RANDOX

DIABETES PORTFOLIO

HIGH QUALITY TESTS FOR THE DIAGNOSIS OF DIABETES AND MONITORING OF ASSOCIATED COMPLICATIONS

DIABETES PORTFOLIO

Diagnosis & Monitoring | Complications Monitoring

Key:

UF **UNIQUE feature**

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

NP **NICHE product**

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

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 an extensive test menu of 100 assays, covering over 100 disease markers including: antioxidants, diabetes, cardiology & lipid testing, clinical chemistry, specific proteins, therapeutic drug monitoring and veterinary testing. A wide range of formats and methods are available providing greater flexibility and choice for any laboratory size. In addition to flexible pack sizes and a comprehensive list of analyser applications, we can also provide dedicated reagent packs (Randox Easy Read and Easy Fit regents) for a wide range of clinical chemistry analysers, providing you with freedom of choice from an independent manufacturer.

Expand your test menu without expanding your lab

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

Expand routine testing

With speciality assays for 195 of the most common clinical chemistry analysers; assays which usually require dedicated equipment (or was previously only available as an ELISA) can now be run on automated clinical chemistry analysers; allowing your laboratory to expand its routine test menu.

Reduce costs

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

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Reduce the risk of errors and have confidence in patient results

Our traceability of material and extremely tight manufacturing tolerances ensure uniformity across reagent batches reducing lot-to-lot variability. All our assays are validated against gold-standard methods, offering low % CV's and excellent precision giving you the confidence that you are sending out the correct patient results.

All ordering information can be found on pages 16-21.

Introduction

Randox is committed to advancing diabetes testing, including the associated complications. In doing so, Randox offers a comprehensive range of high quality reagents ranging from diabetes risk assessment to the diagnosis and monitoring of diabetes, to the diagnosis and monitoring of associated complications. The Randox diabetes portfolio covers the full spectrum of clinical biochemistry laboratory testing requirements including several niche and superior performance assays.

Type 2 diabetes mellitus (T2DM) has reached epidemic levels, now attaining the status of global pandemic, spreading from developed countries to developing countries. The burden on healthcare systems and epidemiological trends indicate that the prevalence will continue to increase dramatically in the coming years. The prevalence, mortality and morbidity rates of T2DM can be reduced and progression halted or slowed with early diagnosis and treatment1. According to the World Health Organization (WHO), diabetes is estimated to be the seventh leading cause of death globally with 1.6 million deaths attributed to diabetes in 2016 [2].

Not only does Randox offer assays, diagnosis and monitoring of diabetes, but we also offer assays for the monitoring of associated complications including: renal dysfunction, ketoacidosis and metabolic status.

Diabetic nephropathy (diabetic kidney disease) is a serious complication of T2DM, affecting a third of T2DM patients. The kidneys are vital organs in glycaemic control as they contribute to tubular reabsorption of glucose and gluconeogenesis. Not only has outpatient care increased due to diabetic nephropathy, but hospital visits, in-hospital stays and mortality rates have also increased. Moreover, diabetic nephropathy has also increased the demand for renal replacement therapies including dialysis and kidney transplants [3].

Diabetic ketoacidosis (DKA) is a serious complication of both Type I Diabetes Mellitus (T1DM) and T2DM and often marks the beginning of diabetes onset, accounting for 6% of cases. DKA is an extreme metabolic state attributed to both relative and absolute insulin deficiency. Insulin deficiency causes lipolysis (breakdown of fatty acids) and ketogenesis (production of ketones). Acidosis occurs when the acidic ketone bodies are excessive [4].

Metabolic status is a key area in determining diabetes risk. Those who are metabolically unhealthy, including metabolic abnormalities, are at a greater risk of T2DM compared to those who are defined as metabolically healthy, irrespective of obesity / BMI status [5, 6].

1. Unnikrishnan R, Pradeepa R, Joshi SR, Mohan V. Type 2 Diabetes: Demystifying the Global Epidemic.. Diabetes 2017; 66(6): 1432-1442.

2. World Health Organization (WHO). Diabetes. https://www.who.int/news-room/fact-sheets/detail/diabetes (accessed 2 May 2019).

3. Pecoits-Filho R, Abensur H, Abensur H, Betonico CC, Machado AD, Parente EB, et al.. Interactions between kidney disease and diabetes: dangerous liaisons. Diabetology & Metabolic Syndrome 2016; 8(50): 1758-5996.

