settings for the convenient use of Radox High Sensitivity CRP assays on a variety of systems

Clinical Significance

Risk Assessment - High Sensitivity CRP (hsCRP) in addition to lipid evaluation and risk scoring systems helps 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 Fig. 7.



NP ADIPONECTIN

Key Features of Randox Adiponectin

- **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
- **Extensive measuring range** - for measurement of clinically important results
- **Complementary controls and calibrators available** - offering a complete testing package
- **Applications available for an extensive range of biochemistry analysers** – which detail instrument-specific settings for the convenient use of Randox Adiponectin on a variety of systems

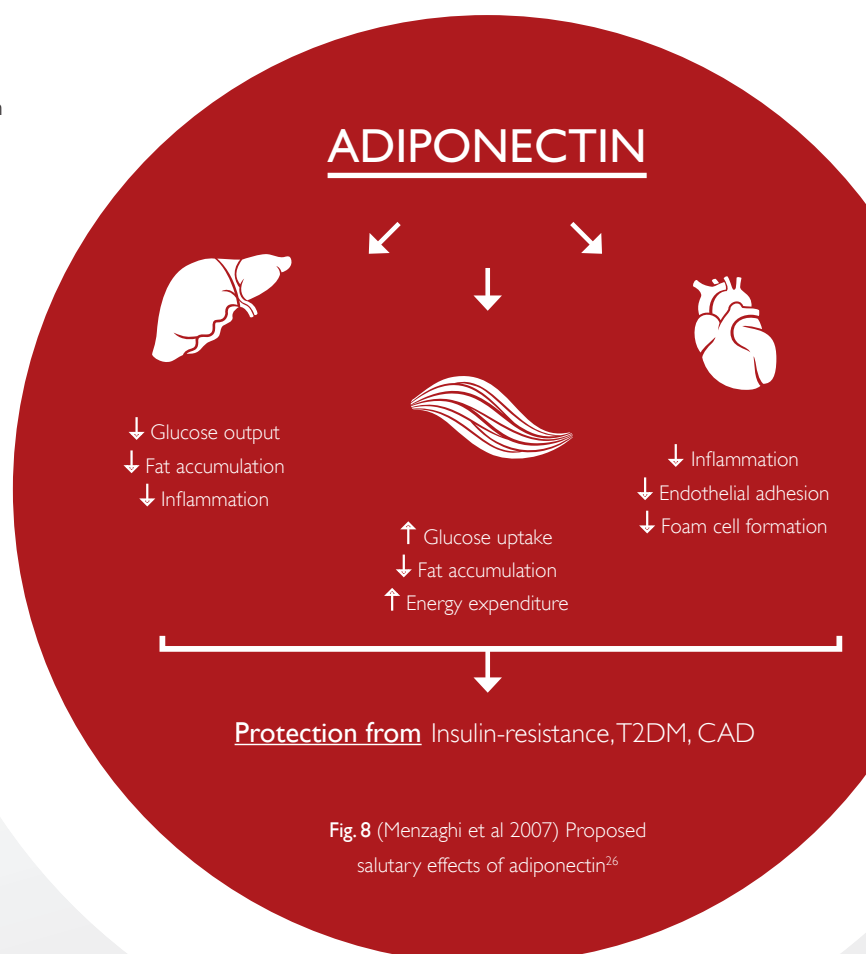
Clinical Significance

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 cardiovascular disease. It is widely recognised that people who are overweight are at higher risk of developing these diseases. Body mass index (BMI) (weight kg / height m²) is the common method of determining which patients are classed as overweight or obese, however it has limitations in measuring athletes and varies in reliability 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 CHD in caucasian men initially free of CHD. Raising plasma adiponectin level is highly protective of future CHD events in men²²
- 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 cholesterol, smoking and BMI²³
- Low levels of adiponectin are associated with an increased risk of new-onset hypertension in men and postmenopausal women²⁴
- 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 hypertension²⁵



