



CE

RANDOX

Diabetes

High quality tests for the diagnosis of diabetes
and the monitoring of its complications





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The World Health Organisation (WHO) estimates that more than 220 million people worldwide have diabetes and in 2004, an estimated 3.4 million people died from consequences of high blood sugar. Early diagnosis and preventative medicine is the only viable strategy to manage the ever-increasing issues caused by diabetes. Randox provides the complete solution for reliable diabetes assessment, enabling correct treatment to be administered in a timely manner.

As a major non-communicable disease, diabetes claims on average around 8% of total health budgets in developed countries. Diabetes is indiscriminate, but although risk increases with age, anyone can develop it. There are two types of diabetes:

Type 1 Caused by a deficiency, inherited and/or acquired, in production of insulin by the pancreas. This type requires daily administration of insulin. The cause of Type 1 diabetes is not yet known.

Type 2 The body produces insulin, but does not use it effectively. Type 2 diabetes is more common than Type 1, and is usually caused by excess body weight and lack of physical activity.

Gestational diabetes This can occur in women who have never had diabetes before pregnancy. It develops when the body cannot produce enough insulin to cope with the changes during pregnancy.

Tests to assess diabetes

Randox provides all the tests needed to accurately assess diabetes. Early and correct diagnosis is key in controlling this chronic disease.

- Glucose
- Fructosamine
- HbA1c

Tests to monitor the complications of diabetes

We also provide high quality tests to provide reliable monitoring of the complications of diabetes.

- Albumin
- Creatinine
- Cystatin C
- Microalbumin
- Non-esterified fatty acid (NEFA)
- Total protein
- Ranbut
- Beta-2-Microglobulin

Diabetes complications

Ketoacidosis

This is a life threatening condition that can develop in insulin dependent diabetics. When the body has a lack of glucose to be used as energy, it begins to use stored fat as an alternative source of energy. This produces ketones, which change the pH in the blood. This leads to ketoacidosis.

Cardiovascular disease

High blood sugar levels in a diabetic can cause damage to arteries, leading to cardiovascular disease (CVD), the most common cause of death in industrialised countries.

Gestational diabetes

This can occur in women who have never had diabetes before pregnancy. It develops when the body cannot produce enough insulin to cope with the changes during pregnancy.

Eye disease

Diabetes affects the blood vessels feeding the retina and decreases blood flow. This is known as retinopathy. Diabetes is the most common cause of blindness in working age adults.

Foot problems

15% of diabetics develop foot ulcers, with many resulting in foot amputation. Diabetes is the most common cause of non-traumatic lower limb amputation.

Kidney disease

Diabetes can cause severe kidney damage, known as Diabetic Nephropathy. This is recognised as the single most prevalent cause of End Stage Renal Failure.



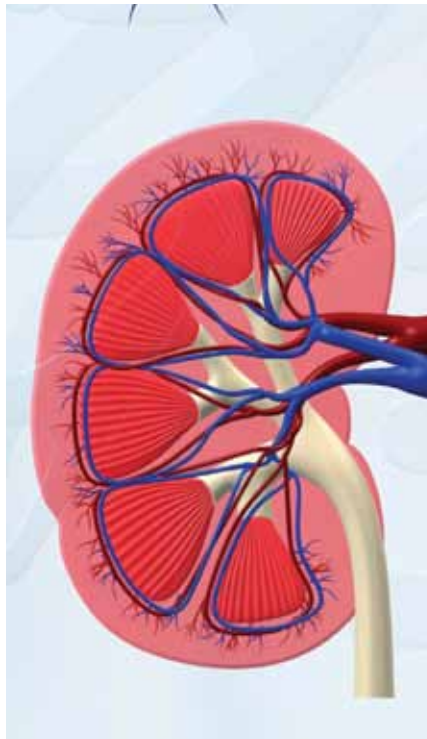
Diabetes Complications

Kidney disease

Diabetes may cause severe kidney damage, referred to as diabetic nephropathy. Nephropathy develops in 30-40% of Type 1 diabetes patients, two-thirds of whom will progress to end-stage renal failure (ESRF). It may also occur in up to 15-20% of Type 2 diabetes patients, 50% of whom will progress to develop renal failure. Diabetic nephropathy is recognised as the single most prevalent cause of ESRF.

