【Product Name】

Kidney Profile (11+6)

【Packing Specification】

Type B: 1 Test / Disc, 10 Discs / Box.
Type B with diluent container.

【Testing Instrument】

Celercare V or Pointcare V chemistry analyzer

【Intended Use】

The Kidney Profile (11+6) used with the Celercare V or the Pointcare V chemistry analyzer, is intended to be used for the in vitro quantitative determination of albumin (ALB), total Protein (TP), creatinine (CRE),urea nitrogen(BUN), glucose (GLU),potassium (K^+), sodium (Na^+),chloride (Cl^-), calcium (Ca), phosphorus (P), total carbon dioxide (tCO_2) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Kidney Profile (11+6) measurements are used in the diagnosis of urinary system diseases.

【Principles of Testing】

The Kidney Profile (11+6) is used to quantitatively test the concentration of the 11 biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:

1. Albumin (ALB)

Bromcresol green (BCG), when bound with albumin, changes color from a yellow to green color. The absorbance maximum changes with the color shift.

$$\text{BCG} + \text{Albumin} \xrightarrow{\text{Acid pH}} \text{Albumin Complex}$$

Bound albumin is proportional to the concentration of albumin in the sample. This is an endpoint reaction that is measured as the difference in absorbance between 600 nm and 700 nm.

2. Total Protein (TP)

The total protein method is a Biuret reaction, the protein solution is treated with cupric [Cu(II)] ions in a strong alkaline medium. The Cu(II) ions react with peptide bonds between the carbonyl oxygen and amide nitrogen atoms to form a colored Cu-protein complex.
The amount of total protein present in the sample is directly proportional to the absorbance of the Cu-protein complex. The total protein test is an endpoint reaction and the absorbance is measured as the difference in absorbance between 546 nm and 800 nm.

$$\text{Total Protein} + \text{Cu(II)} \xrightarrow{OH^-} \text{Cu-Protein Complex}$$

3. Creatinine (CRE)

In the coupled enzyme reactions, creatinineamidohydrolase (CAH) hydrolyzes creatinine to creatine. A second enzyme, creatineamidinohydrolase (CRH), catalyzes the formation of sarcosine from creatine. Sarcosine oxidase (SAO) causes the oxidation of sarcosine to glycine, formaldehyde and hydrogen peroxide (H_2O_2). In a Trinder finish, peroxidase (POD) catalyzes the reaction among the hydrogen peroxide, 2, 4, 6-tribromo-3-hydroxybenzoic acid (TBHBA) and 4-aminoantipyrine (4-AAP) into a red

quinoneimine dye. Potassium ferrocyanide and ascorbate oxidase are added to the reaction mixture to minimize the potential interference of bilirubin and ascorbic acid respectively.

$$\text{Creatinine} + H_2O \xrightarrow{CAH} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{CRH} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + H_2O + O_2 \xrightarrow{SAO} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 + \text{TBHBA} + \text{4-AAP} \xrightarrow{POD} \text{Red Quinoneimine Dye} + H_2O$$

Two cuvettes are used to determine the concentration of creatinine in the sample. Endogenous creatine is measured in the blank cuvette, which is subtracted from the combined endogenous creatine and the creatine formed from the enzyme reactions in the test cuvette. Once the endogenous creatine is eliminated from the calculations, the concentration of creatinine is proportional to the intensity of the red color produced. The endpoint reaction is measured as the difference in absorbance at 546 nm and 700 nm.

4. Urea Nitrogen (BUN)

In the coupled-enzyme reaction, urease hydrolyzes urea into ammonia and carbon dioxide. Upon combining ammonia withα-oxoglutarate and reduced nicotinamide adenine dinucleotide (NADH), the enzyme glutamate dehydrogenase (GLDH) oxidizes NADH to NAD^+.

$$\text{Urea} + 2H_2O \xrightarrow{\text{Urease}} 2NH_4^+ + CO_3^{2-}$$

$$NH_4^+ + \alpha\text{-Oxoglutarate} + \text{NADH} \xrightarrow{GLDH} \text{L-Glutamate} + H_2O + NAD^+$$

The rate of change of the absorbance difference between 340 nm and 405 nm is caused by the conversion of NADH to NAD^+ and is directly proportional to the amount of urea present in the sample.

