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RANDOX

Renal Function

A comprehensive range of reagents for
renal function assessment

Albumin

Sodium Phosphorus

Albumin Ammonia Beta-2- Microglobulin

Phosphorus (Inorganic) Urea

Ammonia Beta-2- Microglobulin Calcium

Phosphorus (Inorganic) Urea Uric Acid Creatinine

Beta-2- Microglobulin Calcium Chloride

(Inorganic) Urea Uric Acid Creatinine Cystatin

Microglobulin Calcium Chloride Glucose HbA1c

Cystatin C Microalbumin Total Urinary Protein

HbA1c IgG LDH Magnesium Potassium Sodium Phosphorus

Microalbumin Total Urinary Protein Albumin Ammonia

LDH Magnesium Potassium Sodium Phosphorus (Inorganic)

Total Urinary Protein Albumin Ammonia Beta-2- Microglobulin

Sodium Potassium Sodium Phosphorus (Inorganic) Urea

Protein Albumin Ammonia Beta-2- Microglobulin Calcium

Sodium Phosphorus (Inorganic) Urea Uric Acid Creatinine

Albumin Ammonia Beta-2- Microglobulin Calcium Chloride

Phosphorus (Inorganic) Urea Uric Acid Creatinine

Renal Function

Introduction

The kidneys play an important role within the body and have three main functions- excretion of waste, maintenance of extracellular fluid and hormone synthesis.

When the kidneys are not functioning efficiently, waste products and fluids begin to accumulate instead of being excreted which can cause serious health problems. Furthermore, kidney disorders can often develop and advance over a period of time

without showing any signs; alternatively, symptoms are not recognised as being associated with kidney problems.

Kidney function testing is therefore essential for diagnosing and monitoring disease and will assist in the development of appropriate treatment plans. Randox offers a comprehensive range of high performance reagents for use in the detection and characterisation of renal function problems.

Renal function testing reagents available from Randox

- Cystatin C
- Creatinine Enzymatic
- Creatinine Jaffe
- Microalbumin
- Total Urinary Protein
- Urea
- Sodium
- Potassium
- Albumin
- Ammonia
- Beta-2- Microglobulin
- Calcium
- Chloride
- Glucose
- HbA1c
- IgG
- LDH
- Magnesium
- Phosphorus (Inorganic)
- Uric Acid

