SPECIFIC PROTEINS

EXCELLENT MEASUREMENT OF SPECIFIC PROTEINS
SPECIFIC PROTEINS

Alpha-1-Acid Glycoprotein | Alpha-1-Antitrypsin | Anti-Streptolysin O
Apolipoproteins | Ceruloplasmin | Complement C3 | Complement C4
C-Reactive Protein | Cystatin C | Ferritin | Haptoglobin
IgA, IgE, IgG, IgM | Lipoprotein (a) | Microalbumin | Myoglobin
Rheumatoid Factor | Transferrin | Transthyretin
BENEFITS

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2. ALPHA-1-ANTITRYSIN
3. ANTI-STREPTOLYSIN O
4. APOLIPOPROTEIN A-I
5. APOLIPOPROTEIN A-II
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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 the largest test menu of 118 assays, covering over 100 disease markers including specific proteins, lipids, therapeutic drug monitoring, drugs of abuse, antioxidants, coagulation, diabetes 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 ROUTINE TESTING

With speciality assays for 195 of the most common clinical chemistry analysers; assays which usually require dedicated equipment such as nephelometers (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™, cystatin C, adiponectin, CRP, Lp(a) and many more.

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 and our assays are validated against gold-standard methods; giving you the confidence that you are sending out the correct patient results.

REDUCE COSTS

We can help create cost-savings for your laboratory through excellent reagent stability; by eliminating the need for costly re-runs through the excellent quality of products; and by offering a range of kit sizes (including smaller kit sizes for niche tests to reduce waste).

BRING TESTING IN-HOUSE

With smaller kit sizes and excellent reagent stability (most are stable for 28 days on-board the analyser), you don’t have to worry about reagent wastage, allowing testing to be brought in-house.

REDUCE LABOUR

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

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.
Alpha-1-Acid Glycoprotein

WHAT IS ALPHA-1-ACID GLYCOPROTEIN?

Alpha-1-Acid Glycoprotein (AAG), also known as orosomucoid, is an acute-phase reactant synthesised in the liver in response to inflammation and tissue damage. The normal range for healthy individuals is 50-120 mg/dl.

CLINICAL SIGNIFICANCE

Markedly higher AAG levels are observed in a number of conditions such as inflammatory disease, acute myocardial infarction, trauma, pregnancy and surgery. AAG concentrations rise rapidly until 48 hours after surgery followed by little change until about 120 hours, regardless of the severity of the injury. Serum AAG levels also provide a useful diagnostic tool in neonates with bacterial infections, most infected neonates produce increased levels of AAG.

BENEFITS OF RANDOX ALAG

• Wide measuring range – 24.6-453 mg/dl for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrator available

Alpha-1-Antitrypsin

WHAT IS ALPHA-1-ANTITRYPsin?

Alpha-1-Antitrypsin (AAT) primarily serves to protect the elastin fibres of the lungs by inhibiting neutrophil elastase. The normal range for healthy individuals is 90-200 mg/dl.

CLINICAL SIGNIFICANCE

Low levels of AAT (<80 mg/dl) have major clinical importance in association with emphysema and liver disease. Increased levels (3-4 times normal) can occur as a result of trauma, pregnancy, administration of oestrogens or typhoid vaccine.

BENEFITS OF RANDOX ALAT

• Wide measuring range – 38.7-660 mg/dl for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrator available
WHAT IS ANTI-STREPTOLYSIN O?

Streptolysin O (SLO) is a lethal, exocellular protein produced by Group A Streptococci bacteria. It is so named because it is reversibly inactivated by atmospheric oxygen. The toxin lyses erythrocytes and many other animal cells by disruption of the cytoplasmic and similar membranes, following the binding of reduced, active SLO on the cell surface. Consequently, anti-streptolysin O antibodies (ASO) are produced by the host to neutralise the haemolytic action of the SLO. Levels of ASO in serum are dependent on the age of the patient, geographical location and the local incidence of streptococcal infection. 200 IU/ml is regarded internationally as the upper limit of the normal range, since this value is rarely exceeded without symptoms indicative of streptococcal infection.

CLINICAL SIGNIFICANCE

About 80% of patients show a response to a single streptococcal antigen but if multiple responses are measured, the percentage approaches 95%. For this reason, the World Health Organisation (WHO) recommends the use of ASO to aid the diagnosis of streptococcal infections such as rheumatic fever and glomerulonephritis.

The ASO level can be regarded as a measure of the extent and degree of infection. A streptococcal infection is considered to be one where there is a two-dilution rise in titre between acute and convalescent stage serum. Hence, the test should be repeated after 1 to 2 weeks. Raised ASO levels may also be present in other conditions such as scarlet fever, acute rheumatic arthritis, tonsillitis and various other streptococcal infections as well as in healthy carriers.