5. Glucose (GLU)

The reaction of glucose with adenosine triphosphate (ATP) catalyzed by hexokinase (HK), produces glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) catalyzes the reaction of G-6-P into 6-phosphogluconate and the reduction of nicotinamide adenine dinucleotide phosphate ($NADP^+$) to NADPH.

$$\text{Glucose} + \text{ATP} \xrightarrow{HK} \text{Glucose-6-Phosphate} + \text{ADP}$$

$$\text{G-6-P} + NADP^+ \xrightarrow{\text{G-6-PDH}} \text{6-Phosphogluconate} + NADPH + H^+$$

The absorbance is measured bichromatically at 340 nm and 405 nm. The production of NADPH is directly proportional to the amount of glucose present in the sample.

6. Total Carbon Dioxide (tCO_2)

In the enzymatic method, the specimen is first made alkaline to convert all forms of carbon dioxide (CO_2) to bicarbonate (HCO_3^-). Phosphoenolpyruvate (PEP) and HCO_3^- then react to form oxaloacetate and phosphate in the presence of phosphoenolpyruvate carboxylase (PEPC). Malate dehydrogenase (MDH) catalyzes the reaction of oxaloacetate and reduced nicotinamide adenine dinucleotide (NADH) to NAD^+ and malate. The rate of change in absorbance due to the conversion of NADH to NAD^+ is directly proportional to the amount of CO_2 in the sample.

$$\text{PEP} + HCO_3^- \xrightarrow{\text{PEPC}} \text{Oxaloacetate} + \text{Phosphate}$$

$$\text{Oxaloacetate} + \text{NADH} + H^+ \xrightarrow{\text{MDH}} NAD^+ + \text{Malate}$$

7. Potassium (K^+)

In the coupled enzyme reaction, pyruvate kinase (PK) dephosphorylates phosphoenolpyruvate (PEP) to form pyruvate. Lactate dehydrogenase (LDH) catalyzes conversion of pyruvate to lactate. Concomitantly, NADH is oxidized to NAD^+. The rate of change in absorbance due to the conversion of NADH to NAD^+ is directly proportional to the amount of potassium in the sample.
Interferences from other ions are minimized with the addition of some special ingredients.

$$\text{ADP} + \text{PEP} \xrightarrow{K^+,\ \text{PK}} \text{Pyruvate} + \text{ATP}$$

$$\text{Pyruvate} + \text{NADH} + H^+ \xrightarrow{LDH} \text{Lactate} + NAD^+$$

8. Sodium (Na^+)

In the enzymatic reaction, β-D-galactosidase is activated by the sodium in the sample. The activated enzymecatalyzes the reaction of o-nitrophenyl-β-D-galactopyranoside (ONPG) to o-nitrophenolandgalactose.

$$\text{ONPG} \xrightarrow{Na^+,\ \beta\text{-D-galactosidase}} \text{o-Nitrophenol} + \text{Galactose}$$

9. Chloride (Cl^-)

The method is based on the determination of chloride-dependent activation of α-amylase activity. Deactivated α-amylase is reactivated by addition of the chloride ion. The reactivation of α-amylase activity is proportional to the concentration of chloride ion in the sample. The reactivated α-amylase converts the substrate,2-chloro-4-nitrophenyl-β-1,4-galactopyranosylmaltoside (CNP-G2) to 2-chloro-4-nitrophenol (CNP) producing color and 1,4-galactopyranosylmaltoside. The reaction is measured bichromatically and the increase in absorbance is directly proportional to the reactivated α-amylase activity and the concentration of chloride ion in the sample.

$$\text{CNP-G2} \xrightarrow{Cl^-,\ \alpha\text{-amylase}} \text{CNP} + \text{G2}$$

10. Calcium (Ca)

Calcium in the patient sample binds with arsenazo III to form a calcium-dye complex.

$$Ca^{2+} + \text{Arsenazo III} \longrightarrow Ca^{2+}\text{-Arsenazo III Complex}$$

It is an endpoint reaction. The amount of total calcium in the sample is proportional to the absorbance.