In Europe, over 10% of those requiring dialysis or transplantation have diabetes mellitus and this figure is at least twice as high in the USA. The incidence (number of new cases) and prevalence (number of existing cases) of diabetic nephropathy is two to three times higher in Asian and Afro-Caribbean Americans.

There are five distinct stages in the development of diabetic nephropathy, shown in the table below.



Foot problems

High blood glucose can damage the blood vessels supplying the nerves and this can lead to a loss of sensation. If this occurs in the nerves of the feet, a person with diabetes may not feel small cuts or nicks on their skin. These can develop into ulcers. Approximately one in 10 people with diabetes suffer from foot ulcers. Diabetics should inspect their feet every day and should have a foot examination once a year. If an ulcer is left untreated, a serious infection may develop and this can lead to a need for amputation.



The five stages of renal disease in Type 2 diabetes patients:

Stage	Characteristics	Clinical symptoms	Diagnostic Parameters	Onset	Percentage of patients progressing to next stage
1	Early hypertrophy and hyperfiltration	None	Microalbuminuria <20mg/day	With onset of diabetes	100
2	Microscopic renal lesion	None	Microalbuminuria 20 - 300mg/day Creatinine normal	2 - 3 years	35 - 40
3	Incipient nephropathy	Hypertension +/- oedema	Albuminuria 300mg - 15g/day Creatinine normal	10 - 15 years	80 - 100
4	Clinically overt nephropathy	Hypertension and oedema	Albuminuria 300mg - 15g/day Creatinine raised slightly	10 - 30 years	75 - 100
5	End-stage renal failure	Hypertension and oedema and uraemic symptoms	Albuminuria > 300mg/day, but level can fall. Creatinine raised	20 - 40 years	



Eye disease

The retina is the sight centre at the back of the eyeball. Diabetes affects the blood vessels feeding the retina and decreases blood flow. This condition is called retinopathy and is a major cause of blindness, particularly severe in persons who have Type 1 diabetes mellitus. It also frequently occurs in people with Type 2 diabetes. The degree of retinopathy is highly correlated with the duration of diabetes. If untreated there is a 50% risk of blindness within five years.

The first signs of diabetic retinopathy are often enlarged blood vessels and small red dots seen ophthalmoscopically in the retina. Later symptoms include generalised swelling of the retina, called macular oedema, which is a common cause of visual impairment in diabetics.

Pregnancy and diabetes

When a diabetic woman falls pregnant, she needs to be closely monitored. The blood sugar needs to be as close to normal levels as possible at all times, or the foetus may develop into a big baby with immature organs due to the nutritional imbalance.

Gestational diabetes

Gestational diabetes occurs during pregnancy and is also caused by a defect in the processing of dietary sugars. Gestational diabetes however, has characteristics that are different from other types of diabetes.

In gestational diabetes, the placenta produces a number of hormones that interfere with the body's usual response to insulin. This is known as insulin resistance. Most pregnant women will not suffer from gestational diabetes, as their pancreas works to produce extra quantities of insulin. However, when a woman's pancreas cannot produce enough extra insulin, blood levels of glucose stay abnormally high and gestational diabetes occurs.

1-3% of all pregnant women develop gestational diabetes. Most women with the condition have no recognisable symptoms. However, untreated gestational diabetes is risky for the developing foetus. It can lead to full term babies with a high birth weight and immature organs. These babies commonly develop breathing difficulties. There is also a slightly increased risk of foetal or neonatal death when the mother has gestational diabetes, but this risk can be lowered with effective treatment.

Sufferers of gestational diabetes have a higher risk of developing Type 2 diabetes in later life. These women should be checked for the onset of Type 2 diabetes once a year.



Cardiovascular disease

The high blood sugar levels in a diabetic can cause damage to arteries, leading to cardiovascular disease (CVD). It is a major cause of hospitalisation and morbidity in diabetic individuals.

Lifestyle changes have the potential to reduce most of the risks associated with CVD. Regular physical activity, weight loss and quitting smoking will have a dramatic effect. Blood glucose should be maintained between 4-7mmol/L and blood pressure should be treated if it rises above 140/90mmHg. Physical activity improves insulin action in addition to lowering blood pressure and cholesterol levels.



Ketoacidosis

Ketoacidosis is a life threatening condition that can develop in insulin dependent diabetics. A strict balance between insulin and food intake is required. In an imbalanced state, the cells can't use glucose, and have to metabolise fat which produces ketones. Ketones change the pH in the blood; untreated this leads to ketoacidosis, and eventually diabetic coma. These patients are confused and sluggish and have a smell of pear drops on their breath. They must be re-hydrated and treated with glucose and insulin straight away.

