MNCHIP

Renal Function Panel Lyophilized Kit

【Product Name】
Renal Function Panel Lyophilized Kit
【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 M or Pointcare M chemistry analyzer
【Intended Use】
The Renal Function Panel Lyophilized Kit used with the Celercare M or the Pointcare M chemistry analyzer, is intended to be used for the in vitro quantitative determination of albumin (ALB), blood urea, creatinine (CRE), uric acid (UA), calcium (Ca^{2+}), phosphorus (P) and carbon dioxide (CO_2) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Renal Function Panel Lyophilized Kit measurements are used in the diagnosis of urinary system diseases.
【Test Principles】
The Renal Function Panel Lyophilized Kit 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:
Albumin (ALB)
Bromocresol green (BCG), when bound with albumin, changes color from a yellow to green color. The absorbance maximum changes with the color shift.
BCG + Albumin $\xrightarrow{Acid\ pH}$ 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.
Urea
In the coupled-enzyme reaction, urease hydrolyzes urea into ammonia and carbon dioxide. Upon combining ammonia with α-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^+ +α-Oxoglutarate + NADH $\xrightarrow{GLDH}$ 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.
Creatinine (CRE)
In the coupled enzyme reactions, creatinine amidohydrolase (CAH) hydrolyzes creatinine to creatine. A second enzyme, creatine amidinohydrolase (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 between 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.
Creatinine + H_2O $\xrightarrow{CAH}$ Creatine
Creatine + H_2O $\xrightarrow{CRH}$ Sarcosine + Urea
Sarcosine + H_2O + O_2 $\xrightarrow{SAO}$ Glycine + Formaldehyde + H_2O_2
H_2O_2 +TBHBA + 4-AAP $\xrightarrow{POD}$ 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.
Uric Acid (UA)
The uricase method is coupled through a Trinder peroxidase finish. In this method, uricase catalyzes the oxidation (UAO) of uric acid to allantoin and hydrogen peroxide. Peroxidase (POD) catalyzes the reaction between the hydrogen peroxide (H_2O_2), 4-aminoantipyrine (4-AAP) and 3,5-dichloro-2-hydroxybenzenesulfonic acid (DHBSA) into a red quinoneimine dye. Sodium ferrocyanide and ascorbate oxidase are added to the reaction mixture to minimize the potential interference of bilirubin and ascorbic acid.
Uric acid + O_2 + H_2O $\xrightarrow{UAO}$ Allantoin + CO_2 + H_2O_2
H_2O_2 + 4-AAP + DHBSA $\xrightarrow{POD}$ Quinoneimine dye + H_2O
The amount of uric acid in the sample is directly proportional to the absorbance of the quinoneimine dye. The final absorbance of this endpoint reaction is measured bichromatically at 505 nm and 600 nm.
Calcium (Ca^{2+})
Calcium in the patient sample binds with arsenazo III to form a calcium-dye complex.
Ca^{2+} + Arsenazo III $\longrightarrow$ Ca^{2+}-Arsenazo III Complex
It is an endpoint reaction. The amount of total calcium in the sample is proportional to the absorbance.
Phosphorus (P)
The enzymatic method for the MNCHIP system uses maltose phosphorylase (MP) coupled through β-phosphoglumutase (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-1-Phosphate (G-1-P) + Glucose
Glucose-1-Phosphate (G-1-P) $\xrightarrow{β-PGM}$ Glucose-6-Phosphate (G-6-P)
Glucose-6-Phosphate (G-6-P) + NAD^+ $\xrightarrow{G6PDH}$ NADH+ 6-Phosphogluconate+H^+
Carbon Dioxide (CO_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 M or the Pointcare M chemistry analyzer Operator's Manual, for the Principles and Limitations of the Procedure.
【Description of Reagents】
Each Renal Function Panel Lyophilized Kit contains lyophilized test-specific reagent beads. A lyophilized blank reagent bead is included in each disc to enable judgment of error code 0209.
Type B is the reagent disc with diluent container.
Type A is the reagent disc without diluent container.
The calibration parameters /information can be found in the unique two-dimensional barcode on the label of the sealing pouch.
Please check the barcode on the label.
The component of each Renal Function Panel Lyophilized Kit is as follows (after redissolution):

Component	Quantity
Albumin assay reagent	13.5 μL
Urea assay reagent	13.5 μL
Creatinine assay reagent	13.5 μL
Uric Acid assay reagent	13.5 μL
Calcium assay reagent	9.7 μL
Phosphorus assay reagent	13.5 μL
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 M or the Pointcare M 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 M or the Pointcare M 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 430μL 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 starting the test, shake the lithium heparin blood collection tube gently upside down several times.
Use only lithium heparin evacuated specimen collection tubes for whole blood or plasma samples.
After transferring the sample to the reagent disc, the test should be started within 10 minutes.