4. Misra S, Oliver NS. Diabetic ketoacidosis in adults. British Medical Journal (BMJ) 2015; 351(): . https://www.bmj.com/content/351/bmj.h5660 (accessed 5 August 2019).

5. Rhee EJ, Lee MK, Kim JD, Jeon WS, Bae JC, Park SE, et al.. Metabolic Health Is a More Important Determinant for Diabetes Development than Simple Obesity: A 4-Year Retrospective Longitudinal Study. A Peer-Reviewed, Open Access Journal (PLoS One) 2014; 9(5): https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0098369 (accessed 7 August 2019).

6. Janghorbani M, Salamat MR, Amini M, Aminorroaya A. Risk of diabetes according to the metabolic health status and degree of obesity. Diabetic & Metabolic Syndrome 2017; 11(1): 439-444.

All ordering information can be found on pages 16-21.

DIAGNOSIS & MONITORING

Glucose | HbA1c (Indirect) | Fructosamine (Glycated Protein)

Glucose

Key Benefits of the Randox Glucose Assay

- **GOD-PAP and Hexokinase methods available**, satisfying individual laboratory testing preferences.
- **Wide measuring range** of 0.200 - 35.5mmol/l, comfortably detecting levels outside of the healthy range.
- **Exceptional correlation** coefficient of r=0.99 when compared against other commercially available methods.
- **Calibrator and controls available** offering a complete testing package.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox glucose assay on a wide range of clinical chemistry analysers.

Biological Significance

Glucose is a fundamental metabolic substrate for tissue energy production. Glucose falls under three classifications: monosaccharide, hexose and aldose. Half of the total carbohydrates consumed through diet are polysaccharides which are hydrolysed to monosaccharides. Glucose is regulated within the body at a stable concentration, however, conditions such as diabetes increase glucose concentrations [1].

Clinical Significance

It is well-known that strict glycaemic control can prevent secondary complications. Numerous studies highlight that hyperglycaemia is an independent and clinically significant risk factor for CVD 2. A patient is diagnosed with diabetes if blood glucose levels are >125mg/dl. If left untreated, hyperglycaemia can result in serious and life-threatening complications including: CVD, hepatic impairment, renal impairment and diabetic eye disease [3].

1. McMillin JM. Clinical Methods: The History, Physical, and Laboratory Examinations. Boston: Butterworths; 1990. https://www.ncbi.nlm.nih.gov/books/NBK248/ (accessed 31 July 2019).

2. Gerich JE. Clinical significance, pathogenesis, and management of postprandial hyperglycemia. Archives of Internal Medicine 2003; 163(11): 1306-1316.

3. Mouri M, Badireddy M. Hyperglycemia. Treasure Island: StatPearls Publishing; 2019. https://www.ncbi.nlm.nih.gov/books/NBK430900/ (accessed 31 July 2019).

All ordering information can be found on pages 16-21.

HbA1c (Indirect)

Key Benefits of the Randox HbA1c Assay

- **Latex enhanced immunoagglutination** method delivering high performance.
- **Exceptional correlation** coefficient of r=0.98 when compared against other commercially available methods.
- **Excellent precision** of <5% CV.
- **Dedicated calibrator and controls available** offering a complete testing package.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox HbA1c assay on a wide range of clinical chemistry analysers.

A direct HbA1c assay is available for the RX series only. The direct HbA1c assay is certified by the National Glycohemoglobin Standardization Program (NGSP) for the RX daytona+, RX imola and RX modena.

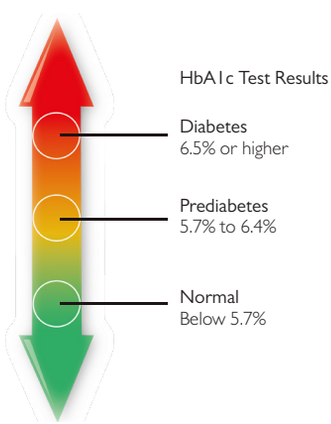
Biological Significance

Haemoglobin is a protein found in red blood cells (RBC's). The role of haemoglobin is to transport oxygen around the body. When glucose levels increase, it binds to the haemoglobin in RBC's. HbA1c levels reflect the average blood sugar levels for the preceding 2 to 3 months; making HbA1c an ideal marker of long-term glucose monitoring [1].

Clinical Significance

HbA1c testing is utilised in the diagnosis and monitoring of diabetes as it highlights how much glucose is bound to the RBC's. When monitoring diabetes, the HbA1c test is utilised to ensure glucose levels remain within the normal range. Moreover, high HbA1c levels increase the risk of associated complications. The target value for those with diabetes is usually <7%. Fig 2 provides a visual representation of the HbA1c testing criterion [1].