BENEFITS OF RANDOX ASO

- Wide measuring range – 28-1314 IU/ml for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents - for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available - with instrument specific settings for a wide range of analysers
- Complementary controls and calibrator available
- Single point calibration, directly calibrated against NIBSC 97/662
- No interference - from C1q complement
Apolipoprotein A-I

WHAT IS APO A-I?
Apo A-I is the major protein component of HDL particles in plasma. Chylomicrons secreted from the intestinal enterocyte also contain Apo A-I, but it is quickly transferred to HDL in the bloodstream.

CLINICAL SIGNIFICANCE
The main role of Apo A-I is in the activation of lecithin cholesterol acyl transferase (LCAT) and removal of free cholesterol from extra hepatic tissues. Apo 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 Apo A-I and coronary artery disease and a direct relationship with Apo B such that patients with coronary artery disease have generally reduced levels of Apo A-I and increased levels of Apo B.

BENEFITS OF RANDOX APO A-I
- Wide measuring range – 6.50-233 mg/dl for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Calibrators supplied with some kits – simplifying the ordering process
- Complementary controls and calibrators available
- Limited interference – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results

Apolipoprotein A-II

WHAT IS APO A-II?
Apo A-II is a major constituent of High Density Lipoprotein (HDL) particles and plays an important role in the reverse cholesterol transport and lipid metabolism. The distribution of Apo A-I in the HDL is primarily determined by the production rate of Apo A-II.

CLINICAL SIGNIFICANCE
Increased production of Apo A-II promotes atherosclerosis by decreasing the proportion of anti-atherogenic HDL containing Apo A-I.

BENEFITS OF RANDOX APO A-II
- Wide measuring range – 6.75-61.1 mg/dl for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Calibrators supplied with some kits – simplifying the ordering process
- Complementary controls and calibrators available
- Limited interference – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
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**Apolipoprotein B**

**WHAT IS APO B?**

Apo B is a component of LDL cholesterol and enables tissue cells to take up cholesterol.

**CLINICAL SIGNIFICANCE**

Elevated levels of Apo B indicate increased cardiovascular risk even when total and LDL cholesterol levels are within the normal range.

**BENEFITS OF RANDOX APO B**

- **Wide measuring range** – 11.2-184 mg/dl for accurate measurement of clinically important results
- **Automated immunoturbidimetric assay** – without the need for any dedicated equipment
- **Liquid ready-to-use reagents** – for convenience and ease of use
- **Stable to expiry when stored at +2 to +8°C** – minimising reagent waste
- **Applications available** – with instrument specific settings for a wide range of analysers
- **Standard supplied with some kits** – simplifying the ordering process
- **Complementary controls and calibrators available**
- **Limited interference** – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results

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**Apolipoprotein C-II**

**WHAT IS APO C-II?**

Apo C-II acts as a co-factor for lipoprotein lipase, an enzyme that hydrolyses triglycerides in chylomicrons and VLDL.

**CLINICAL SIGNIFICANCE**

Patients have been identified with excessive hypertriglyceridemia due to a deficiency in Apo C-II. Deficient patients present with chylomicronemia, xanthomas, and recurrent pancreatitis.

**BENEFITS OF RANDOX APO C-II**

- **Excellent sensitivity** – of 1.48 mg/dl, ensuring depleted levels are detected
- **Automated immunoturbidimetric assay** – without the need for any dedicated equipment
- **Liquid ready-to-use reagents** – for convenience and ease of use
- **Stable to expiry when stored at +2 to +8°C** – minimising reagent waste
- **Applications available** – with instrument specific settings for a wide range of analysers
- **Complementary controls and calibrators available**
- **Limited interference** – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
Apolipoprotein C-III

WHAT IS APO C-III?
Apo C-III modulates the uptake of triglyceride-rich lipoproteins by the LDL receptor related protein through inhibition of lipoprotein lipase.

CLINICAL SIGNIFICANCE
Elevated levels of Apo C-III are associated with both primary and secondary hypertriglyceridemia.
Genetically determined Apo C-III deficiency in humans has shown to increase the rate of triglyceride clearance from the plasma by 6 to 7-fold. Apo C-III levels have been reported higher in many pathological conditions including type 2 diabetes, hyperbilirubinemia, kidney deficiency and decreased thyroid function. Factors that influence Apo C-III levels are gender, age, menopause and genetic polymorphisms in the Apo C-III gene.

BENEFITS OF RANDOX APO C-III
• Excellent linearity – 21.7 mg/dl for comfortable detection of elevated levels
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrators available
• Limited interference – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results

Apolipoprotein E

WHAT IS APO E?
There are three similar isoforms of Apo E: Apo E2, E3 and E4 with E3 being the most common. Apo E has a variety of functions depending on which lipoprotein it is in.

CLINICAL SIGNIFICANCE
Apo E deficiency gives rise to high cholesterol and triglyceride levels, promoting atherosclerosis. The polymorphism has been associated with diseases other than cardiovascular disease, for example E4 is implicated in Alzheimer’s disease.

BENEFITS OF RANDOX APO E
• Wide measuring range – 1.04-12.3 mg/dl for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrators available
• Limited interference – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
Ceruloplasmin

WHAT IS CERULOPLASMIN?