Early screening

- Cystatin C
- Microalbumin

Diagnosis

- Creatinine
- Urea

Monitoring

- Total Urinary Protein
- Sodium
- Potassium

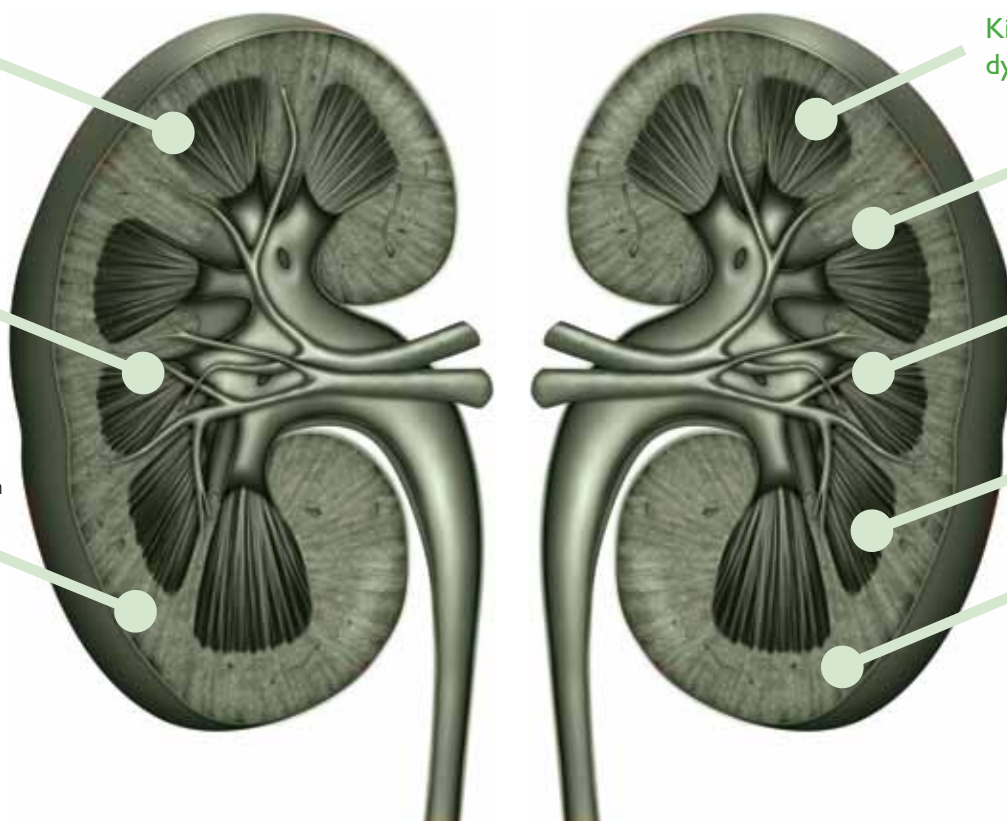
Kidney dysfunction

Nephrotic syndrome

Nephritic syndrome

Chronic kidney disease

Renal failure



Cystatin C

What is Cystatin C?

Cystatin C is a small (13 kDa) cysteine proteinase inhibitor that is produced at a constant rate by all nucleated cells. The small molecular weight of Cystatin C allows it to be completely removed and broken down by the kidneys, levels therefore remain steady if the kidneys are working efficiently and the Glomerular Filtration Rate (GFR) is normal.

Clinical significance

Cystatin C is a particularly useful marker of renal function in patients where creatinine measurements are not suitable e.g. individuals who are obese, malnourished, have liver cirrhosis or reduced muscle mass. Furthermore, unlike creatinine, Cystatin C does not have a 'blind area' - up to 50% of renal function can be lost before significant creatinine elevation occurs. Cystatin C is extremely sensitive to very small changes in GFR and is therefore capable of detecting early stage kidney dysfunction.

Randox Cystatin C performance characteristics

- **Sample type** - serum and plasma
- **Method** - immunoturbidimetric
- **Liquid ready-to-use reagents** - for ease of use and convenience
- **Excellent on board stability** - 28 days at +10°C minimising reagent waste
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides
- **Wide measuring range** - 0.4-10 mg/l, allowing normal and abnormal values to be measured without any additional dilution
- **Applications available** - for a variety of clinical chemistry analysers

Product description	Size	Cat. No.
Cystatin C	R1 2 x 17.6ml, R2 2 x 6.1ml	CYS4004

Related controls and calibrators

Product description	Size	Cat. No.
Cystatin C Normal Control	3 x 2ml	CYS5019
Cystatin C Elevated Control	3 x 2ml	CYS5020
Cystatin C Calibrator Set	5 x 2ml	CYS2699

Randox Cystatin C

- Superior linearity capable of detecting extremely high Cystatin C concentrations
- Reduced interference for truly accurate results
- Cystatin C can be used where creatinine measurements are not suitable e.g. with individuals who are obese
- Cystatin C does not suffer from a 'blind area' like creatinine and it is also very sensitive to small changes in GFR, therefore Cystatin C can highlight early stage kidney problems

Creatinine

What is creatinine?

Creatinine is a waste product excreted at a constant rate from the blood into the urine via the kidneys. The way in which creatinine is excreted by the kidneys means its measurement is used almost exclusively in the assessment of renal function- 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.

Clinical significance

Creatinine measurement has a number of advantages - the plasma level of creatinine is relatively independent of protein ingestion, water intake, rate of urine production and exercise. Since its rate of production is constant, elevation of plasma creatinine is indicative of under-excretion, suggesting kidney impairment. Two creatinine measurement methods are available from Randox - Enzymatic and Jaffe.