Fig. 2: HbA1c Testing Criterion [1]



1. WebMD. Hemoglobin A1c (HbA1c) Test for Diabetes. https://www.webmd.com/diabetes/guide/glycated-hemoglobin-test-hba1c (accessed 31 July 2019).

All ordering information can be found on pages 16-21.

Fructosamine (Glycated Protein)

Key Benefits of the Randox Fructosamine (Glycated Protein) Assay

- **Enzymatic method** offering improved specificity and reliability compared to conventional NBT-based methods. The Randox enzymatic method does not suffer from non-specific interferences unlike the existing methods which can also be time-consuming and difficult to automate.
- **Standardisation to the highest level** as the Randox calibrator and controls are assigned relative to human serum glycated with 14C - glucose, directly reflecting the nature of the patient sample.
- **Excellent stability** on board the analyser when stored at +10°C.
- **Dedicated calibrator and controls available** offering a complete testing package.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox fructosamine assay on a wide range of clinical chemistry analysers.

Biological Significance

In a diabetic patient where blood glucose levels are abnormally elevated, the concentration of fructosamine (glycated protein) also increases as fructosamine is formed by a non - enzymatic Maillard reaction between glucose and amino acid residues of proteins. During this glycation process, an intermediate labile Schiff base is produced which is converted to a more stable ketoamine (fructosamine) via an Amadori rearrangement [1].

Clinical Significance

Fructosamine (glycated protein) has been identified as an early indicator of diabetic control compared to other markers such as HbA1c. RBCs live for approximately 120 days. HbA1c represents the average blood glucose levels for the previous 2 to 3 months. Conversely, fructosamine has a shorter lifespan, of about 14 to 21 days, reflecting average blood glucose levels from the previous 2 to 3 weeks [2]. Fructosamine testing has been identified as being the best for patient care as HbA1c results can be inconclusive for several reasons. Genetic, haematological and disease-related factors negatively impact HbA1c levels, with low levels observed in late stage chronic kidney disease, conditions that shorten the lifespan of erythrocytes such as haemolytic anaemia, and in certain haemoglobinopathies such as sickle cell disease. In gestational diabetes, fructosamine should be tested as HbA1c levels are difficult to interpret as HbA1c integrates glycaemia over the lifespan of the erythrocyte. Therefore, HbA1c is relatively insensitive to short term changes. Consequently, HbA1c testing isn't suitable in the monitoring of the effects of changes in medication. Fructosamine is a medium-term marker (shorter life span) and is a much more suitable test [3].

1. Gounden V, Jialal I. Fructosamine. Treasure Island: StatPearls Publishing; 2019. https://www.ncbi.nlm.nih.gov/books/NBK470185/ (accessed 31 July 2019).

2. Manzella, D. What Is the Fasting Plasma Glucose Test?. https://www.verywellhealth.com/understanding-the-fasting-plasma-glucose-test-1087680 (accessed 31st July 2019).

3. Rodriguez-Segade S, Rodriguez J, Camiña F. Corrected fructosamine improves both correlation with HbA1c and diagnostic performance. Clinical Biochemistry 2017; 50(2017): 110-115.

All ordering information can be found on pages 16-21.

COMPLICATIONS & MONITORING

Renal Dysfunction

Cystatin C | Creatinine (Enzymatic) | Creatinine (Jaffe) | Microalbumin | Albumin | ß2Microglobulin (ß2M)

Cystatin C NP

Key Benefits of the Randox Cystatin C Assay

- **Latex enhanced immunoagglutination** method delivering high performance.
- **Exceptional correlation** coefficient of r=1.00 when compared against commercially available methods.
- **Excellent precision** of <6.2% CV.
- **Dedicated calibrator and controls available** offering a complete testing package.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox cystatin C assay on a wide range of clinical chemistry analysers.

Biological Significance

Cystatin C is a 122 - amino acid, 13.3kDa cysteine proteinase inhibitor, fashioned by all nucleated cells at a constant rate. Cystatin C travels through the bloodstream to the kidneys where it is freely filtered by the glomerular membrane, resorbed and fully catabolised by the proximal renal tubes. Cystatin C is a sensitive biomarker for GFR function [1,2].