Afterwards the level of ketones and glucose needs to be measured to ensure proper correction of the acidosis. Insulin and diet adjustment may be required.



Did you know?

Death rates for mother and baby around the time of birth are 2-3 times higher than in non-diabetics.

Did you know?

Diabetes is a contributing factor in 30% of all cardiovascular disease

Assessing Diabetes

Glucose

Glucose, a sugar, is the primary source of energy for the body. The body obtains glucose through the digestion of the sugar and starch in carbohydrates. Glucose is vital and interacts with the digestive and endocrine system. Due to this it is imperative to maintain glucose levels within the normal range.

Benefits

- Liquid ready-to-use reagents available
- Excellent sensitivity with a minimum level of detection determined as 0.060mmol/l (1.8mg/dl)
- Fully automated applications available for the RX series and a wide range of clinical analysers
- Randox manufacture two kits for the measurement of glucose levels, including a GOD-PAP method and Hexokinase method using NAD+.

Ordering information

	Product Description	Method	Size (ml)	Cat Nos
	GLUCOSE	GOD-PAP	10x100	GL364
	GLUCOSE	GOD-PAP	6x500	GL366
	GLUCOSE	GOD-PAP	2x500	GL1021
◆	GLUCOSE (NAD)	HEXOKINASE	4x100	GL1611
◆	GLUCOSE	GOD-PAP	2x500	GL2614
◆	GLUCOSE	GOD-PAP	6x100	GL2623
◆	GLUCOSE	HEXOKINASE	96OT	GL2822
◆	GLUCOSE	GOD-PAP	9X51	GL3815
◆	GLUCOSE	UV (RX series)	R1 4x51, R2 3x20	GL3816
◆	GLUCOSE (Mono reagent)	HEXOKINASE	4X50	GL3881
	GLUCOSE	GOD-PAP	4x20	GL7660
◆	GLUCOSE	HEXOKINASE	6x500	GL7660
◆	GLUCOSE	GOD-PAP	R1 10x100	GL7952
◆	GLUCOSE (NAD)	HEXOKINASE	R1 5x100, R2 3x40	GL7954

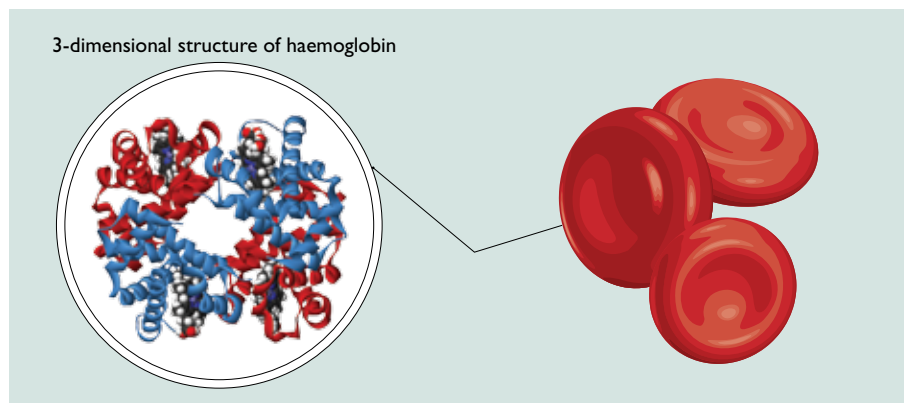
◆ Liquid ready-to-use reagents

HbA1c (glycated haemoglobin)

Haemoglobin consists of four protein chains with four haem portions, and is located in red blood cells. Its main function is to transport oxygen in the blood. When glucose levels are elevated, the glucose binds to haemoglobin, changing it into HbA1c. The level of HbA1c correlates to the level of blood glucose. As red blood cells have a life span of four months, HbA1c gives an indication of long term control of a patient's blood sugar levels.

Benefits

- Liquid ready-to-use reagent
- Wide measuring range 0.25 - 2.4 g/dl
- Fully automated applications available for the RX series and a wide range of clinical analysers



Description	Method	Size	Cat no.
HbA1c / Hb ◆	Latex enhanced immunoturbidimetric	R1 3 x 14 R2 3 x 14	HA3830

◆ Liquid ready-to-use reagents

Fructosamine (glycated serum protein)

Serum fructosamine levels are elevated in diabetic patients with elevated blood glucose. When blood sugar levels are elevated, glucose binds to proteins such as albumin to form fructosamine, the concentration of which also increases.