Randox enzymatic creatinine performance characteristics

- **Sample type** - serum and urine
- **Method** - enzymatic colorimetric
- **Liquid and lyophilised reagents available** - providing greater choice
- **Stability** - stable to expiry date when stored at +2 to +8°C
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides
- **Wide measuring range** - 11.4-2460 µmol/l. The normal creatinine range for men is 53-106 µmol/l and for women is 44-88 µmol/l, therefore the Randox test will comfortably detect abnormal levels of creatinine within a sample
- **Applications available** - for a variety of clinical chemistry analysers

Product description	Size	Cat. No.
Creatinine (Liquid Enzymatic)	R1 4 x 50ml, R2 4 x 19.5ml	CR4037
Creatinine (Liquid Enzymatic)	R1 4 x 65ml, R2 4 x 28ml	CR8122
Creatinine (Liquid Enzymatic)	R1 4 x 20ml, R2 4 x 9.5ml	CR8317
Creatinine (Enzymatic)	4 x 50ml	CR2336
Creatinine (Enzymatic)	4 x 100ml	CR2337

Randox enzymatic creatinine

- **Highly specific test**
- **Reduced interference for truly accurate results**
- **Extensive measuring range ensuring abnormal results are detected**

Related controls and calibrators

Product description	Size	Cat. No.
Assayed Chemistry Premium Plus Level 2	20 x 5ml	HNI530
Assayed Chemistry Premium Plus Level 3	20 x 5ml	HEI532
Clinical Chemistry Calibration Serum Level 3	20 x 5ml	CAL2351

Randox Jaffe creatinine performance characteristics

- **Sample type** - serum, plasma and urine
- **Method** - colorimetric
- **Liquid ready-to-use reagents** - for ease of use and convenience
- **Excellent working reagent stability** - 21 days when capped and stored at +2 to +8°C
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides
- **Wide measuring range** - 26.4-2844 µmol/l. The normal creatinine range for men is 53-106 µmol/l and for women is 44-88 µmol/l, therefore the Randox test will comfortably detect abnormal levels of creatinine within a sample
- **Applications available** - for a variety of clinical chemistry analysers

Product description	Size	Cat. No.
Creatinine (Liquid)	1 x 200ml	CR510
Creatinine (Liquid)	6 x 500ml	CR524
Creatinine (Dimension®)	480T	CR2804
Creatinine (Liquid)	R1 6 x 51ml, R2 3 x 28ml	CR3814
Creatinine (Liquid)	R1 7 x 50ml, R2 2 x 40ml	CR7948
Creatinine	R1 6 x 68ml, R2 6 x 20ml	CR8022
Creatinine	R1 6 x 68ml, R2 6 x 20ml	CR9767
Creatinine	R1 4 x 20ml, R2 4 x 7ml	CR8316

Randox Jaffe creatinine

- Compatible with different sample types
- Excellent 21 day working reagent stability
- Superior linearity capable of detecting dangerously high creatinine concentrations

Related controls and calibrators

Product description	Size	Cat. No.
Assayed Chemistry Premium Plus Level 2	20 x 5ml	HN1530
Assayed Chemistry Premium Plus Level 3	20 x 5ml	HE1532
Clinical Chemistry Calibration Serum Level 2	20 x 5ml	CAL2350
Clinical Chemistry Calibration Serum Level 3	20 x 5ml	CAL2351

Microalbumin

What is microalbumin?

Albumin is one of the major plasma proteins and 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. When damage occurs to the glomerular basement membrane, its permeability can change and albumin is then able to enter the urine. Sustained elevations of urinary albumin concentrations are called microalbuminuria.

Clinical significance

The detection of albumin in urine can be an indicator of kidney injury and can result in irreversible damage if left untreated. Very small amounts of albumin, up to 20 mg/day measured from a 24 hour urine sample, are normal. However, low albumin concentrations in the urine (20-200 mg/day), otherwise known as microalbuminuria, is the earliest marker of renal damage and therefore enables preventative measures to be taken.

Randox microalbumin performance characteristics

- **Sample type** - urine
- **Method** - immunoturbidimetric
- **Liquid ready-to-use reagents** - for ease of use and convenience
- **Stability** - stable to expiry date when stored at +2 to +8°C
- **Limited interference** - from Bilirubin and Haemoglobin
- **Wide measuring range** - 5.1 l-234 mg/l, ensuring abnormal levels can be detected
- **Applications available** - for a variety of clinical chemistry analysers