Clinical Significance

Cystatin C has been identified as a stronger predictor of clinical outcomes associated with chronic kidney disease (CKD) compared to creatinine [3]. Cystatin C levels inversely correlates with the GFR function. Cystatin C measurements are unaffected by non - renal factors such as muscle mass, sex, age and race, unlike creatinine [4]. The main disadvantage of using creatinine to screen for renal impairment is that up to 50% of renal function can be lost before significant creatinine levels become detectable. Cystatin C does not have a 'blind area' and is highly sensitive to small changes in GFR enabling early detection of renal impairment [5].

The National Institute for Health and Care Excellence (NICE) UK have updated their chronic kidney disease in adults: assessment and management guidelines, recommending cystatin C testing due to its higher specificity for significant disease outcomes than those based on creatinine [6]. More reliable and robust eGFR measurements produced from Cystatin C testing will mitigate the burden of incorrectly staged and misdiagnosed CKD patients [7]. NICE recommend using eGFR cystatin C when a patient has an eGFR creatinine of 45 - 53ml/min/1.73 m^2, sustained for a minimum of 90 days and no proteinuria or other marker of kidney disease is present [6].

1. Murty MS, Sharma UK, Pandey VB, Kankare SB. Serum cystatin C as a marker of renal function in detection of early acute kidney injury. Indian Journal of Nephrology 2013; 23(3): 180-183.

2. Chew JS, Saleem M, Florkowski CM, George PM. Cystatin C–A Paradigm of Evidence Based Laboratory Medicine. The Clinical Biochemist Reviews 2008; 29(2): 47-62.

3. Peralta CA, Katz R, Sarnak MJ, Ix J, Fried LF, De Boer I, et al.. Cystatin C identifies chronic kidney disease patients at higher risk for complications1. Journal of the American Society of Nephrology 2011; 22(1): 147-155.

4. Fiseha T. Clinical Significance of Cystatin C-Based Estimates of Renal Function in Type 2 Diabetic Patients: Review. Annals of Clinical and Laboratory Research 2015; 3 (2:11) .

5. Mishra U. New technique developed to detect chronic kidney disease. https://www.thehindubusinessline.com/news/science/new-technique-to-detect-chronic-kidney-disease/article23803316.ece# (accessed 6 March 2020).

6. National Institute for Health and Care Excellence (NICE). Chronic kidney disease in adults: assessment and management. https://www.nice.org.uk/guidance/cg182/chapter/2-Implementation-getting-started (accessed 6 March 2020).

7. Krishnamurthy N. Biochemistry. Biochemistry and Analytical Biochemistry 2017; 6(3 (Suppl)): 54.

All ordering information can be found on pages 16-21.

Creatinine Enzymatic & Jaffe

Key Benefits of the Randox Enzymatic Creatinine Assay

- **Enzymatic UV method** delivering high performance.
- **Excellent stability** of 30 days when stored at +2 to +8°C.
- **Excellent measuring range** of 11.4-2460µmol/l for the comfortable detection of clinically important results.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox enzymatic creatinine assay on a wide range of clinical chemistry analysers.
- **Calibrator and controls available** offering a complete testing package.

Key Benefits of the Randox Jaffe Creatinine Assay

- **Excellent open vial stability** of 21 days when stored in a refrigerator at +2 to +8°C.
- **Excellent measuring range** of 16 - 2448µmol/l for the comfortable detection of clinically important results.
- **Liquid ready-to-use reagents** for convenience and ease-of-use.
- **Calibrator and controls available** offering a complete testing package.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox jaffe creatinine assay on a wide range of clinical chemistry analysers.

Biological Significance

Creatinine is the end-product of muscle catabolism of creatine. In humans, creatinine production is relatively stable, but mainly depends on muscles mass. Consequently, any physiological changes in muscle mass will cause a variation in the creatinine pool independently of GFR changes. Creatinine is freely filtered by the glomerulus at a constant rate with 10% to 40% secreted by the tubules [1].

Clinical Significance

Creatinine measurements are useful in the diagnosis and monitoring of diabetic nephropathy, the leading cause of kidney disease in patients commencing renal replacement therapy, affecting 40% of diabetics (type 1 and type 2) [2]. The RENAAL risk score for end-stage renal disease (ESRD) emphasizes the importance of the identification of elevated SCr, alongside other renal markers, in the prediction of end-stage renal disease (ESRD) development in patients with type 2 diabetes mellitus (T2DM) and nephropathy [3].

1. Bargnoux AS, Kuster N, Cavalier E, Piéroni L, Souweine JS. Serum creatinine: advantages and pitfalls. Journal of laboratory and Precision Medicine 2018; 3(71): 1-7.