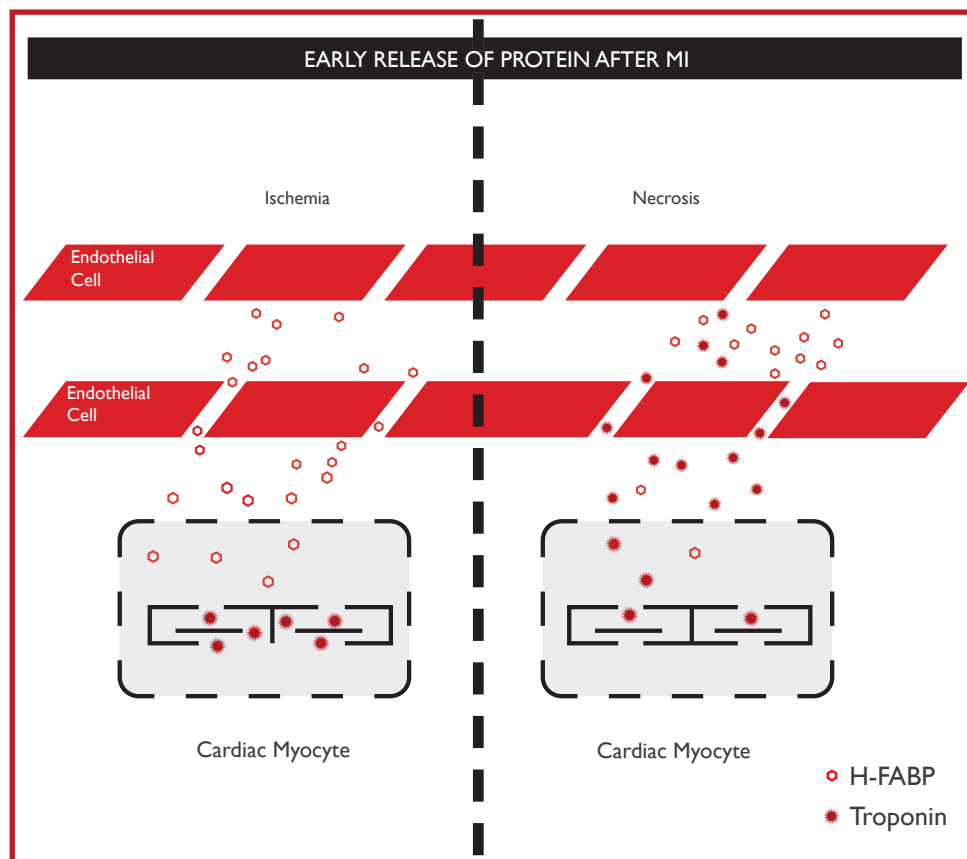
NP HEART-TYPE FATTY ACID BINDING PROTEIN (H-FABP)

Key Features of Randox H-FABP

- 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 for an extensive range of biochemistry analysers - which detail instrument-specific settings for the convenient use of Randox H-FABP on a variety of systems

H-FABP: The Protein

- Heart-type Fatty Acid Binding Protein (H-FABP) is an unbound, low molecular weight protein, located in the cytoplasm of cardiac myocytes.²⁷
- 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.



Prognostic Value in ACS

- Elevated H-FABP is a significant predictor of death or MI up to 1 year.³¹
- H-FABP provides additional prognostic information, independent of Troponin T, ECG and clinical examination.²⁸

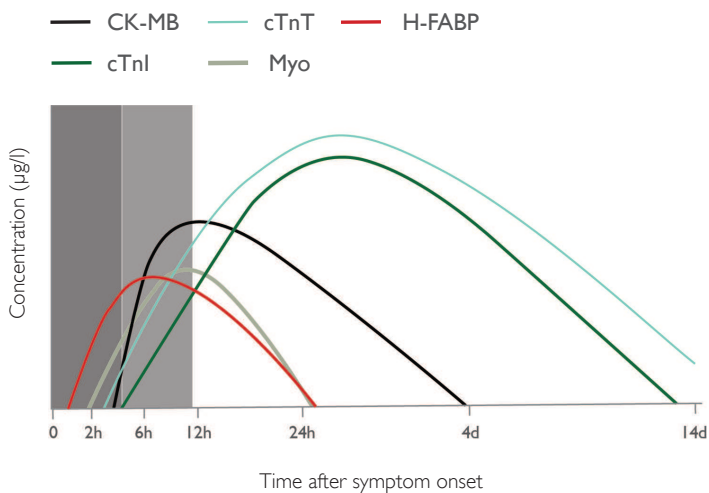
H-FABP and Troponin - the optimum biomarker strategy