Product description	Size	Cat. No.
Microalbumin (2-shot only) (Liquid)	R1 3 x 100ml, R2 5 x 7ml	MA2423
Microalbumin (2-shot only) (Liquid)	R1 1 x 60ml, R2 1 x 7ml	MA2426
Microalbumin (Dimension®)	200T	MA2864
Microalbumin (Liquid)	R1 6 x 20ml, R2 3 x 8ml	MA3828
Microalbumin	R1 4 x 20ml, R2 4 x 4.3ml	MA8056
Microalbumin	R1 1 x 20ml, R2 1 x 4.6ml	MA8325

Randox microalbumin

- **Reduced interference** for truly accurate results
- **Calibrator** conveniently supplied with selected Microalbumin kits
- **Excellent sensitivity** capable of detecting low albumin concentrations

Related controls and calibrators

Product description	Size	Cat. No.
Microalbumin Control Level 1 and Level 2 (Liquid)	3x2x1 ml	MA1361
Microalbumin Calib. Series	6x2ml	MA1567

Total Urinary Protein

What is total urinary protein?

Total urinary protein is a test that measures the amount of protein being excreted in the urine; however proteins are normally found in the blood, not urine. Kidneys functioning normally filter protein molecules and then return them to the blood- damaged kidneys have diminished filtering ability and protein is therefore found in the urine. The amount of protein found in the urine will increase if kidney damage continues.

Clinical significance

Determination of total urinary protein is valuable in the diagnosis of renal disorders. Elevated levels of urinary protein are commonly seen in nephrosis, diabetic nephropathy and urinary tract infections. The amount of protein found in the urine is associated with the extent of the kidney damage and increasing concentrations indicate continually deteriorating kidney function.

Randox total urinary protein performance characteristics

- **Sample type** - urine
- **Method** - colorimetric
- **Liquid ready-to-use reagents** - for ease of use and convenience
- **Standard supplied with kit** - simplifying the ordering process
- **Stability** - stable to expiry date when stored at +15 to +25°C
- **Limited interference** - from Acetaminophen, Ascorbic Acid, Creatinine, Glucose, Haemoglobin, Salicylate, Sodium Citrate and Urea
- **Wide measuring range** - 0.04-1.61 g/l, ensuring abnormal levels can be detected
- **Applications available** - for a variety of clinical chemistry analysers

Product description	Size	Cat. No.
Urinary Protein (Liquid)	3 x 100ml	UPI570
Urinary Protein (Liquid)	RI 6 x 100ml	UPI571
Urinary Protein	4 x 20ml	UP8113

Randox total urinary protein

- **Excellent sensitivity** enabling even slight increases in urinary protein concentration to be detected
- **Standard conveniently supplied with kits**
- **Applications available** with instrument specific settings for a wide range of clinical chemistry analysers

Related controls and calibrators

Product description	Size	Cat. No.
Assayed Urine Chemistry Level 2	12 x 10ml	AU2352
Assayed Urine Chemistry Level 3	12 x 10ml	AU2353

Urea

What is urea?

Urea is a waste product which is produced as a result of protein being broken down by the body. Urea is released from the liver into the blood- it is then transported to the kidneys where it is filtered out of the blood and excreted from the body in urine. Kidneys functioning normally should remove over 90% of the urea produced by the body, therefore blood urea levels can be a good indicator of renal function.

Clinical significance

Testing urea levels is useful in the evaluation of kidney function- the majority of urea within the body should be removed by the kidneys therefore elevated levels can indicate poor renal function. A urea test may be carried out in a number of circumstances e.g. to check kidney function both before a course of drugs is started as well as during the consumption period, to monitor the effectiveness of kidney disease treatment plans and to observe how a patient is responding to dialysis.

Randox urea performance characteristics

- **Sample type** - serum, plasma and urine
- **Method** - UV, Berthelot and Kinetic methods available
- **Liquid and lyophilised reagents available** - providing greater choice
- **Stability** - stable to expiry date when stored at +2 to +8°C
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides
- **Wide measuring range** - 0.866-56.7 mmol/l .The normal range in serum is 1.7-8.3 mmol/l therefore the Randox test will comfortably detect abnormal levels of urea within a sample
- **Applications available** - for a variety of clinical chemistry analysers