2. Gross JL, de Azevedo MJ, Silveiro SP, Canani LH, Caramori ML, et al. Diabetic Nephropathy: Diagnosis, Prevention, and Treatment. Diabetes Care 2005; 28(1): 164-176.

3. Dabla PK. Renal function in diabetic nephropathy. World Journal of Diabetes 2010; 1(2): 48-56.

All ordering information can be found on pages 16-21.

Microalbumin

Key Benefits of the Randox Microalbumin Key Assay

- (UF) **Calibrator supplied with kit** simplifying the ordering process.
- **Exceptional correlation** coefficient or r=0.99 when compared against other commercially available methods.
- **Extensive range** of 4.06 - 396mg/l for the comfortable detection of clinically important results.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox microalbumin assay on a wide range of clinical chemistry analysers.
- **Dedicated calibrator** and control available offering a complete testing package.

Biological Significance

Albumin is one of the major plasma proteins and is usually present in very low concentrations in urine. Damage to the glomerular basement membrane can alter its permeability meaning albumin and other proteins usually reabsorbed and recirculated in the blood enter the urine. Sustained elevations of urinary albumin concentrations are called microalbuminuria [1].

Clinical Significance

Microalbumin is strongly associated with poor glycaemic control, hypertension and other diabetic complications including ischaemic heart disease, diabetic retinopathy and neuropathy. Microalbumin is an early biomarker of diabetic nephropathy, the most common complication of T2DM [2].

1. Lab Tests Online UK. Urine Albumin to Creatinine Ratio or ACR. https://labtestsonline.org.uk/tests/urine-albumin-creatinine-ratio-or-acr (accessed 27 November 2018).

2. Ahmad T, Ulhaq I, Mawani M, Islam N. Microalbuminuria in Type-2 Diabetes Mellitus; the tip of iceberg of diabetic complications. Pakistan Journal of Medical Sciences 2017; 33(3): 519-523.

All ordering information can be found on pages 16-21.

ß2Microglobulin (ß2M)

Key Benefits of the Randox ß2M Assay

- **Wide measuring range** of 0.476 - 20.9mg/l for the comfortable detection of clinically important results.
- **Stable to expiry date** when stored at +2 to +8°C.
- **Liquid ready-to-use reagents** for convenience and ease-of-use.
- **Calibrator and controls available** offering a complete testing package.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox B2M assay on a wide range of clinical chemistry analysers.

Biological Significance

ß2M is a small (11,800Da) protein located on the surface of nucleated cells and most biological fluids, including: synovial fluid, urine and serum, and is especially abundant in monocytes and lymphocytes [1,2]. Under normal conditions, intracellular release causes small amounts of ß2M to be released into the blood which is then filtered and removed via the kidneys. The concentration levels of ß2M is determined by two factors: generation and secretion into circulation and elimination via the kidneys. Elevated cell turnover and/or renal impairment are the two contributing factors to elevated ß2M concentrations [2].

Clinical Significance

Elevated ß2M concentrations have been observed in autoimmune, immunodeficiency and renal diseases [2]. ß2M has been identified as a strong marker in the assessment of tubular and glomerular function in adults. It has been recognised that ß2M testing offers similar estimating equations as creatinine, however, ß2M appears to be more strongly associated with cardiovascular mortality and morbidity compared to creatinine or other renal markers. ß2M is reliable and cost - effective, making it the ideal screening tool for diabetic nephropathy [3].

1. Li L, Dong M, Wang XG. The Implication and Significance of Beta 2 Microglobulin: A Conservative Multifunctional Regulator. Clinical Medical Journal 2016; 129(4): 448-455.

2. Prizment AE, Linabery AM, Lutsey PL, Selvin E, Nelson HH, Folsom AR, et al.. Circulating Beta-2 Microglobulin and Risk of Cancer: The Atherosclerosis Risk in Communities Study (ARIC). Cancer Epidemiology, Biomarkers & Prevention 2016; 25(4): 657-664.

3. Argyropoulos CP, Chen SS, Ng YH, Roumelioti ME, Shaffi K, Singh PP. Rediscovering Beta-2 Microglobulin As a Biomarker across the Spectrum of Kidney Diseases. Frontiers in Medicine 2017; 4(): 73.

All ordering information can be found on pages 16-21.