- In the early hours after chest pain onset (CPO), H-FABP offered superior diagnostic sensitivity for AMI than Troponin.²⁹
- The optimal combination of biomarkers across all timepoints was Troponin I and H-FABP.²⁹
- 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.³⁰

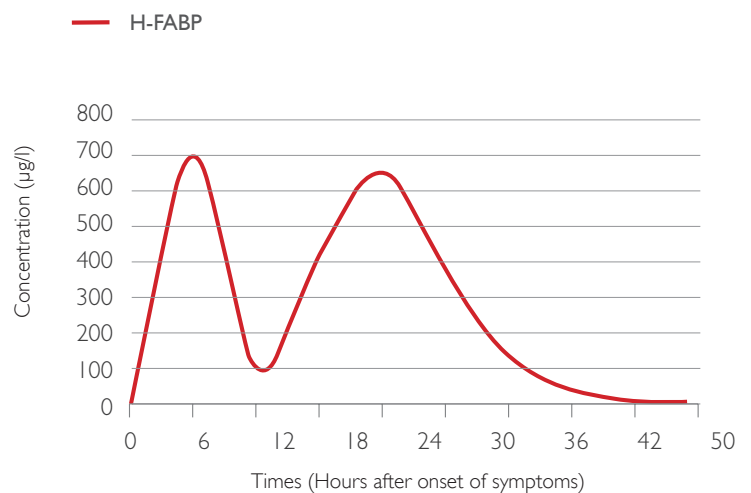
Diagnostic Value in ACS

- Using the combination approach consistently improved the NPV, negative likelihood ratio, and the risk ratio.³¹
- Measurement of plasma h-FABP and hs-TropT together on admission appears to be more precise predictor of ACS rather than either hs-Trop T or h-FABP alone.³²

Release Kinetics



H-FABP in reinfarction



- H-FABP is highly specific to the heart – approximately 15-20 times more specific than Myoglobin.³³
- The normal serum/plasma value is also much lower, compared to Myoglobin.³⁴
- 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.^{35,36}

- Furthermore, the rapid return to baseline within 24 hours, offers significant potential utility in patients with suspected reinfarction, instead of CK-MB.³⁷





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** - these reagents 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** - these reagents are packaged in dedicated bottles and are barcoded for use, removing the need for any additional steps to be completed
- **Applications available for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox CK-MB on a variety of systems

MYOGLOBIN

Key Features of Randox Myoglobin

- **Latex Enhanced Immunoturbidimetric methodology** - delivers high 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 for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of Randox Myoglobin on a variety of systems

DIGOXIN

Key Features of Randox Digoxin

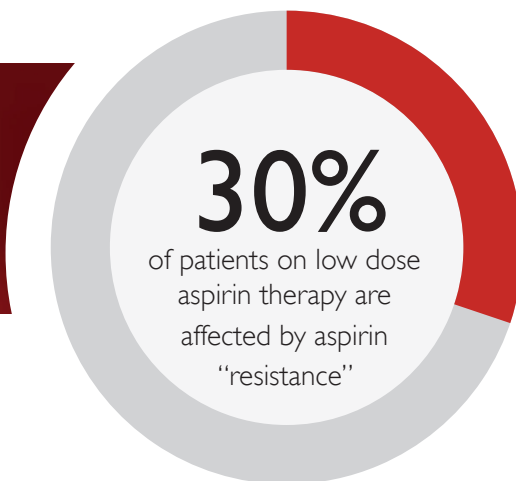
- **Latex Enhanced Immunoturbidimetric methodology** - delivers high performance
- **Liquid ready-to-use reagents** - for convenience and ease-of-use
- **Excellent stability** - of 21 days on-board the analyser at +2 to +8°C, minimising reagent waste
- **Applications available** - for an extensive range of biochemistry analysers which detail instrument-specific settings for the convenient use of Randox Digoxin on a variety of systems

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.