Fructosamine is a much earlier indicator of diabetic control compared to HbA1c providing information on a person's average blood glucose levels over the preceding 14-21 days. As such the American Diabetes Association recognises fructosamine as a useful tool in monitoring diabetes control.

Due to the shorter time span of fructosamine, it is often used to evaluate the effectiveness of medication changes and to monitor the treatment of gestational diabetes. The test is also particularly useful in situations where HbA1c cannot be reliably measured e.g. haemolytic anaemia, thalassemia or with genetic haemoglobin variants.

Benefits

- Liquid ready-to-use reagent
- Enzymatic method – offering improved specificity and reliability compared to conventional NBT-based methods. This method does not suffer from non-specific interferences unlike existing methods which can also be time consuming and difficult to automate
- Standardisation to the highest level – our fructosamine calibrator and control is assigned relative to human serum glycated with 14C-glucose, thus standardisation is to the highest level and directly reflects the nature of the patient sample.
- Excellent Sensitivity - 8.12µmol/l
- Excellent stability – stable on board the analyser for 28 days at +10°C
- Fully automated applications available for the RX series and a wide range of clinical analysers.

Fructosamine and Gestational Diabetes

Approximately 1-3% of all pregnant women develop gestational diabetes. If poorly treated diabetes can be fatal and often leads to larger than normal babies with immature organs. The needs of the mother change frequently during pregnancy; fructosamine measurements are therefore requested alongside glucose to closely monitor insulin requirements.

Unlike HbA1c the fructosamine tests can be performed on a more regular basis during pregnancy providing a more accurate and reliable picture of diabetes control.

Fructosamine and Thalassemia

Thalassemia is an inherited disorder affecting the synthesis of haemoglobin. The disorder results in the destruction of red blood cells and often leads to haemolytic anaemia.

Traditional HbA1c tests are based on the presence of normal haemoglobin. Abnormal haemoglobin will therefore interfere with the test adversely affecting the results. In such cases fructosamine is recommended as an alternative to HbA1c.

Ordering information

Description	Method	Size	Cat no.
Fructosamine ♦	Enzymatic	R1 5 x 25ml R2 5 x 6.3ml	FR3133
Fructosamine ♦	Enzymatic	R1 4 x 19.8ml R2 4 x 6.9ml	FR4030

♦Liquid ready-to-use reagents



Monitoring the Complications of Diabetes

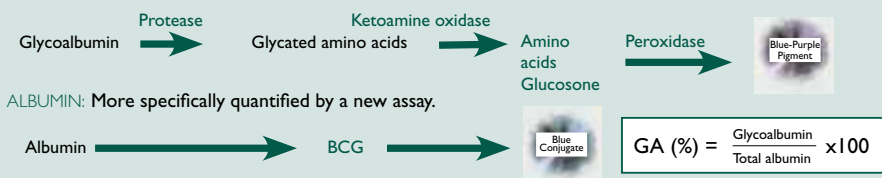
Albumin

Albumin is the most abundant protein in serum with a high binding affinity to glucose. It has special relevance to people with diabetes because its presence in urine is a marker of diabetic kidney disease. Timely assessment of kidney disease will allow adjustment of treatment, improving patient diagnosis.

Benefits

- Liquid ready-to-use reagents available
- Fully automated applications available for the RX series and a wide range of clinical analysers
- Linear up to 50 g/l (5 g/dl)
- Excellent sensitivity - 3.20g/dl

GLYCOALBUMIN: The influence of endogenous glycated amino acids is eliminated by an enzymatic system.



Ordering information

Description	Method	Size	Cat no.
Albumin	BCG	6x100	AB362
Albumin	BCP	480T	AB2806
Albumin	BCG	9x51	AB3800

Liquid ready-to-use reagents

Creatinine

Creatinine is a waste product excreted from the blood into the urine via the kidney. Kidney damage results in creatinine being retained in the blood. Creatinine clearance in the kidney gives a measure of the Glomerular Filtration Rate (GFR) and is the standard marker for renal function. Since its rate of excretion is constant, elevation of plasma creatinine is indicative of under-excretion, suggesting kidney impairment.