Product description	Size	Cat. No.
Urea (Modified Berthelot)	5 x 100ml	UR107
Urea (Kinetic) 3 Minute Read	6 x 15ml	UR220
Urea (Kinetic) 3 Minute Read	10 x 50ml	UR221
Urea (Kinetic) 1 Minute Read	10 x 50ml	UR446
Urea (Kinetic) 1 Minute Read (High Sensitivity)	6 x 15ml	UR456
Urea (Kinetic) 1 Minute Read (High Sensitivity)	10 x 50ml	UR457
Urea (Manual Only) (Berthelot)	300 Tests	UR1068
Urea (BUN) (UV GLDH)	480 Tests	UR2821
Urea (Liquid) (Kinetic)	R1 6 x 51ml, R2 4 x 20ml	UR3825
Urea (Liquid) (Mono Reagent) (UV GLDH)	6 x 20.5ml	UR3873
Urea (Liquid) (Kinetic)	R1 5 x 50ml, R2 4 x 45ml	UR7975
Urea (Liquid) (Kinetic)	R1 5 x 100ml, R2 5 x 60ml	UR7976
Urea (Liquid) (UV GLDH)	R1 6 x 68ml, R2 6 x 20ml	UR8070
Urea (UV GLDH)	R1 4 x 20ml, R2 4 x 7ml	UR8334
Urea (Liquid) (Kinetic)	R1 6 x 66ml, R2 6 x 43ml	UR9729
Urea (Kinetic)	R1 6 x 68ml, R2 6 x 44ml	UR9781

Related controls and calibrators

Product description	Size	Cat. No.
Assayed Chemistry Control Premium Plus Level 2	20 x 5ml	HN1530
Assayed Chemistry Control Premium Plus Level 3	20 x 5ml	HE1532
Clinical Chemistry Calibration Serum Level 3	20 x 5ml	CAL2351

Randox urea

- **Range of methodologies available to meet different laboratory needs**
- **Liquid and lyophilised reagent formats, giving more choice**
- **Excellent linearity ensuring elevated levels of urea are detected**

Sodium

What is sodium?

Sodium is an essential electrolyte which can be found in all body fluids. Along with other electrolytes, sodium is vital as it supports normal cell function and helps regulate the amount of fluid within the body. However, to contribute to these beneficial functions, sodium levels must be kept within a narrow range.

Clinical significance

Sodium levels within the blood can be too high (Hypernatraemia) or too low (Hyponatraemia). Renal problems can be characterised, and made worse, by both depleted and elevated sodium concentrations making this a useful test for both renal function assessment and the monitoring of kidney disease treatment plans.

Randox sodium performance characteristics

- **Sample type** - serum and plasma
- **Method** - enzymatic
- **Liquid and lyophilised reagents available** - providing greater choice
- **Stability** - lyophilised reagents have a reconstituted stability of 2 weeks at +2 to +8°C or 5 days at +15 to +25°C
- **Limited interference** - from Bilirubin, Haemoglobin and Triglycerides
- **Wide measuring range** - 37.3-187.8 mmol/l. The normal range is 136-146 mmol/l therefore the Randox test will comfortably detect abnormal levels of sodium within a sample
- **Applications available** - for a variety of clinical chemistry analysers

Product description	Size	Cat. No.
Sodium	R1 3 x 20ml R2 3 x 9ml	NA3851
Sodium	R1 4 x 45ml R2 2 x 39ml	NA7167
Sodium	R1 4 x 10ml R2 4 x 6ml	NA8327

Randox sodium

- Excellent stability minimising reagent waste
- Comprehensive measuring range able to detect both abnormally low and high levels of sodium
- Applications available with instrument specific settings for an extensive range of clinical chemistry analysers

Related controls and calibrators

Product description	Size	Cat. No.
Assayed Chemistry Control Premium Plus Level 2	20 x 5ml	HN1530
Assayed Chemistry Control Premium Plus Level 3	20 x 5ml	HE1532
Clinical Chemistry Calibration Serum Level 3	20 x 5ml	CAL2351

Potassium

What is potassium?

Like sodium, potassium is a vital electrolyte which exists in all fluids within the body. Normally, only small amounts of potassium are found in the blood as the vast majority of this electrolyte is contained within the body's cells. Due to the fact potassium assists with many bodily functions, both elevated and depleted levels can have a negative impact on a patient.

Clinical significance

One of the functions of the kidneys is to get rid of excess potassium therefore elevated concentrations can be an indicator of reduced renal function. High levels of potassium, known as hyperkalaemia, are the most common cause of kidney disease and potassium testing is also useful in the monitoring of patients receiving dialysis treatment.