Ceruloplasmin is an alpha 2 globulin synthesised primarily in the liver. It binds to copper after it is absorbed from the gastrointestinal (GI) tract and is responsible for transporting more than 90% of all copper to various tissues within the body. Ceruloplasmin has several important functions including ferroxidase activity, amine oxidase activity and superoxidase activity. It is also involved in homeostasis.

CLINICAL SIGNIFICANCE

The main use of ceruloplasmin is in the diagnosis of Wilson disease, a rare inherited disorder characterised by liver damage and neurological deterioration. Individuals with Wilson disease often have decreased levels of ceruloplasmin which subsequently leads to a build-up of copper in the liver, brain and other organs. If Wilson disease is identified before significant copper deposits affect the function of the major organs, serious damage can be avoided. If left undiagnosed and untreated, Wilson disease can be fatal. Early detection and treatment is therefore crucial in order to prevent permanent damage and halt disease progression. As an acute-phase reactant, ceruloplasmin concentrations are also elevated in cases of bacterial infection, stress, pregnancy, leukemia, Hodgkin’s disease, systemic lupus erythematosi s and rheumatoid arthritis.

BENEFITS OF RANDOX CERULOPLASMIN

- Wide measuring range – 6.29-73.8 mg/dl for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Complementary controls and calibrators available
- Limited interference – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
Complement C3

WHAT IS COMPLEMENT C3?
Complement C3 is a complex biological system which works in conjunction with antibody and other factors to protect the body from invasion by pathogens. When activated by either the classical or alternative pathway, complement C3 acts on biological membranes and may cause cell death. The human complement cascade consists of several distinct plasma proteins and C3 is the rate-limiting factor for both the classic and alternative pathways.

CLINICAL SIGNIFICANCE
Decreased complement C3 levels are important in determining inherited or acquired deficiencies. Conversely, levels may rise in a variety of inflammatory and necrotic disorders as part of the acute-phase plasma protein response.

BENEFITS OF RANDOX CC3
• Wide measuring range – 15.5-502 mg/dl for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrators available
• Limited interference – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results

Complement C4

WHAT IS COMPLEMENT C4?
Complement C4 is a complex biological system which works in conjunction with antibody and other factors to protect the body from invasion by pathogens. When activated by either the classical or alternative pathway, complement C4 acts on biological membranes and may cause cell death. The human complement cascade consists of several distinct plasma proteins. C4 is activated in the classical pathway.

CLINICAL SIGNIFICANCE
Decreased complement C4 levels are important in determining inherited or acquired deficiencies. Conversely, levels may rise in a variety of inflammatory and necrotic disorders as part of the acute-phase plasma protein response.

BENEFITS OF RANDOX CC4
• Wide measuring range – 3.41-152 mg/dl for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrators available
• Limited interference – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
C-Reactive Protein

WHAT IS C-REACTIVE PROTEIN?

C-Reactive Protein or CRP is an acute phase reactant found at low concentrations in the serum of normal patients. During the acute phase response of an inflammatory reaction, CRP levels are elevated up to 1000-fold making it an excellent early indicator of infection.

WHY MEASURE CRP?

Elevated CRP levels indicate an inflammatory response has been activated and levels above the normal range (>6mg/L) are used to diagnose and monitor rheumatic diseases and other inflammatory conditions. Recent research has however widened the clinical significance of CRP and measurement within the normal range can be used for risk assessment of cardiovascular disease, detection of infection in neonates and in early detection of renal allograft rejection.

Inflammation and Infection

CRP is useful in monitoring recovery from surgery, rheumatic disorders, infectious diseases and both bacterial and viral infection.

Cardiovascular Disease

Inflammation is being linked to the development of atherosclerosis. CRP levels at the upper end of the normal range may indicate that a low-level inflammatory response has been initiated and there is an increased risk of cardiovascular disease and stroke.

Neonate Infection

Neonatal susceptibility to bacterial infection is a well-established complication. Early detection of infection is important to enable rapid and effective antibiotic treatment and to minimise antibiotic dose. This will lead to a reduction in risk of antibiotic-related kidney damage and enable earlier neonatal recovery from infection.

Renal Allograft Rejection

Monitoring postoperative CRP levels in renal transplant patients enables early detection of allograft rejection. CRP levels peak around 3 days earlier than the creatinine levels, a standard biochemical marker for allograft assessment. Recent studies have indicated significant elevations in CRP levels in all cases of rejection indicating 100% sensitivity.

Viral Infections

During viral infections such as upper respiratory tract infections, influenza, pneumonia and meningitis, CRP levels will be slightly elevated to around 10-20 mg/l.