NP TxBCARDIO™

Key Features of RandoxTxBCardio™

- **Highly accurate method for the evaluation of aspirin therapy effectiveness** - the primary target of aspirin therapy is TxA_2 however this has a very short half-life making accurate measurement difficult. When TxA_2 degrades it is converted into a number of metabolites, the most abundant of which is $11dhTxB_2$. RandoxTxBCardio™ specifically measures $11dhTxB_2$ offering a highly accurate method for TxA_2 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 for an extensive range of biochemistry analysers** - which detail instrument-specific settings for the convenient use of RandoxTxBCardio™ on a variety of systems

Clinical Significance

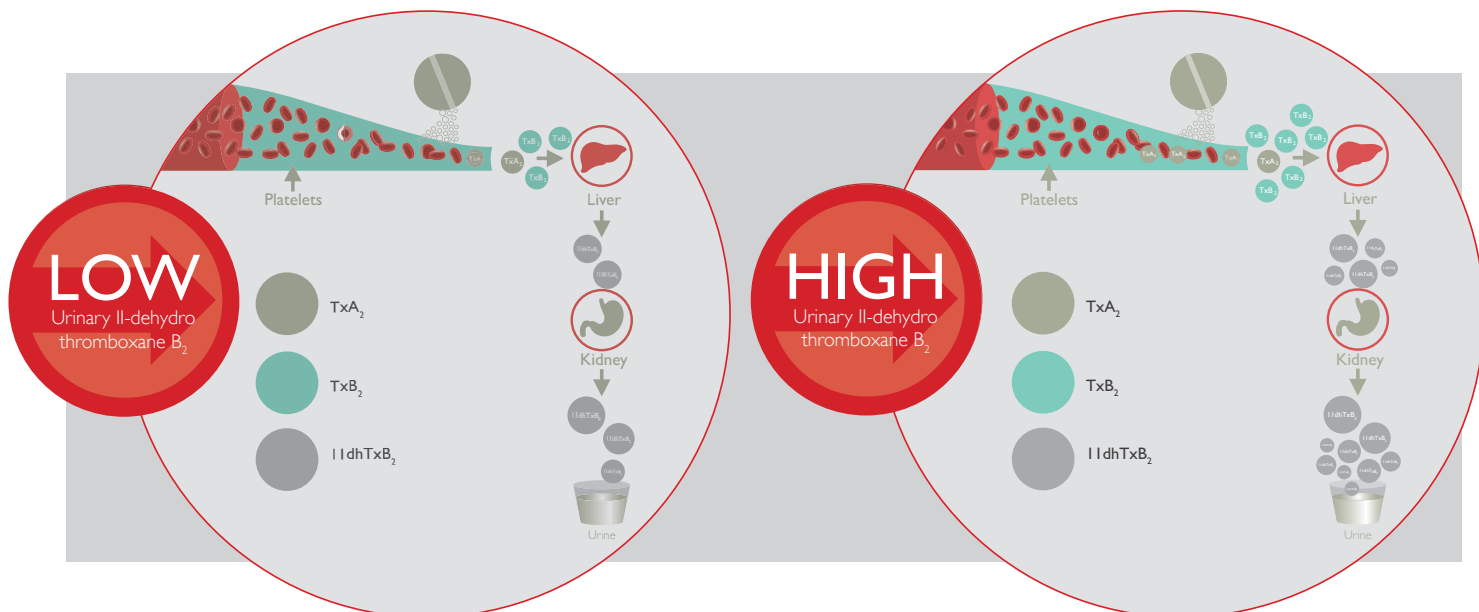
Aspirin is the foundation of antiplatelet therapy and is widely prescribed in the primary and secondary prevention of cardiovascular disease. However, not all patients receiving aspirin therapy respond in the same way with many suffering from a lack of aspirin effect, also known as aspirin resistance.