COMPLICATIONS & MONITORING

Ketoacidosis | D - 3 - Hydroxybutyrate (Ranbut)

D - 3 - Hydroxybutyrate (Ranbut) NP

Key Benefits of the Randox D - 3 - Hydroxybutyrate (Ranbut) Assay

- **Superior methodology** when compared to other commercially available ketone detection tests. For example, the nitroprusside method used in semi-quantitative dipstick tests only detects acetone and acetoacetate. D - 3 - hydroxybutyrate is the most abundant ketone produced during ketosis the measurement of this analyte is more sensitive and specific.
- **Exceptional correlation** coefficient of r=0.9954 when compared against other commercially available methods.
- **Excellent precision** of <3.5% CV.
- **Calibrator and controls available** offering a complete testing package.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox D - 3 - Hyroxybutyrate (Ranbut) assay on a wide range of clinical chemistry analysers.
- **New liquid stable Ranbut assays** available

Biological Significance

During prolonged periods of starvation or impaired carbohydrate metabolism, starved cells begin to signal for energy from fat metabolism. Ketone bodies (acetoacetate, D-3-hydroxybutyrate and acetone) are produced from fatty acid beta-oxidation; a process called ketosis which takes place in the liver. Of the three ketones, D-3-hydroxybutyrate is the major ketone in the body [1,2].

Clinical Significance

Ketosis produces ketones which is not normally dangerous. If left untreated, especially in diabetes, ketoacidosis (high levels of ketones) develops which can be fatal and damage the liver and kidneys [3]. In type 1 diabetes mellitus (T1DM), the body is unable to produce insulin resulting in bodily cells not receiving energy from glucose, causing the body to release hormones to breakdown fat for energy, producing ketones. Diabetic ketoacidosis is commonly triggered by an illness, infection or missing insulin treatments [4].

1. Hsu WS, Kao JT, Tsai KS. Fully automated assay of blood D-3-hydroxybutyrate for ketosis. Journal of Formosan Medical Association 1993; 92(4): 336-340.

2. Vigili de Kreutzenberg S, Avogaro A. The role of point-of-care 3-hydroxybutyrate testing in patients with type 2 diabetes undergoing coronary angiography. Journal of

Endocrinological Investigation 2017; 40(6): 627-634.

3. Hecht M. Ketosis vs. Ketoacidosis: What You Should Know. https://www.healthline.com/health/ketosis-vs-ketoacidosis (accessed 6 August 2019).

4. Mayo Clinic. Diabetic ketoacidosis. https://www.mayoclinic.org/diseases-conditions/diabetic-ketoacidosis/symptoms-causes/syc-20371551 (accessed 6 August 2019).

All ordering information can be found on pages 16-21.

COMPLICATIONS & MONITORING

Metabolic Status | Non - Esterified fatty acids (NEFA)

Non - Esterified Fatty Aids (NEFA) NP

Key Benefits of the Randox NEFA Assay

- **Exceptional correlation coefficient** of r=0.98 when compared against other commercially available methods.
- **Excellent precision** of <5% CV.
- **Extensive measuring range** of 0.072 - 2.24mmol/l for the comfortable detection of clinically important results.
- **Calibrator and controls available** offering a complete testing package.
- **Applications available** detailing instrument-specific settings for the convenient use of the Randox NEFA assay on a wide range of clinical chemistry analysers.

Biological Significance

NEFA are important metabolites stored in adipose tissue. NEFA turnover is swift, with a plasma half - life of 2 to 4 minutes. The dominant source of NEFA is abdominal subcutaneous fat, with considerably less found in leg adipose tissue and a small proportion found in the intra-abdominal adipose tissue. NEFA has been recognised as a vehicle by which triacylglycerol (TG) (stored in the adipose tissue) is transported to its sites of utilisation [1]. NEFA has been identified as the major energy source for skeletal muscle during fasting stages and long periods between meals. Cross - sectional studies have consistently documented that circulating NEFA levels are proportional to body fat storage and demonstrated positive correlations between fasting NEFA levels and obesity, insulin resistance and glucose tolerance [2].

Clinical Significance

NEFA concentrations are strongly associated with insulin resistance. In the fasting state, the resistance of adipose tissue to the antilipolytic effect of insulin causes the extensive release of NEFA into circulation. Elevated NEFA levels exacerbate insulin resistance through diminishing insulin - stimulated glucose intake into the skeletal muscle, directly affecting insulin signalling [3].

1. Karpe F, Dickmann JR, Frayn KN. Fatty acids, obesity, and insulin resistance: time for a reevaluation. Diabetes 2011; 60(10): 2441-2449.