Bacterial Infections

Elevated CRP levels from 30-200 mg/l are found in bacterial infections such as septic arthritis, meningitis, pneumonia and also in rheumatoid arthritis. In addition, CRP levels can rise to 30-100 mg/l after surgery.
CRP LEVELS SHOWING CARDIAC RISK AND DISEASES

CRP KITS FROM RANDOX

- **Full Range CRP**
  - Test for measurement of CRP levels within and outside the normal range (0.263-160 mg/l)

- **CRP**
  - Test for measurement of CRP levels outside the normal range (3.57-219 mg/l)

- **High Sensitivity CRP**
  - Test for measurement of low CRP levels within the normal range (0.477-10 mg/l)
CRP

WHY USE RANDOX CRP ASSAY?
C-reactive protein is present in the serum of normal individuals at levels between 0-5 mg/L. Elevated levels outside the normal range are associated with the acute phase response. Measurements may also be useful in the detection of infection, tissue injury, inflammatory disorders and associated diseases. Recent research has indicated that CRP levels within the normal range can be used for assessing the risk of cardiovascular disease, the detection of infection in neonates and in the early detection of renal allograft rejection. Levels within the normal range are associated with cardiac risk.

BENEFITS OF RANDOX CRP
• Wide measuring range – 3.57-219 mg/L for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrators available
• Limited interference – from Bilirubin, Haemoglobin, Intralipid® and Triglycerides, producing more accurate results
Full-Range CRP

WHY USE RANDOX FULL-RANGE CRP ASSAY?

The Randox Full Range CRP assay is a latex-enhanced immunoturbidimetric assay for measurement of CRP levels within and outside the normal range. One single kit is now needed for measurement of both elevated and low CRP levels.

The Randox Full Range CRP assay combines exceptional sensitivity in the low CRP range with excellent linearity at elevated levels for all your CRP testing. With an assay range of 0.18 - 165 mg/l you can accurately and precisely measure CRP both above and within the normal range using a single kit, eliminating the need for a dedicated high sensitivity CRP assay. Full Range CRP can be automated on a range of clinical analysers for rapid routine assessment.

BENEFITS OF RANDOX frCRP

- Wide measuring range – 0.18-165 mg/l for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Complementary controls and calibrator available
**High-Sensitivity CRP**

**WHY USE RANDOX HIGH-SENSITIVITY CRP ASSAY?**

High sensitivity CRP, or hsCRP, in addition to lipid evaluation and risk scoring systems helps in the assessment of cardiovascular disease (CVD) risk. The American Heart Association (AHA) and Centre for Disease Control and Prevention (CDC) now recommend the use of hsCRP as a more sensitive marker of CVD risk compared to traditional CRP assays. The hsCRP assay is particularly useful in predicting future cardiac events in individuals with no previous history of CVD. Healthy individuals with CRP levels higher than 3mg/l are 2 to 4 times more likely to have a heart attack or stroke. 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 therefore help clinicians to identify these individuals earlier; it can also be used to evaluate the risk of a recurrent cardiac event. In high risk groups there have even been indications that CRP could be used as a prognostic tool.

**BENEFITS OF RANDOX hsCRP**

- **Wide measuring range** – 0.477-10 mg/l for accurate measurement of clinically important results
- **Automated immunoturbidimetric assay** – without the need for any dedicated equipment
- **Liquid ready-to-use reagents** – for convenience and ease of use
- **Stable to expiry when stored at +2 to +8°C** – minimising reagent waste
- **Applications available** – with instrument specific settings for a wide range of analysers
- **High sensitivity CRP control and calibrator available**

**AHA/CDC RISK ASSESSMENT GUIDELINES:**

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>hs-CRP (mg/L)</th>
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<tbody>
<tr>
<td>Low</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Average</td>
<td>1-3</td>
</tr>
<tr>
<td>High</td>
<td>&gt;3</td>
</tr>
</tbody>
</table>
WHAT IS CYSTATIN C?

Cystatin C is a small (13 kDa) cysteine proteinase inhibitor that is steadily produced by all nucleated cells. The normal range for healthy individuals is 0.57-1.05 mg/l.

CLINICAL SIGNIFICANCE

The small molecular weight of cystatin C means it can be freely filtered by the glomerular membrane; cystatin C levels in the blood are therefore indicative of a normal or impaired Glomerular Filtration Rate (GFR). Creatinine is perhaps the most widely used marker of GFR however unlike cystatin C, levels are affected by age, gender, race, muscle mass, diet and disease. As creatinine is secreted by tubular cells into the bloodstream a 24 hour urine sample is required, furthermore creatinine is unable to detect small decreases in GFR. Cystatin C on the other hand is degraded in renal tubular cells and is not secreted by the kidneys meaning plasma and serum levels are dependent on the GFR.

Cancer therapeutics can damage renal function; early indication of such damage through the measurement of cystatin C levels is therefore important as it allows the oncologist to adjust drug dosage.

Poor diabetes control can also affect renal function, therefore monitoring cystatin C levels is also useful in diabetic patients.

