【Product Name】

Kidney Profile

【Packing Specification】

Type A: 1 Test / Disc, 10 Discs / Box;
Type B: 1 Test / Disc, 10 Discs / Box.
Type A without diluent container; Type B with diluent container.

【Testing Instrument】

Celercare V or Pointcare V chemistry analyzer

【Intended Use】

The Kidney Profile 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), creatinine (CRE),urea nitrogen(BUN), potassium (K^+), 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 measurements are used in the diagnosis of urinary system diseases.

【Principles of Testing】

The Kidney Profile is used to quantitatively test the concentration of the seven 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. 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.

3. 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^+.

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

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

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.

4. 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.

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

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

5. Calcium (Ca)

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

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

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

6. 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.

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

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

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

7. 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.

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

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

【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 contains lyophilized test-specific reagent beads. A lyophilized blank reagent bead includes in each disc for a judgment of error 0209.
Type B is the reagent disc with diluent container.
Type A is the reagent disc without diluent container.
Calibration information is included in barcode code. Please check it on the label.
The componen of each Kidney Profile is as follows (after redissolution):

Component	Quantity
Albumin assay reagent	13.5 µL
Creatinine assay reagent	13.5 µL
Urea assay reagent	13.5 µL
Potassium assay reagent	13.5 µL
Calcium assay reagent	9.7 µL
Phosphorus assay reagent	13.5 µL
Total Carbon Dioxide assay reagent	5.3 µL
Stabilizer	Appropriate amount

【Storage】

Store reagent discs in their sealed pouches at 2-8°C (36-46°F). Do not expose opened or unopened discs to direct sunlight or temperatures above 32°C (90°F). Reagent discs may be used until the expiration date included on the package. The expiration date is also encoded in the unique code printed on the sealing pouch. An error message will appear on the Celercare V or the Pointcare V chemistry analyzer display if the reagents have expired.
A torn or otherwise damaged pouch may allow moisture to reach the unused disc and adversely affect reagent performance. Do not use a 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. Please add diluent when using Type A. The required diluent usage is 430 μL of sterilized water for injection.

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.

Light may cause total bilirubin to decompose, causing deviations in the test results. Whole blood samples that are not tested immediately should be stored in a dark environment.

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	Intralipid	Hemoglobin	Vitamin C	Creatine	NH_4Cl	Mg^{2+}
	mg/dL	mg/dL	mg/dL	mg/dL	μmol/L	mmol/L	mmol/L
ALB	40	600	1000	——	——	——	——
CRE	40	1050	500	25	600	——	——
BUN	25	600	1000	——	——	1	——
K^+	16	150	50	75	——	——	——
Ca	180	210	200	75	——	——	3
P	45	525	100	27	——	——	——
tCO_2	45	525	250	75	——	——	——

【Procedure】

■ Materials Provided

Kidney Profile

Celercare V or Pointcare V chemistry analyzer

Please add diluent into the diluent port when using Type A (sterilized water for injection); please tear off the aluminum strip before using for Type B.

Transfer pipettes (fixed volume 100 μL for sample and 430μL for diluent) and tips

■ Test Procedure

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

■ 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 Celercare V or the Pointcare V chemistry analyzer Operator's Manual for the 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.
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 of the endpoint and rate reaction calculations are 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
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
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
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
tCO_2	Dog: 12 ~ 27mmol/L; Cat: 15 ~ 24mmol/L	Dog: 12 ~ 27mmol/L; Cat: 15 ~ 24mmol/L

【Interpretation of Results】

Physiological interferents (hemolysis, icterus and lipemia) cause changes in the reported concentrations of some analytes. The sample indices are printed on the bottom of each printout to inform the operator about the abnormal sample. The operator should avoid sample hemolysis caused by irregular blood collection.
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 result of using anticoagulant whole blood and plasma is 0.2 - 0.5 mmol/L lower than those using serum.

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 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%
CRE	B% ≤ 10.0%
BUN	B% ≤ 15.0%
K^+	B% ≤ 15.0%
Ca	B% ≤ 5.0%
P	B% ≤ 10.0%
tCO_2	B% ≤ 10.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
ALB	2.0%
CRE	5.0%
BUN	5.0%
K^+	5.0%
Ca	3.0%
P	5.0%
tCO_2	5.0%

Inter batch precision

Analyte	Relative Range (≤ *)
ALB	5.0%

CRE	10.0%
BUN	10.0%
K^+	10.0%
Ca	5.0%
P	10.0%
tCO_2	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
ALB	10 ~ 60g/L
CRE	20 ~ 2000 μmol/L
BUN	0.9 ~ 35.7mmol/L
K^+	1 ~ 8 mmol/L
Ca	0.5 ~ 4mmol/L
P	0.2 ~ 7mmol/L
tCO_2	10 ~ 35mmol/L

【Notes】

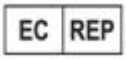
Used reagent discs contain animal body fluids. Follow good laboratory safety practices when handling and disposing of used discs. See the Celercare V or the Pointcare V chemistry analyzer Operator's Manual for instructions on cleaning biohazardous spills.

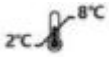
The reagent discs are plastic and may crack or chip if dropped. Never use a dropped disc as it may spray biohazardous material throughout the interior of the analyzer.

Reagent beads may contain acids or caustic substances. The operator does not come into contact with the reagent beads when following the recommended procedures. The operator should avoid ingestion, skin contact, or inhalation of the reagent beads.

The diluent can be selected from purified water having a conductivity(measured at 25℃) greater than 10 MΩ/cm, we recommend using the sterilized water for injection to reduce discrepancies or errors in test results due to the water, and it should be prevented from being exposed to the air for a long time after opening.

【Symbols Used in Labelling】

Symbol	Explanation
	Veterinary use only
	Manufacturer
	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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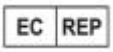
Service email: service@mnchip.com

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



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