2. Il'yasova D, Wang F, D'Agostino RB Jr, Hanley A, Wagenknecht LE. Prospective association between fasting NEFA and type 2 diabetes: impact of post-load glucose. Diabetologia 2010; 53(5): 866-874.

3. Saad MI, Kamel MA, Hanafi MY. Modulation of Adipocytokines Production and Serum NEFA Level by Metformin, Glimepiride, and Sitagliptin in HFD/STZ Diabetic Rats. Biochemistry Research International 2015; 2015(138134): . https://www.hindawi.com/journals/bri/2015/138134/ (accessed 7 August 2019).

All ordering information can be found on pages 20-25.

ORDERING INFORMATION

Ordering Information

Description	Method	Size	Cat. No.
Albumin	BCG	6 x 100ml (S)♦	AB362
Albumin	BCG	9 x 51ml♦	AB3800
Albumin	BCG	4 x 68ml♦	AB8000
Albumin	BCG	4 x 20ml♦	AB8301
ß2Microglobulin	L.E.I	R1 2 x 11ml♦ R2 2 x 4.3ml	BM3887
Creatinine	Jaffe	1 x 200ml (S)♦	CR510
Creatinine	Jaffe	R1 6 x 51ml♦ R2 3 x 28ml	CR3814
Creatinine	Jaffe	R1 6 x 68ml♦ R2 6 x 20ml	CR8022
Creatinine	Enzymatic UV	R1 4 x 20ml♦ R2 4 x 7ml	CR8316
Creatinine	Enzymatic UV	R1 4 x 50ml (S) R2 4 x 10ml	CR2336
Creatinine	Enzymatic UV	R1 4x50ml♦ R2 4x19.5ml	CR4037

(C) indicates calibrator included in kit

(S) indicates standard included in kit

♦ indications liquid option

Ordering Information

Description	Method	Size	Cat. No.
Creatinine	Enzymatic UV	R1 4 x 100ml (S) R2 4 x 20ml	CR2337
Creatinine	Enzymatic UV	R1 4 x 65ml♦ R2 4 x 32.3ml	CR8122
Creatinine	Enzymatic UV	R1 4 x 20ml♦ R2 4 x 9.5ml	CR8317
Cystatin C	L.E.I	R1 2 x 17.6ml♦ R2 2 x 6.1ml	CYS4004
D - 3 - Hydroxybutyrate (Ranbut)	Enzymatic	10 x 10ml (S)	RB1007
D - 3 - Hydroxybutyrate (Ranbut)	Enzymatic	10 x 50ml (S)	RB1008
D - 3 - Hydroxybutyrate (Ranbut)	Enzymatic	R1 2 x 20ml♦ R2 2 x 5.8ml	RB4067
D - 3 - Hydroxybutyrate (Ranbut)	Enzymatic	R1 2 x 20ml♦ R2 2 x 6.1ml	RB8378
Fructosamine (Glycated Protein)	Enzymatic	R1 5 x 25ml♦ R2 5 x 6.3ml	FR3133
Fructosamine (Glycated Protein)	Enzymatic	R1 4 x 19.8ml♦ R2 4 x 6.9ml	FR4030
Glucose	GOD-PAP	4 x 68ml♦	GL8038

(C) indicates calibrator included in kit

(S) indicates standard included in kit

♦ indications liquid option

Ordering Information

Description	Method	Size	Cat. No.
Glucose	GOD-PAP	10 x 100ml (S)	GL364
Glucose	GOD-PAP	4 x 20ml♦	GL3981
Glucose	GOD-PAP	2 x 500ml (S)♦	GL2614
Glucose	GOD-PAP	9 x 51ml♦	GL3815
Glucose	GOD-PAP	4 x 20ml♦	GL8318
Glucose	Hexokinase	4 x 50ml	GL3881
Glucose	Hexokinase	R1 4 x 51ml♦ R2 3 x 20ml	GL3816
Glucose	Hexokinase	R1 4 x 20ml♦ R2 4 x 6.5ml	GL8319
HbA1c (Indirect)	Latex Immunoagglutination	R1 3 x 14ml♦ R2 3 x 14ml	HA3830
HbA1c (Indirect)	Latex Immunoagglutination	R1 4 x 7.8ml♦ R2 4 x 7.8ml	HA8321
HbA1c Indirect Haemoglobin Denatured Reagent Denatured Reagent	Latex Immunoagglutination	2 x 50ml♦	HA3450