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 RandoxTxBCardio™. Results generated by the RandoxTxBCardio™ 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 $11dhTxB_2$

Lack of Aspirin effect correlates to high urinary $11dhTxB_2$





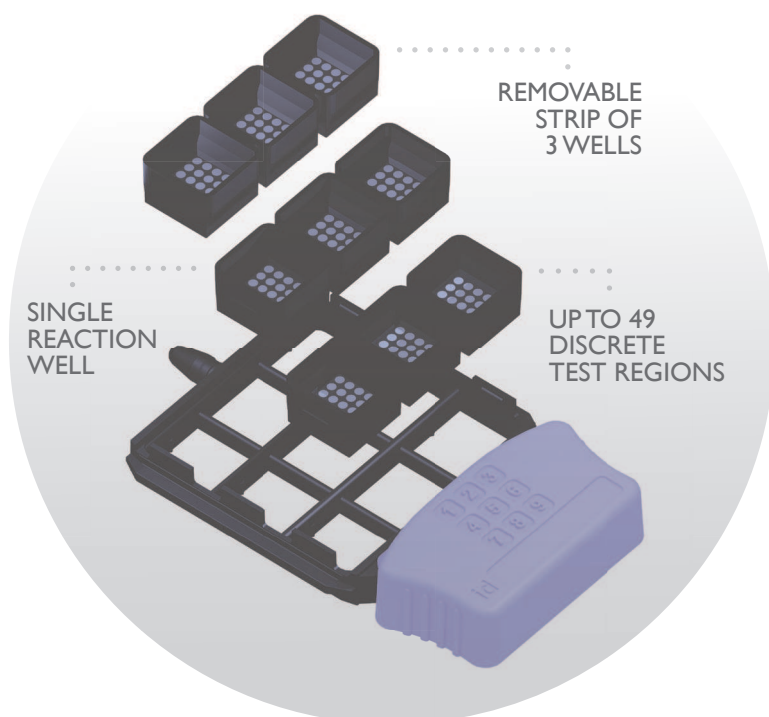
RANDOX MULTIPLEX BIOCHIP ARRAY TECHNOLOGY

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

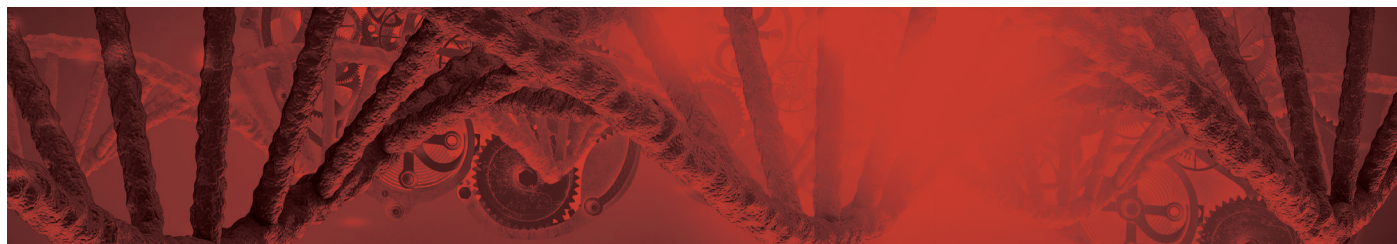
Patient

- 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





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.

Acute coronary syndrome (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

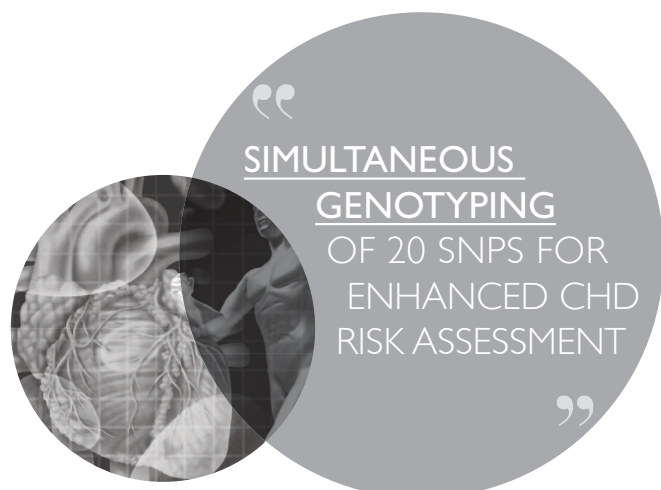
- Creatine-Kinase Muscle Brain (CK-MB)
- Heart-Type Fatty Acid Binding Protein (H-FABP)
- Myoglobin (MYO)
- Troponin I (cTnI)