BENEFITS OF RANDOX CYSTATIN C

- **Wide measuring range** – 0.4-10 mg/L for accurate measurement of clinically important results
- **Automated immunoturbidimetric assay** – without the need for any dedicated equipment
- **Liquid ready-to-use reagents** – for convenience and ease of use
- **Stable to expiry when stored at +2 to +8°C** – minimising reagent waste
- **Applications available** – with instrument specific settings for a wide range of analysers
- **Cystatin C control and calibrators available**
Ferritin

WHAT IS FERRITIN?
Iron is essential for respiration forming part of haemoglobin. It is also found in myoglobin and other proteins and enzymes. Ferritin is a metalloprotein that stores iron intracellularly, mainly in the liver, spleen and bone marrow. Ferritin is a good indicator of the body’s iron stores and levels are measured in iron deficiency and in iron overload.

CLINICAL SIGNIFICANCE
Anaemia is a shortage of red blood cells with a wide range of causes including excessive bleeding, haemolysis and reduced red blood cell production. Anaemia symptoms tend to be vague, for example fatigue and shortness of breath, therefore anaemia is diagnosed using a full blood count. Tests such as ferritin, glucose and renal function are used to confirm the diagnosis and determine the cause of anaemia. In iron overload, iron accumulates in the body causing organ dysfunction. It is caused by diseases such as haemochromatosis, where there is an increase in iron absorption, and by frequent blood transfusions.

Early diagnosis is critical as treatment is relatively simple: periodic phlebotomies and minor dietary changes. Serum iron, total iron-binding capacity and transferrin tests are also used in diagnosis. CRP may be used to rule out elevated ferritin levels due to inflammation.

BENEFITS OF RANDOX FERRITIN
• Wide measuring range – 5.78-434 ng/ml for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrators available
Haptoglobin

WHAT IS HAPTOGLOBIN?
Haptoglobin is an acute phase protein made primarily in the liver. Its main function is to bind free oxyhaemoglobin and remove it from circulation in order to prevent renal injury and iron loss following haemolysis. Haptoglobin is also thought to have both anti-inflammatory and antioxidant properties.

CLINICAL SIGNIFICANCE
Haptoglobin measurements are used in the diagnosis of haemolytic anaemia and to distinguish it from other types of anaemia. In haemolytic anaemia haptoglobin levels in the blood decrease significantly, low levels however may also indicate red blood cell destruction due to sickle cell anaemia or thalassemia. In certain cases of liver disease haptoglobin levels may also be low as the liver cannot manufacture normal levels of the protein.

As an acute phase reactant, haptoglobin levels in the blood are significantly increased in response to infection, inflammation, acute tissue necrosis, malignant tumours, burns, surgery and trauma.

BENEFITS OF RANDOX HAPTOGLOBIN
• Wide measuring range – 0.1-3.68 g/l for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrators available
IgA

WHAT IS IgA?
IgA makes up 15% to 20% of the body's immunoglobulin pool. Its main role is to provide antibody activity at or near mucosal surfaces, such as in the gastrointestinal system, genitourinary system and respiratory system. For this reason, secretions from these areas contain high levels of IgA (in a specialised secretory IgA form). Examples of secretions with high IgA levels include saliva, bile, airway secretions, genitourinary secretions and milk. IgA fixes complement via the alternative pathway.

CLINICAL SIGNIFICANCE
Measurement of IgA is used to diagnose diseases of the respiratory tract e.g. tuberculosis, Chron's disease and early cirrhosis of the liver. It is also useful in monitoring therapy of IgA myeloma and evaluating IgA immunity. IgA in colostrum and milk is important in neonatal defence against infection.

BENEFITS OF RANDOX IgA
- Wide measuring range – 0.21-5.9 g/l for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Complementary controls and calibrators available

IgE

WHAT IS IgE?
IgE is an immunoglobulin with a molecular weight of approximately 190,000Da and is normally present in the blood in trace amounts. IgE antibodies are the chief immunoglobulin responsible for immediate hypersensitivity reactions in humans.

CLINICAL SIGNIFICANCE
Continual production of IgE antibodies in response to common naturally occurring allergens and the production of excessive amounts of histamine by the IgE bound mast cells results in the development of such clinically important allergic reactions such as asthma, hay fever, dermatitis and food allergies. Elevated IgE levels are also seen in parasitic diseases, IgE myeloma and in hepatitis.

BENEFITS OF RANDOX IgE
- Wide measuring range – 19.6-1007 IU/ml for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Complementary controls and calibrators available
IgG

WHAT IS IgG?
This is the principle immunoglobulin in normal human serum, and makes up 80% of the total serum immunoglobulin in adult humans. IgG is the main form of antibody produced in response to secondary infections. This immunoglobulin provides one of the body’s major defences against bacterial infection in adults, unborn children and newborn babies as it can cross the placenta.

CLINICAL SIGNIFICANCE
Measurement of immunoglobulin G is the basis of the serological diagnosis of several infectious diseases. Uses of IgG measurement include diagnosis of infectious and inflammatory diseases, diagnosis of malignancies, to detect the presence of soluble antigens and monitoring therapy in myeloma.

BENEFITS OF RANDOX IgG
• Wide measuring range – 2.8-27.6 g/l for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrators available

IgM

WHAT IS IgM?
IgM is the major antibody found in serum in the first week following infection. This antibody is particularly effective in combating bacterial infections because of its high binding affinity for proteins responsible for destroying bacterial cells (complement proteins). IgM is usually present in humans as groups of five molecules. IgM does not cross the placenta.