(C) indicates calibrator included in kit

(S) indicates standard included in kit

♦ indications liquid option

Ordering Information

Description	Method	Size	Cat. No.
HbA1c II Direct	Latex Immunoagglutination	R1 4 x 16.2ml♦ R2 2 x 8.2ml	HA8123
HbA1c II Direct	Latex Immunoagglutination	R1 4 x 12.7ml♦ R2 4 x 6ml	HA8379
HbA1c II Direct	Latex Immunoagglutination	R1 4 x 20ml♦ R2 4 x 8.6ml	HA4068
Microalbumin	PEG Enhanced Immunoturbidimetric	R1 1 x 60ml (C)♦ R2 1 x 7ml	MA2426
Microalbumin	PEG Enhanced Immunoturbidimetric	R1 6 x 20ml♦ R2 3 x 8ml	MA3828
Microalbumin	PEG Enhanced Immunoturbidimetric	R1 2 x 20ml♦ R2 2 x 6.6ml	MA8056
Microalbumin	PEG Enhanced Immunoturbidimetric	R1 1 x 20ml♦ R2 1 x 4.6ml	MA8325
Microalbumin 2	PEG Enhanced Immunoturbidimetric	R1 3 x 20ml♦ R2 3 x 7.5ml	MA4072
Microalbumin 2	PEG Enhanced Immunoturbidimetric	R1 2 x 20ml♦ R2 2 x 9ml	MA8160
Microalbumin 2	PEG Enhanced Immunoturbidimetric	R1 1 x 20ml♦ R2 1 x 7.8ml	MA8388

(C) indicates calibrator included in kit

(S) indicates standard included in kit

♦ indications liquid option

Ordering Information

Description	Method	Size	Cat. No.
NEFA	Colorimetric	R1 3 x 10ml (C)♦ R2 3 x 20ml	FA115

(C) indicates calibrator included in kit

(S) indicates standard included in kit

♦ indications liquid option

Portfolio of Reagents

Diabetes Portfolio

Reagent	Page No
Albumin	17
Creatinine	17-18
Cystatin C	18
D - 3 - Hydroxybutyrate (Ranbut)	18
Fructosamine (Glycated Serum Protein)	18
ß2Microglobulin (ß2M)	11

Reagent	Page No
Glucose	18-19
HbA1c, Direct	20
HbA1c, Indirect	19
Microalbumin	20
Non-Esterified Fatty Acids (NEFA)	21

OTHER ASSAYS AVAILABLE FROM RANDOX

Aldolase
Alkaline Phosphatase
Alanine Aminotransferase (ALT)
Ammonia
Amylase
Amylase Pancreatic
Anti-Streptolysin O (ASO)
Apolipoprotein A-I
Apolipoprotein A-II
Apolipoprotein B
Apolipoprotein C-II
Apolipoprotein C-III
Apolipoprotein E
Aspartate Aminotransferase (AST)
Bile Acids, 4th Gen
Bile Acids, 5th Gen
Bilirubin, Direct
Bilirubin, Total
Calcium
Carbamazepine
Cholesterol, Total
Cholesterol, HDL
Cholesterol, LDL
Cholesterol, sdLDL
Cholinesterase (Butyryl)
CK-MB
CK-NAC
CO2 Total
Complement C3
Complement C4
Copper
CRP
CRP, Canine
CRP, Full Range
CRP, High Sensitivity
Digoxin
Ferritin
G6PDH
Gamma GT
Gentamicin
GLDH
Glutamate
Glutathione Peroxidase (Ransel)
Glutathione Reductase
Glycerol
Haemoglobin
Haptoglobin
Heart-type Fatty Acid Binding Protein (H-FABP)
Homocysteine
IgA
IgE
IgG
IgM
Iron
L-Lactate
Lactate Dehydrogenase (L-P)
Lactate Dehydrogenase (P-L)
Lipase
Lipoprotein(a)
Magnesium
Myoglobin
Phenobarbital
Phenytoin
Phosphorus (Inorganic)
Potassium
Rheumatoid Factor (RF)
Sodium
Soluble Transferrin Receptor (sTfR)
Superoxide Dismutase (Ransod)
Syphilis
Total Antioxidant Status (TAS)
Total Iron Binding Capacity (TIBC)
Total Protein
Transferrin
Transthyretin (Prealbumin)
Triglycerides
Urea
Uric Acid
Urinary Protein
Valproic Acid
Zinc

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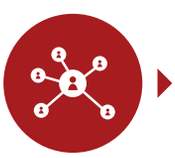

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All ordering information can be found on pages 16-21.

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