11. Phosphorus (P)

The enzymatic method for the MNCHIP system uses maltose phosphorylase (MP) coupled through β-phosphoglucomutase (β-PGM) and glucose-6-phosphate dehydrogenase (G6PDH). The amount of NADH formed can be measured as an endpoint at 340/405 nm.

$$\text{Maltose} + \text{Pi} \xrightarrow{MP} \text{Glucose-1-Phosphate (G-1-P)} + \text{Glucose}$$

$$\text{Glucose-1-Phosphate (G-1-P)} \xrightarrow{\beta\text{-PGM}} \text{Glucose-6-Phosphate (G-6-P)}$$

$$\text{Glucose-6-Phosphate (G-6-P)} + NAD^+ \xrightarrow{\text{G6PDH}} \text{NADH+ 6-Phosphogluconate} + H^+$$

【Principle of Operation】

Refer to the Celercare V or the Pointcare V chemistry analyzer Operator's Manual, for the Principles and Limitations of the Procedure.

【Description of Reagents】

Each Kidney Profile (11+6) contains lyophilized test-specific reagent beads. A lyophilized blank reagent bead includes in each disc for a judgment of error 0233.
Type B is the reagent disc with diluent container.
Calibration information is included in barcode code. Please check it on the label.
The componen of each Kidney Profile (11+6) is as follows (after redissolution):

Component	Quantity
Albumin assay reagent	13.5 μL
Total protein assay reagent	13.5 μL
Creatinine assay reagent	13.5 μL
Urea assay reagent	13.5 μL
Glucose assay reagent	6.6 μL
Total Carbon Dioxide assay reagent	6.6μL
Potassium assay reagent	13.5 μL
Sodiumassay reagent	13.5 μL
Chloride assay reagent	13.5 μL
Calcium assay reagent	9.7 μL
Phosphorus assay reagent	13.5 μL
Stabilizer	Appropriate amount

【Storage】

Store reagent discs in their sealed pouches at a temperature of 2-8°C (36-46°F). Do not expose opened or unopened discs to direct sunlight or temperatures exceeding 32°C (90°F). Reagent discs may be used until the expiration date indicated on the package, which is also encoded in the unique code printed on the sealing pouch.
A torn or damaged pouch may allow moisture to reach the unused disc, adversely affecting its performance. Therefore, do not use any disc from a damaged pouch.

【Sample Requirements】

Sample collection techniques are described in the 'Sample requirement' section of the Celercare V or the Pointcare V-chemistry analyzer Operator's Manual.
The required sample usage is 100 μL of lithium heparin whole blood, lithium heparin plasma, serum or quality controls.
Whole blood samples collected by venipuncture must be homogeneous before transferring the sample to

a reagent disc.

At the same time, it is necessary to carry out the test within 60 minutes. Before taking the test, shake the lithium heparin blood collection tube gently upside down several times.

The glucose concentration is affected by the patient's feeding time and the storage environment after the sample is collected. In order to accurately measure glucose, a sample of the patient should be taken after at least 12 hours of fasting. For uncentrifuged samples stored at room temperature, the glucose concentration is reduced by about 5-12 mg / dL in 1 hour.

Use only lithium heparin evacuated specimen collection tubes for whole blood or plasma samples.

The test was started within 10 minutes after transferring the sample to the reagent disc.

【Interfering Substances】

Studies on known drugs or chemicals have found that when the interfering substances contained in the sample exceed the contents in the table below, the final test results are affected.

Analyte	Interfering substances concentration （≤）						
	Bilirubin mg/dL	Intralipid mg/dL	Hemoglobin mg/dL	Vitamin C mg/dL	Creatine μmol/L	NH_4Cl mmol/L	Mg^{2+} mmol/L
ALB	40	600	1000	——	——	——	——
TP	25	1050	200	——	——	——	——
CRE	40	1050	500	25	600	——	——
BUN	25	600	1000	——	——	1	——
GLU	40	600	1000	50	——	——	——
tCO_2	45	525	250	75	——	——	——
K^+	16	150	50	75	——	——	——
Na^+	10	150	50	75	——	——	——
Cl^-	18	210	50	75	——	——	——
Ca	180	210	200	75	——	——	3
P	45	525	100	27	——	——	——

【Procedure】

■ **Materials Provided**

Kidney Profile (11+6)

Celercare V or Pointcare V chemistry analyzer

Please tear off the aluminum strip before using Type B.