CLINICAL SIGNIFICANCE
IgM measurement has the following uses: to establish diagnosis and monitor therapy in Waldenström’s macroglobulinemia and plasma cell myeloma, to detect intra-uterine infection by measuring levels in newborn babies, diagnosis of primary biliary cirrhosis, viral hepatitis, rheumatoid arthritis and parasitic infections.

BENEFITS OF RANDOX IgM
• Wide measuring range – 0.23-3.77 g/l for accurate measurement of clinically important results
• Automated immunoturbidimetric assay – without the need for any dedicated equipment
• Liquid ready-to-use reagents – for convenience and ease of use
• Stable to expiry when stored at +2 to +8°C – minimising reagent waste
• Applications available – with instrument specific settings for a wide range of analysers
• Complementary controls and calibrators available
Lipoprotein (a)

WHAT IS LIPOPROTEIN (A)?
Lp(a) is an LDL-like particle with a cholesterol rich core and a molecule of apo B-100 linked by a disulphide bridge to the glycoprotein apo(a). Apo (a) is unique in that it is extremely heterogeneous in size due to the Kringle 4 type 2 domain which can be present in up to 40 copies. The size heterogeneity of apo(a) affects to varying degrees the outcome of many commercially available Lp(a) kits resulting in over estimation of samples containing large apo(a) molecules and an under estimation of samples containing small apo(a) molecules. Research has documented and shown the Randox method to be one of only a few to exhibit minimum size related bias.

CLINICAL SIGNIFICANCE
Lipoprotein (a) in combination with other lipid tests can provide clinicians with much needed additional information on an individual’s risk of CVD. High levels of Lp(a) are known to occur in individuals with an otherwise normal lipid profile and as such it is thought to contribute to an increased risk of cardiovascular disease independent of other lipids. It is also of particular use in assessing the risk of coronary heart disease in specific populations as Lp(a) concentrations are genetically determined and vary with ethnic population.

Although not a routinely requested test the National Cholesterol Education Programme and the National Academy of Clinical Biochemistry recommend the use of Lp(a) and recommend testing patients with a family history of premature CVD or those classified as moderate/ high risk. In June 2010, the European Atherosclerosis Society (EAS) also published a consensus paper recommending the widespread use of Lp(a) as a screening tool in those at intermediate or high risk of cardiovascular disease.

BENEFITS OF RANDOX Lp(a)
- 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 calibrators with accuracy-based assigned target values are provided – which accurately reflect the heterogeneity of isoforms present in the general population
- Wide measuring range – 3-90 mg/dl for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- 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
- Lp(a) controls and calibrator available
Microalbumin

WHAT IS MICROALBUMIN?
Kidney function may be assessed through measurement of albumin levels in the urine. Normal kidney function entails filtering of waste products from the blood across tiny capillaries in the glomerulus. Kidney malfunction results when the capillaries become blocked, resulting in a build-up of waste products in the blood and a loss of important proteins. Kidney deterioration is progressive and begins with small amounts of albumin leaking into the urine. This is known as microalbuminuria and indicates early signs of nephropathy. The term ‘micro-’ refers to low concentrations of urinary albumin. Progression of kidney disease will lead to larger amounts of albumin leaking into the urine which may develop further to end stage renal disease. Kidney disease is a major concern in diabetic patients and early detection and treatment may slow the onset and progression of the condition.

CONDITION ALBUMIN LEVELS

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<td>Macroalbuminuria</td>
<td>≥300</td>
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CLINICAL SIGNIFICANCE
Albumin is one of the major plasma proteins. In normal circumstances, albumin molecules are too large to cross the glomerular basement membrane, therefore, albumin is usually present in very low concentrations in urine. Damage to the glomerular basement membrane can alter its permeability allowing albumin to enter the urine. Sustained elevations of urinary albumin concentrations are called microalbuminuria. Microalbumin testing can identify individuals with diabetic nephropathy approximately 5-10 years earlier than proteinuria tests helping reduce the incidence of end-stage renal disease.

BENEFITS OF RANDOX MICROALBUMIN
- Calibrator supplied with the kit – simplifying the ordering process
- Excellent sensitivity – of 5.11 mg/l ensuring even low albumin concentrations are detected
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Microalbumin control and calibrator available

ALL ORDERING INFORMATION CAN BE FOUND ON PAGE 23–24
Myoglobin

WHAT IS MYOGLOBIN?
Myoglobin is an oxygen binding haem-protein found in cardiac and skeletal muscle. It is released into blood circulation when muscle cells are damaged.

CLINICAL SIGNIFICANCE
Myoglobin determination can be useful in the diagnosis of myocardial infarction, myositis and in the treatment of myopathy and muscular dystrophy.