Benefits

- Liquid ready-to-use reagents available
- Excellent sensitivity of 26.4 $\mu\text{mol/l}$ (0.29 mg/dl) in serum or plasma and 311 $\mu\text{mol/l}$ (3.51 mg/dl) in urine
- Multiple matrices available including urine, plasma and serum
- Fully automated applications available for the RX series and a wide range of clinical analysers
- Linear up to 32.5mg/dl in serum or plasma

Ordering information

Description	Method	Size	Cat No.
Creatinine	JAFFE	1x200	CR510
Creatinine	JAFFE	6x500	CR524
Creatinine	ENZYMATIC	4x50	CR2336
Creatinine	ENZYMATIC	4x100	CR2337
Creatinine	JAFFE (Dimension)	480T	CR2804
Creatinine	JAFFE (RX series)	R1 6x51, R2 3x28	CR3814
Creatinine	JAFFE	6x500	CR7658
Creatinine	JAFFE	R1 7x50, R2 2x40	CR7948

Liquid ready-to-use reagents

Cystatin C

The liquid ready-to-use Cystatin C kit from Randox provides an excellent tool for the early detection of kidney disease and is a good indicator of Glomerular Filtration Rate (GFR).

GFR is an estimate of the volume of blood that can be completely cleared of a particular substance or filtered by the kidneys each minute. It is often used to determine how well the kidneys are functioning.

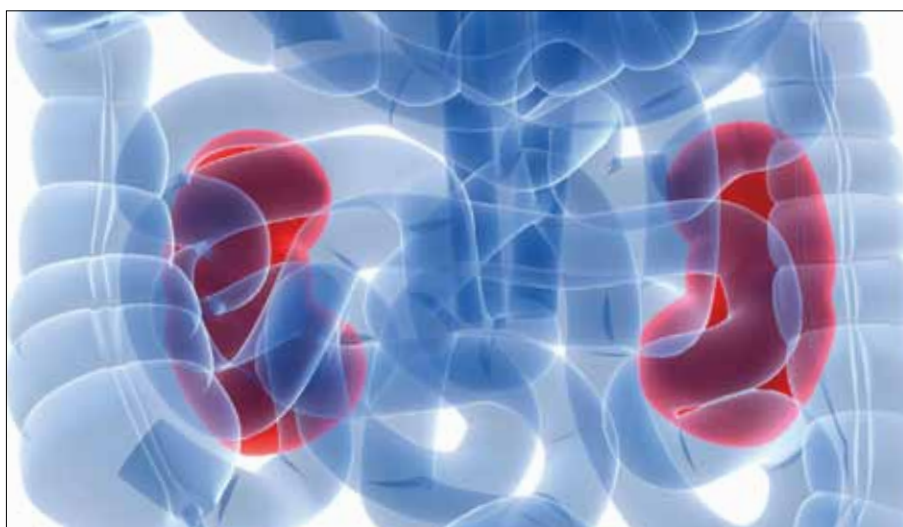
Creatinine is the most widely used marker of GFR however is affected by several endogenous factors including age, gender, race, muscle mass, physical activity, fever and diet. Unlike creatinine, Cystatin C does not have a 'blind area' meaning it is extremely sensitive to very small changes in GFR and therefore capable of detecting early reductions in GFR. Furthermore Cystatin C is *not* affected by age, gender, race, muscle mass, physical activity or diet. In addition to this Cystatin C shows several advantages over creatinine in terms of estimating GFR in children, the elderly, people with diabetes and patients in intensive care who may have reduced muscle mass.

Uses of Cystatin C

- Cystatin C is an important marker of renal function in kidney transplant patients
- Cancer therapeutics can damage renal function, therefore early indication of this damage shown through Cystatin C levels would allow the oncologist to adjust the drug dosage, preventing irreversible kidney damage
- Decreased protein intake or muscle wastage in cancer patients may prevent creatinine levels from rising despite renal function failure. Cystatin C therefore provides excellent information on renal function

Benefits

- Liquid ready-to-use reagent is suitable for use with both serum and plasma samples
- Wide measuring range 0.4 to 10 mg/l – allows normal and abnormal values to be measured accurately and reliably without the need for additional dilutions
- Fully automated applications available for the RX series and a wide range of clinical analysers
- An onboard reagent stability of 28 days minimises reagent waste and subsequently saves money
- Excellent sensitivity – 0.4 mg/l