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



ORDERING INFORMATION 24

<u>DESCRIPTION</u>	<u>METHOD</u>	<u>SIZE</u>	<u>CAT. NO.</u>
			
Adiponectin ♦	L.E.I.	R1 4 × 65ml, R2 4 × 33.5ml	AO2799
Adiponectin ♦	L.E.I.	R1 2 × 15.8ml, R2 2 × 8.4ml	AO2999
Apolipoprotein A-I ♦	Immunoturbidimetric	R1 4 × 40ml, R2 4 × 17ml (S)	LP2116
Apolipoprotein A-I ♦	Immunoturbidimetric	I 60T	LP2866
Apolipoprotein A-I ♦	Immunoturbidimetric	R1 4 × 60ml, R2 4 × 36ml	LP2989
Apolipoprotein A-I ♦	Immunoturbidimetric	R1 4 × 30ml, R2 4 × 12ml	LP3838
Apolipoprotein A-I ♦	Immunoturbidimetric	R1 2 × 10ml, R2 2 × 4.9ml	LP8007
Apolipoprotein A-II ♦	Immunoturbidimetric	R1 2 × 11ml, R2 2 × 5ml	LP3867
Apolipoprotein B ♦	Immunoturbidimetric	R1 4 × 50ml, R2 4 × 9ml (S)	LP2117
Apolipoprotein B ♦	Immunoturbidimetric	R1 4 × 60ml, R2 4 × 15ml (S)	LP2990
Apolipoprotein B ♦	Immunoturbidimetric	R1 4 × 20ml, R2 4 × 6ml	LP3839
Apolipoprotein B ♦	Immunoturbidimetric	R1 2 × 10ml, R2 2 × 4ml	LP8008
Apolipoprotein C-II ♦	Immunoturbidimetric	R1 2 × 11ml, R2 2 × 5ml	LP3866
Apolipoprotein C-III ♦	Immunoturbidimetric	R1 2 × 11ml, R2 2 × 5ml	LP3865
Apolipoprotein E ♦	Immunoturbidimetric	R1 2 × 11ml, R2 2 × 5ml	LP3864
Cardiac Array	Biochip	54 biochip kit	EV3692 (Investigator kit)
Cardiac Array	Biochip	180 biochip kit	EV3688 (Evidence Kit)
Cardiac Risk Predication Array	Biochip	72 biochip kit	EV3836A&B
CK-MB	Immunoinhibition (UV)	19 × 2.5ml	CK1296
CK-MB	Immunoinhibition (UV)	5 × 20ml	CK1553
CK-MB	Immunoinhibition (UV)	R1 4 × 20ml, R2 4 × 6ml	CK3813
CK-MB ♦	Immunoinhibition (UV)	R1 4 × 20ml, R2 4 × 6ml	CK4043
CK-MB	Immunoinhibition (UV)	R1 6 × 20ml, R2 3 × 10ml	CK7946
CK-MB	Immunoinhibition (UV)	R1 4 × 20ml, R2 4 × 6ml	CK8026
CK-MB	Immunoinhibition (UV)	R1 6 × 21ml, R2 2 × 15ml	CK9717
FH Arrays I & II	Biochip	54 biochip kit	EV3836A&B
Digoxin ♦	L.E.I.	R1 2 × 8ml, R2 2 × 6ml	TD3410
HDL Cholesterol ♦	Direct Clearance	R1 3 × 2.5L, R2 1 × 2.5L	CH1383
HDL Cholesterol ♦	Direct Clearance	R1 6 × 30ml, R2 3 × 20ml	CH2652
HDL Cholesterol ♦	Direct Clearance	R1 6 × 78ml, R2 3 × 52ml	CH2655
HDL Cholesterol ♦	Direct Clearance	R1 5 × 252ml	CH2664^
HDL Cholesterol ♦	Direct Clearance	R2 3 × 150ml	CH2665^
HDL Cholesterol ♦	Direct Clearance	240T	CH2849
HDL Cholesterol ♦	Direct Clearance	240T (AHDH)	CH2861
HDL Cholesterol ♦	Direct Clearance	R1 3 × 51ml, R2 3 × 20ml	CH3811
HDL Cholesterol ♦	Direct Clearance	R1 4 × 38.2ml, R2 4 × 15.2ml	CH8033
HDL Cholesterol ♦	Direct Clearance	R1 4 × 20ml, R2 4 × 9ml	CH8311
HDL Cholesterol ♦	Direct Clearance	R1 6 × 20ml, R2 2 × 20ml	CH9701
HDL Cholesterol Precipitant ♦	Phosphotungstic Acid	4 × 80ml	CH203*
HDL3 Cholesterol ♦	Immunoturbidimetric	R1 1 × 20ml, R2 1 × 7.5ml	CH10165
HDL3 Cholesterol ♦	Immunoturbidimetric	R1 4 × 38.2ml, R2 4 × 18.2ml	CH10163