BENEFITS OF RANDOX MYOGLOBIN
- Wide measuring range – 20.1-725 ng/ml for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Complementary controls and calibrators available

Rheumatoid Factor

WHAT IS RHEUMATOID FACTOR?
The agglutination reaction between antibody coated red blood cells and rheumatoid arthritis (RA) sera, was first demonstrated by Waaler and Rose in 1940. The reaction has since been shown to be caused by certain factors in the RA sera. These rheumatoid factors (RF) are a heterogeneous group of high molecular weight auto-antibodies directed against the body's own immunoglobulins. They are produced by plasma cells present at sites of tissue injury. The initiating antigen is thought to be one or more viruses or viral antigens that persist in the joint tissues.

CLINICAL SIGNIFICANCE
Research has shown that both environmental and genetic factors can affect the production of RF with various biological properties. Although they may be found in all immunoglobulin classes, the RF most frequently detected is the IgM type; present in about 75% of adult patients with RA and about 10% of children with juvenile RA. RF has also been observed in the serum of patients with lupus erythematosus, hepatitis, liver cirrhosis, syphilis and various other conditions; but the RF titre is much lower than in RA.

BENEFITS OF RANDOX RF
- Wide measuring range – 6.72-104 IU/ml for accurate measurement of clinically important results
- Accurate assessment of RF titre (calibrant standardised against primary WHO material; 1st British Standard 64/2)
- No interference from C1q complement
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Complementary controls and calibrators available
Transferrin

WHAT IS TRANSFERRIN?
Transferrin (siderophilin) is the principal iron binding and transport protein in human plasma and can bind two molecules of iron. The normal range for healthy adults is 200-380 mg/dl. Iron availability in the plasma regulates transferrin levels which increase when plasma iron is low.

CLINICAL SIGNIFICANCE
Transferrin levels increase during pregnancy and oestrogen administration and correlate closely with Total Iron Binding Capacity of serum. Plasma transferrin levels are associated with a range of conditions including anaemia, iron deficiency, inflammation or malignancy, liver disease, malnutrition and protein loss.

BENEFITS OF RANDOX TRANSFERRIN
- Wide measuring range – 7.60-497 mg/dl for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Complementary controls and calibrators available

Transthyretin (Prealbumin)

WHAT IS TRANSTHYRETIN?
Transthyretin, or prealbumin, may be referred to as thyroxin-binding prealbumin as it binds thyroxine and triiodothyronine. Transthyretin has a molecular mass of 55kDa and the prealbumin name is derived from its electrophoretic mobility, as it migrates faster than albumin on electrophoresis. It is manufactured in the liver hepatocytes and forms a complex with retinol-binding protein, to aid the transport of vitamin A.

CLINICAL SIGNIFICANCE
Transthyretin is a negative acute phase reactant and serum levels fall in inflammation, malignancy, cirrhosis of the liver and protein-wasting diseases of the gut or kidneys, owing to decreased synthesis. Elevated levels have been reported in Hodgkinson’s disease. Transthyretin is a good marker of visceral protein status and positive nitrogen balance.

Early Detection of Malnutrition
Transthyretin is a specific clinical indicator of nutritional risk in the management of diseases such as HIV/AIDS, renal disease, diabetes, pneumonia and cancer. Nutritional assessment using transthyretin has also been effective in surgical cases, pre-surgical screening, fractures and wound healing.

Transthyretin Screening
Transthyretin screening can lead to the early identification of patients with Protein Calorie Malnutrition (PCM) and implementation of diet therapy. Transthyretin screening is more specific than albumin for the identification of PCM risk.

BENEFITS OF RANDOX TRANSTHYRETIN
- Wide measuring range – 2.3-65 mg/dl for accurate measurement of clinically important results
- Automated immunoturbidimetric assay – without the need for any dedicated equipment
- Liquid ready-to-use reagents – for convenience and ease of use
- Stable to expiry when stored at +2 to +8°C – minimising reagent waste
- Applications available – with instrument specific settings for a wide range of analysers
- Complementary controls and calibrators available
## SPECIFIC PROTEINS

### ORDERING INFORMATION

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<td>R1 6 x 20ml, R2 2 x 13ml</td>
<td>TF7197</td>
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<tr>
<td>Transferrin</td>
<td>Immunoturbidimetric ✤</td>
<td>R1 6 x 20ml, R2 3 x 14ml</td>
<td>TF3831</td>
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<td>Tranthyretin (Prealbumin)</td>
<td>Immunoturbidimetric ✤</td>
<td>R1 6 x 20ml, R2 3 x 11ml</td>
<td>PA3843</td>
</tr>
</tbody>
</table>

**KEY**

* For use with RX analysers only

 dü Indicates liquid option

(C) Indicates calibrator included in kit

(S) Indicates standard included in kit, and is for manual and semi-automated use only

LEI Latex Enhanced Immunoturbidimetric

T Number of tests

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To receive a quotation or for further enquiries, please contact reagents@randox.com

To place an order, please contact order.entry@randox.com
Immunoturbidimetry methods have become the main technique for performing protein tests. The transition from nephelometry has been cautious but is increasing as laboratories enjoy the comparability and flexibility of immunoturbidimetry.