Transfer pipettes (fixed volume 100 μL for sample) and tips.

■ **Test Procedure**

The complete sample collection and step-by-step operating procedures are detailed in the Operator’s Manual for the Celercare V or Pointcare V chemistry analyzer.

■ **Calibration**

Each batch of reagent is calibrated using Randox standard serum to obtain the disc-specific calibration parameters before shipment.

The calibration parameters stored in the two-dimentional code printed on the sealed pouch are provided to analyzer at the time of scanning the code.

Refer to the Operator's Manual for specific information.

■ **Quality Control**

Refer to Operator's Manual of the Celercare V or the Pointcare V chemistry analyzer. Performance of the Celercare V or the Pointcare V chemistry analyzer can be verified by running controls. For a list of approved quality control materials with acceptance ranges, please consult the manual.
If control results are out of range, repeat one time. If still out of range, call MNCHIP customer service or local distributers for technical support. Do not report the results if controls are outside their labeled limits.

■ **Results**

The Celercare V or the Pointcare V chemistry analyzer automatically calculates and prints the analyte concentrations in the sample. Details regarding endpoint and rate reaction calculations can be found in the Celercare V or the Pointcare V chemistry analyzer Operator's Manual.

【Normal Reference Ranges】

These ranges are provided as a guideline only. It is recommended that your office or institution establish normal ranges for your particular patient population.

Analyte	SI Units	Common Units
ALB	Dog: 22 ~ 44g/L; Cat: 22 ~ 45g/L	Dog: 2.2 ~ 4.4 g/dL; Cat: 2.2 ~ 4.5 g/dL
TP	Dog: 52 ~ 82g/L; Cat: 54 ~ 89g/L	Dog: 5.2 ~ 8.2g/dL; Cat: 5.4 ~ 8.9g/dL
CRE	Dog: 27 ~ 149μmol/L; Cat: 27 ~ 223μmol/L	Dog: 0.3 ~ 1.7mg/dL; Cat: 0.3 ~ 2.5mg/dL
BUN	Dog: 2.5 ~ 11.5mmol/L Cat: 3.6 ~ 15.5mmol/L	Dog: 7 ~ 32mg/dL Cat: 10 ~ 43mg/dL
GLU	Dog: 3.89 ~ 7.95mmol/L Cat: 4.11 ~ 8.84mmol/L	Dog: 70 ~ 143mg/dL Cat: 74 ~ 159mg/dL
tCO_2	Dog: 12 ~ 27mmol/L; Cat: 15 ~ 24mmol/L	Dog: 12 ~ 27mmol/L; Cat: 15 ~ 24mmol/L
K	Dog: 3.7 ~ 5.8mmol/L; Cat: 3.7 ~ 5.8mmol/L	Dog: 3.7 ~ 5.8mmol/L; Cat: 3.7 ~ 5.8mmol/L
Na^+	Dog:138 ~ 160mmol/L; Cat: 142 ~ 164mmol/L	Dog:138 ~ 160mmol/L; Cat: 142 ~ 164mmol/L
Cl^-	Dog:106 ~ 130mmol/L; Cat: 100 ~ 126mmol/L	Dog:106 ~ 130mmol/L; Cat: 100 ~ 126mmol/L
Ca	Dog: 1.98 ~ 2.95mmol/L; Cat: 1.95 ~ 2.95mmol/L	Dog: 7.9 ~ 11.8mg/dL; Cat: 7.8 ~ 11.8mg/dL
P	Dog: 0.81 ~ 2.2mmol/L; Cat: 1 ~ 2.74mmol/L	Dog: 2.5 ~ 6.8mg/dL; Cat: 3.1 ~ 8.5mg/dL

【Interpretation of Results】

Physiological interferents, such as hemolysis, icterus, and lipemia, can cause changes in the reported concentrations of certain analytes. Sample indices are printed at the bottom of each printout to inform

the operator about any abnormalities in the sample. The operator should take care to avoid hemolysis caused by improper blood collection techniques.