Precision

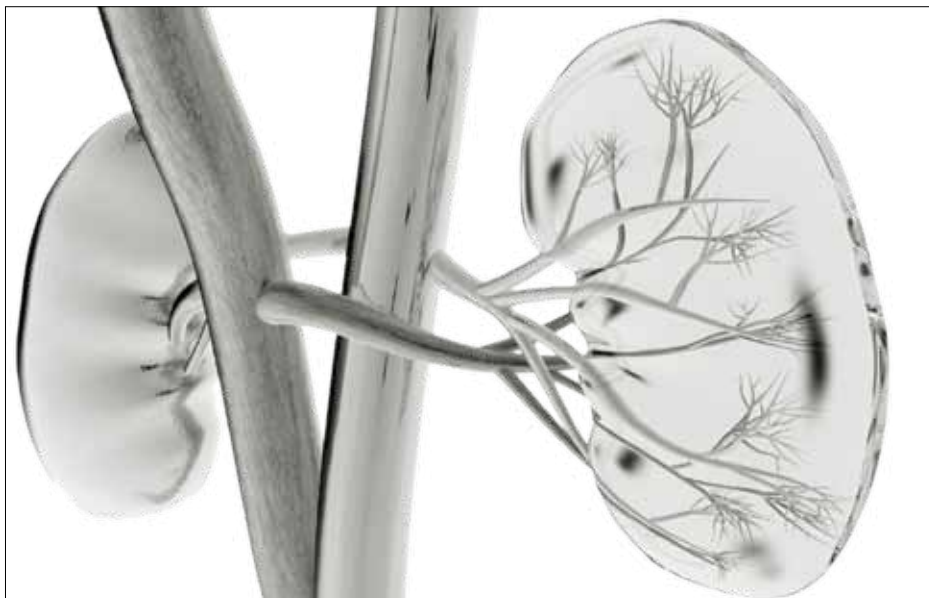
Within Run			
	Level 1	Level 2	Level 3
Mean (mg/l)	0.78	3.37	5.35
SD	0.03	0.09	0.14
CV (%)	4.2	2.6	2.6
n	44	44	44
Total			
	Level 1	Level 2	Level 3
Mean (mg/l)	0.78	3.37	5.35
SD	0.05	0.15	0.24
CV (%)	6.2	4.3	4.4
n	44	44	44

Ordering information

Description	Method	Size	Cat No.
Cystatin C	Immunoturbidimetric	R1 2 x 17.6 R2 2 x 6.1	CYS4004

Microalbumin

The Randox Microalbumin assay detects the presence of albumin in the urine. In healthy individuals albumin is filtered by the kidneys, however if the kidneys are damaged small amounts of albumin leak into the urine. This is known as microalbuminuria and indicates early stages of nephropathy. Microalbumin is an excellent marker of kidney disease and can identify individuals with diabetic nephropathy approximately 5-10 years earlier than proteinuria tests reducing the incidence of end stage renal disease. As such the American Diabetes Association and Diabetes UK recommend all diabetics are screened for microalbuminuria on a yearly basis.



Benefits

- Liquid ready-to-use reagents available
- Wide measuring range - 5-230mg/l
- Excellent Sensitivity – 5mg/l
- Fully automated applications available for the RX series and a wide range of clinical analysers
- Using microalbumin and cystatin C together gives a clearer indication of kidney function and disease.

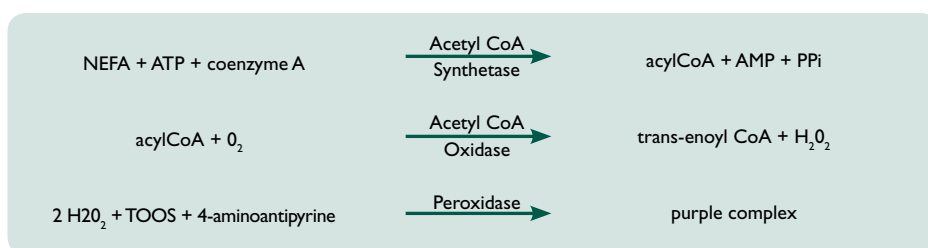
Ordering information

Description	Method	Size	Cat No.
Microalbumin (2-shot only, liquid)	Immunoturbidimetric	R1 3 x 100 R2 5 x 7	MA2423
Microalbumin (2-shot only, liquid)	Immunoturbidimetric	R1 1 x 60 R2 1 x 7	MA2426
Microalbumin (Dimension)	Immunoturbidimetric	4 x 50 Tests	MA2864
Microalbumin (RX series)	Immunoturbidimetric	R1 6 x 20ml R2 3 x 8ml	MA3828