ORDERING INFORMATION 25

<u>DESCRIPTION</u>	<u>METHOD</u>	<u>SIZE</u>	<u>CAT. NO.</u>
			
H-FABP 	Immunoturbidimetric	R1 1 x 19 ml, R2 1 x 7ml	FB4025
High Sensitivity CRP 	L.E.I.	R1 2 x 11ml, R2 2 x 11ml	CP3885
High Sensitivity CRP 	L.E.I.	R1 2 x 13ml, R2 2 x 13ml	CP8029
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	160T	CH2850
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 8.2ml	CH8032
LDL Cholesterol 	Direct Clearance	R1 4 x 20ml, R2 4 x 9ml	CH8312
LDL Cholesterol 	Direct Clearance	R1 6 x 20ml, R2 2 x 20ml	CH9702
Lipoprotein(a) 	Immunoturbidimetric	R1 1 x 30 ml, R2 1 x 15 ml	LP2757
Lipoprotein(a) 	Immunoturbidimetric	R1 1 x 10 ml, R2 1 x 6 ml	LP3403
Lipoprotein(a) 	Immunoturbidimetric	R1 1 x 10ml, R2 1 x 6.5ml	LP8324
Myoglobin 	L.E.I.	R1 1 x 9.5ml, R2 1 x 4.5ml	MY2127
sLDL Cholesterol 	Clearance	R1 1 x 19.8 ml, R2 1 x 8.6 ml	562616
Total Cholesterol 	CHOD-PAP	6 x 30ml (S)	CH200
Total Cholesterol 	CHOD-PAP	6 x 100ml (S)	CH201
Total Cholesterol 	CHOD-PAP	8 x 250ml (S)	CH202
Total Cholesterol 	CHOD-PAP	480T	CH2823
Total Cholesterol 	CHOD-PAP	9 x 51ml	CH3810
Total Cholesterol 	CHOD-PAP	9 x 50ml	CH7945
Total Cholesterol 	CHOD-PAP	12 x 66ml	CH9715
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	5 x 100ml (S)	TR212
Triglycerides	GPO-PAP	10 x 50ml (S)	TR213
Triglycerides	GPO-PAP	4 x 100T (S)	TR1697
Triglycerides 	GPO-PAP	240T	TR2820
Triglycerides	GPO-PAP	6 x 51ml	TR3823
Triglycerides	GPO-PAP	6 x 50ml	TR7971
Triglycerides	GPO-PAP	4 x 58ml	TR8067
Triglycerides 	GPO-PAP	4 x 20ml	TR8332
Triglycerides 	GPO-PAP	12 x 66ml	TR9728
Triglycerides	GPO-PAP	4 x 58ml	TR9780
TxBCardio 	L.E.I.	R1 1 x 9ml, R2 1 x 4.7ml	TBX2759



Indicates liquid option available



Indicates standard included in kit

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