The Celercare V or the Pointcare V chemistry analyzer suppresses any results that are affected by >10% interference from hemolysis, lipemia or icterus. “HEM”, “LIP”, or “ICT” respectively, is printed on the printout in place of the result.

For the same sample, the potassium result of using anticoagulant whole blood and plasma is 0.2 - 0.5 mmol/L lower than those using serum. For the same sample, the result is 0.2 - 0.5 mmol/L lower than that of serum when using plasma or anticoagulant whole blood.

The potassium assay is a coupled pyruvate kinase (PK) / lactate dehydrogenase (LDH) assay. Therefore, in cases of extreme muscle trauma or highly elevated levels of creatine kinase (CK), The Celercare V or the Pointcare V chemistry analyzer may report a falsely elevated potassium (K^+) value. In such cases, unexpected high potassium recoveries need to be confirmed utilizing a different methodology.

Any result for a particular test that exceeds the assay range should be analyzed by another approved test method or sent to a referral laboratory. Do not dilute the sample and run it again on the Celercare V or the Pointcare V chemistry analyzer.

【Limitations of Procedure】

The Kidney Profile (11+6) should be used with the Celercare V or the Pointcare V chemistry analyzer, and is just used for in vitro diagnosis (IVD).

As with any diagnostic test procedure, all other test procedures including the clinical status of the patient, should be considered prior to final diagnosis.

【Performance Characteristics】

Accuracy

Analyte	The relative deviation or absolute deviation should meet the following requirements
ALB	B% ≤ 6.0%
TP	B% ≤ 5.0%
CRE	B% ≤ 10.0%
BUN	B% ≤ 15.0%
GLU	B% ≤ 20.0%
tCO_2	B% ≤ 10.0%
K	B% ≤ 15.0%
Na^+	B% ≤ 15.0%
Cl^-	B% ≤ 15.0%
Ca	B% ≤ 5.0%
P	B% ≤ 10.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
ALB	2.0%
TP	2.0%

CRE	5.0%
BUN	5.0%
GLU	5.0%
tCO_2	5.0%
K	5.0%
Na^+	5.0%
Cl^-	5.0%
Ca	3.0%
P	5.0%

Inter batch precision

Analyte	Relative Range (≤ *)
ALB	5.0%
TP	5.0%
CRE	10.0%
BUN	10.0%
GLU	10.0%
tCO_2	10.0%
K	10.0%
Na^+	10.0%
Cl^-	10.0%
Ca	5.0%
P	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
ALB	10 ~ 60g/L
TP	20 ~ 100g/L
CRE	20 ~ 2000μmol/L
BUN	0.9 ~ 35.7mmol/L
GLU	1 ~ 35mmol/L
tCO_2	10 ~ 35mmol/L
K	1 ~ 8mmol/L
Na^+	90 ~ 170mmol/L
Cl^-	60 ~ 140mmol/L
Ca	0.5 ~ 4mmol/L
P	0.2 ~ 7mmol/L

【Notes】

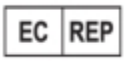
Used reagent discs contain animal body fluids. It is essential to follow good laboratory safety practices when handling and disposing of these used discs. For instructions on cleaning biohazardous spills,

refer to the Celercare V or Pointcare V chemistry analyzer Operator's Manual.

The reagent discs are made of plastic and may crack or chip if dropped. Never use a disc that has been dropped, as it may spray biohazardous material throughout the interior of the analyzer.

Reagent beads may contain acids or caustic substances. Operators do not come into contact with the reagent beads when following the recommended procedures. It is important to avoid ingestion, skin contact, or inhalation of the reagent beads.

【Symbols Used in Labelling】

Symbol	Explanation
	Veterinary use only
	Manufacturer
	Unique device identifier
	Authorized representative in the European Community
	Use-by date
	Batch code
	Date of manufacture
	Consult instructions for use
	Limit of temperature
	Do not re-use

【Manufacturer】

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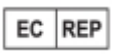
Service email: service@mnchip.com

Learn more about MNCHIP, other products can log in: http://www.mnchip.com



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