Non-Esterified Fatty Acids (NEFA)

Non-esterified fatty acids (NEFA) are molecules released from triglycerides by the action of the enzyme lipase and are transported in the blood bound to albumin. They contribute only a small proportion of the body's fat, however they provide a large part of the body's energy. Measurement of NEFA is important in diabetes where insulin deficiency results in the metabolism of fat. Levels are also frequently increased in obese patients.

The Randox NEFA kit is a colorimetric end point reaction



Benefits

- Excellent sensitivity to 0.29mg/dl
- The method is linear up to 32.5 mg/dl
- Fully automated applications available for the RX series and a wide range of clinical analysers

Ordering information

Description	Method	Size	Cat No.
NEFA (non-esterified fatty acids)	Colorimetric	R1 3x10, R2 3x20	FA115

Ranbut (D-3 hydroxybutyrate)

The function of insulin is to enable the transport of glucose from the blood into the cells. When insulin levels are insufficient, glucose cannot be transported and fat is utilised for energy production instead. Metabolism of fatty acids in the liver produces ketone bodies, consisting of acetone, acetoacetate and D-3 hydroxybutyrate. Increased levels of ketones can be toxic and can lead to ketoacidosis. Symptoms of ketoacidosis include nausea, vomiting, abdominal pain and can even lead to coma or death if the individual is not treated immediately.

Advantages of testing D-3 hydroxybutyrate

- D-3 hydroxybutyrate is the major ketone body in the blood
- During ketosis, D-3 hydroxybutyrate levels increase more than levels of acetone and acetoacetate, making D-3 hydroxybutyrate a more sensitive marker of ketosis
- D-3 hydroxybutyrate is the most stable of the ketone bodies

Benefits

- Only kinetic method available for the measurement of D-3 hydroxybutyrate, making automation easier
- Wide measuring range: approximately 0.56 to 20.9 mg/l in serum and 0.04 to 3 mg/l in urine.
- Excellent sensitivity of 0.07 mmol/l
- Fully automated applications available for the RX series and a wide range of clinical analysers
- Ranbut measures D-3 hydroxybutyrate – the major ketone in the blood, making it a very reliable test
- Measurement of ketones in serum rather than in urine helps eliminate the risk of false negatives due to insensitivity and false positives due to drug interference

Ordering information

Product Description	Method	Size	Cat. No.
Ranbut	Enzymatic	10x10	RBI007
Ranbut	Enzymatic	10x50	RBI008

Precision

Within Run			
	Level 1	Level 2	Level 3
Mean (mg/l)	0.32	1.27	2.41
SD	0.01	0.01	0.01
CV (%)	2.87	0.57	0.54
n	20	20	20
Total			
	Level 1	Level 2	Level 3
Mean (mg/l)	0.33	1.29	2.45
SD	0.01	0.01	0.02
CV (%)	3.22	0.99	0.92
n	20	20	20

β-2-Microglobulin

Beta-2-Microglobulin (β-2-M) is a low molecular weight protein found on the surface of most cells, including white blood cells. In healthy individuals, β-2-M is synthesised at a rate of 9mg/hour and is eliminated mostly by the kidneys. When kidney disease is suspected, comparing blood and urine levels helps identify where the kidney is damaged. β-2-M is normally filtered out of the blood by the kidney's tubules. In glomerular kidney disease, the glomeruli can't filter it out of the blood, so levels increase in blood and decrease in urine. In tubular kidney disease, the tubules can't reabsorb it back into the blood, so urine levels rise and blood levels fall. High levels of β-2-M in urine may help detect the early stages of kidney damage.

Benefits

- Wide measuring range: approximately 0.56 to 20.9 mg/l in serum and 0.04 to 3 mg/l in urine
- The method is linear up to 0.56 mg/l
- Fully automated applications available for the RX series and a wide range of clinical analysers
- Excellent sensitivity - 0.56mg/l



Ordering information

Product Description	Method	Size	Cat. No.
Beta-2-microglobulin	Immunoturbidimetric	R1 2x11, R2 2x4.3	BM3887

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