Immunoturbidimetry and nephelometry both measure the turbidity of a sample to determine the level of an analyte. Upon addition of the assay reagent, antibodies and antigen cluster to form an immune complex that precipitates, increasing the turbidity of the sample. When light is passed through the reaction solution, some light is scattered by the sample, some light is absorbed by the sample and the rest passes through the sample.

Immunoturbidimetry measures the absorbance of the light by the sample, nephelometry measures the light scattered at a fixed angle. The level of analyte is determined by comparison with a calibrator of known concentration.

Immunoturbidimetry is ideal for the detection of proteins, where the analyte concentration is inversely proportional to the transmitted light signal. Historically nephelometry has been more sensitive than conventional immunoturbidimetry. In latex-enhanced immunoturbidimetry, inert microscopic particles enlarge the immune complexes, amplifying the reaction and significantly increasing the sensitivity of the reaction.

Nephelometers are dedicated analysers only capable of performing this type of assay. In addition, they:
- have high consumable costs
- require highly trained personnel

Immunoturbidimetric tests are carried out on routine biochemistry analysers that are:
- versatile
- fast
- cost-effective
- offer longer reagent stability
- sensitive

The main advantage of nephelometry was its sensitivity; however latex-enhanced immunoturbidimetry has closed this gap. Immunoturbidimetric tests are an increasingly accepted alternative to nephelometry for specific protein assays, and studies have shown a close correlation between Randox immunoturbidimetric tests and nephelometry.

Correlation between nephelometric and immunoturbidimetric methods (n=38)

\[ R^2 = 0.99 \]
# A-Z Portfolio of Reagents

<table>
<thead>
<tr>
<th>Specific Proteins</th>
<th>Reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen (Paracetamol)</td>
<td>CK-NAC</td>
</tr>
<tr>
<td>Acid Phosphatase</td>
<td>CO₂ Total</td>
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<tr>
<td>Activated Partial Thromboplastin Time (APTT)</td>
<td>Cocaine Metabolite</td>
</tr>
<tr>
<td>Adiponectin</td>
<td>Complement C3</td>
</tr>
<tr>
<td>Albumin</td>
<td>Complement C4</td>
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<tr>
<td>Aldolase</td>
<td>Copper</td>
</tr>
<tr>
<td>Alkaline Phosphatase</td>
<td>Creatinine</td>
</tr>
<tr>
<td>Alpha-1-Acid Glycoprotein</td>
<td>CRP</td>
</tr>
<tr>
<td>Alpha-1-Antitrypsin</td>
<td>CRP (Canine)</td>
</tr>
<tr>
<td>Alanine Aminotransferase (ALT)</td>
<td>CRP (Full Range)</td>
</tr>
<tr>
<td>Ammonia</td>
<td>CRP (High Sensitivity)</td>
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<tr>
<td>Amylase</td>
<td>Cystatin C</td>
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<tr>
<td>Amylase (Pancreatic)</td>
<td>Digestin</td>
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<tr>
<td>Anti-Streptolysin O (ASO)</td>
<td>Ecstasy</td>
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<tr>
<td>Antithrombin III</td>
<td>EDDP</td>
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<tr>
<td>Apolipoprotein A-I</td>
<td>Ethanol</td>
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<tr>
<td>Apolipoprotein A-II</td>
<td>Fibrinogen</td>
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<td>Apolipoprotein B</td>
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<td>Apolipoprotein C-II</td>
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<td>Apolipoprotein C-III</td>
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<tr>
<td>Apolipoprotein E</td>
<td>Gamma GT</td>
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<td>Aspartate Aminotransferase (AST)</td>
<td>Gentamicin</td>
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<tr>
<td>Barbiturates</td>
<td>GLDH</td>
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<td>Benzodiazepines</td>
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<tr>
<td>ß2 Microglobulin</td>
<td>Glutamate</td>
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<tr>
<td>Bile Acids</td>
<td>Glutamine</td>
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<tr>
<td>Bilirubin (Total/Direct)</td>
<td>Glutathione Peroxidase (Ransel)</td>
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<tr>
<td>Calcium</td>
<td>Glutathione Reductase</td>
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<tr>
<td>Cannabinoids</td>
<td>Glycerol</td>
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<td>Carbamazepine</td>
<td>Haemoglobin</td>
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<td>Ceruloplasmin</td>
<td>Haptoglobin</td>
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<td>Chloride</td>
<td>HbA1c</td>
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<td>Cholesterol (Total)</td>
<td>Heart-type Fatty Acid Binding Protein (H-FABP)</td>
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<td>Cholesterol (HDL)</td>
<td>Homocysteine</td>
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<td>Cholesterol (HDL3)</td>
<td>D-3-Hydroxybutyrate (Ranbut)</td>
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<td>Cholesterol (LDL)</td>
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<td>Lactate Dehydrogenase</td>
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<td>Total Iron Binding Capacity (TIBC)</td>
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<td>Total Antioxidant Status (TAS)</td>
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<td>Total Protein</td>
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<td>Transferrin</td>
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