Radox potassium performance characteristics

- **Sample type** - serum and plasma
- **Method** - Colorimetric, Enzymatic and UV methods available
- **Liquid and lyophilised reagents available** - providing greater choice
- **Stability** - lyophilised reagents have a reconstituted stability of 7 days at +2 to +8°C
- **Limited interference** - from Bilirubin, Haemoglobin, Intralipid® and Triglycerides
- **Wide measuring range** - 2.46-11.2 mmol/l. The normal range for potassium is 3.5-5.1 mmol/l therefore the Radox test will comfortably detect abnormal concentrations within a sample
- **Applications available** - for a variety of clinical chemistry analysers

Product description	Size	Cat. No.
Potassium (Colorimetric)	100	PT1600
Potassium (Enzymatic)	R1 3 × 20ml R2 3 × 9ml	PT3852
Potassium (UV)	R1 4 × 50ml R2 2 × 43ml	PT7168
Potassium (Enzymatic)	R1 4 × 10ml R2 4 × 6ml	PT8329

Radox potassium

- **Excellent linearity ensuring elevated levels of potassium are detected**
- **Liquid and lyophilised reagent formats, giving more choice**
- **Range of methodologies available to meet different laboratory needs**

Related controls and calibrators

Product description	Size	Cat. No.
Assayed Chemistry Control Premium Plus Level 2	20 × 5ml	HN1530
Assayed Chemistry Control Premium Plus Level 3	20 × 5ml	HE1532
Clinical Chemistry Calibration Serum Level 3	20 × 5ml	CAL2351

Additional Renal Function assessment products available from Randox

Albumin	Low levels of albumin in blood serum (Hypoalbuminaemia) are associated with kidney damage
Ammonia	Elevated ammonia levels in the blood (Hyperammonemia) can be an indicator of renal failure
Beta-2- Microglobulin	Beta-2-Microglobulin can be used to assess renal damage / disease as well as to differentiate between conditions of the glomeruli and renal tubules
Calcium	Elevated levels of serum calcium are of diagnostic value in detecting chronic renal disease
Chloride	Excess levels of chloride in the blood (Hyperchloremia) can be an indicator of kidney disease
Glucose	Elevated blood glucose levels (Hyperglycemia) can damage the kidneys and can suggest chronic kidney failure
HbA1c	HbA1c concentrations are related to glucose levels therefore an HbA1c test can also help identify renal dysfunction
IgG	Decreased levels of IgG can be a result of complications associated with kidney failure
LDH	Lactate dehydrogenase measurements can be used in the diagnosis and treatment of kidney tumours
Magnesium	Conditions that interfere with glomerular filtration e.g. renal failure can be characterised by magnesium retention
Phosphorus (Inorganic)	Abnormally elevated levels of phosphorus (inorganic) are most commonly seen in kidney diseases and this test can be used in the diagnosis and treatment of various kidney disorders
Uric Acid	Analysis of uric acid levels is used in the diagnosis and treatment of numerous renal disorders including renal failure and kidney stones

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



For more information on the full Randox product range,
please visit www.randox.com or contact your local
representative.

To access instructions for use (IFU) and instrument specific
applications (ISA) for a wide variety of instruments, visit
www.randox.com/powerline

Urinary Protein
LDH Magnesium Potassium
Total Urinary Protein Albumin
LDH Magnesium Potassium Sodium
Total Urinary Protein Albumin Ammonia
LDH Magnesium Potassium Sodium Phosphorus
Total Urinary Protein Albumin Ammonia
LDH Magnesium Potassium Sodium Phosphorus (Inorganic)
Urinary Protein Albumin Ammonia Beta-2- Microglobulin
Potassium Freedom of choice from an independent manufacturer
Creatinine Ammonia independent manufacturer Glucose HbA1c IgG LDH
Urea Uric Acid Creatinine Cystatin C Microalbumin Total Urinary Protein
Calcium Chloride Glucose HbA1c IgG LDH Magnesium Potassium
Creatinine Cystatin C Microalbumin Total Urinary Protein
de Glucose HbA1c IgG LDH Magnesium Potassium

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