【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.

Interfering substances concentration （≤）

Analyte	Bilirubin	Intralipid	Hemoglobin	Vitamin C	ammonium chloride	Creatine	Mg^{2+}
	mg/dL	mg/dL	mg/dL	mg/dL	mmol/L	μmol/L	mmol/L
CRE	40	1050	500	25	——	600	——
UREA	25	600	1000	——	1	——	——
UA	22.5	120	800	10	——	——	——
CO_2	45	525	250	75	——	——	——
Ca^{2+}	180	210	200	75	——	——	3
P	45	525	100	27	——	——	——
ALB	40	600	1000	——	——	——	——

【Procedure】

Materials Provided

Renal Function Panel Lyophilized Kit

Celercare M or Pointcare M 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 430 μL for diluent) and tips

Test Procedure

The complete sample collection and step-by-step operating procedures are detailed in the Celercare M or the Pointcare M 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-dimensional code printed on the sealed pouch are provided to the analyzer at the time of scanning the code.

Refer to the Celercare M or the Pointcare M chemistry analyzer Operator's Manual for the specific information.

Quality Control

Refer to the Operator's Manual of the Celercare M or the Pointcare M chemistry analyzer. Performance of the Celercare M or the Pointcare M chemistry analyzer can be verified by running controls.

If the control results are out of range, repeat once. If still out of range, call MNCHIP customer service or local distributors for technical support. Do not report the results if controls are outside their labeled limits

Results

The Celercare M or the Pointcare M 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 M or the Pointcare M 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	40 ~ 55 g/L	4.0 ~ 5.5 g/dL
UREA	2.9 ~ 8.2 mmol/L	17.42 ~ 49.25 mg/dL
CRE	Male: 54 ~ 109 μmol/L; Female: 45 ~ 84 μmol/L	Male: 0.61 ~ 1.23 mg/dL; Female: 0.51 ~ 0.95 mg/dL
UA	Male: 208 ~ 428 μmol/L; Female: 155 ~ 357 μmol/L	Male: 3.50 ~ 7.20 mg/dL Female: 2.61 ~ 6.00 mg/dL
Ca^{2+}	Adult: 2.03 ~ 2.54 mmol/L; Children: 2.25 ~ 2.67 mmol/L	Adult: 8.12 ~ 10.16 mg/dL; Children: 9 ~ 10.68 mg/dL
P	0.9 ~ 1.34 mmol/L	2.79 ~ 4.15 mg/dL
CO_2	23 ~ 29 mmol/L	23 ~ 29 mmol/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 M or the Pointcare M 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.

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 M or the Pointcare M chemistry analyzer.

【Limitations of Procedure】

The Renal Function Lyophilised Kit is intended for use with the Celercare M or Pointcare M chemistry analyzer and is for in vitro diagnostic (IVD) use only.

As with any diagnostic test, other test results and the clinical status of the patient should be considered before making a final diagnosis.

【Performance Characteristics】

Accuracy

Analyte	The relative deviation or absolute deviation should meet the following requirements (at least one)
ALB	B% ≤ 6.0%
UREA	B% ≤ 15.0%
CRE	B% ≤ 10.0%
UA	B% ≤ 10.0%
Ca^{2+}	B% ≤ 5.0%
P	B% ≤ 10.0%
CO_2	B% ≤ 10.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
ALB	2.0%
UREA	5.0%
CRE	5.0%
UA	4.0%
Ca^{2+}	3.0%
P	5.0%
CO_2	5.0%

Inter batch precision

Analyte	Relative Range (≤ *)
ALB	5.0%
UREA	10.0%
CRE	10.0%
UA	6.0%
Ca^{2+}	5.0%
P	10.0%
CO_2	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
ALB	10 ~ 60 g/L
UREA	0.9 ~ 35.7 mmol/L
CRE	20 ~ 1500 μmol/L
UA	150 ~ 900 μmol/L
Ca^{2+}	1 ~ 4 mmol/L
P	0.2 ~ 3.5 mmol/L
CO_2	10 ~ 35 mmol/L

【Notes】

Used reagent discs contain human body fluids. Follow good laboratory safety practices when handling and disposing of used discs. See the Celercare M or the Pointcare M 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 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
IVD	In vitro diagnostic medical device
	Manufacturer
EU REP	Authorized representative in the European Community
	Use-by date
LOT	Batch code
	Date of manufacture
CE	CE MARK
	Consult instructions for use
	Limit of temperature
UDI	Unique device identifier
	Do not re-use

【Manufacturer】

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For Use in Thailand Only：【Performance Characteristics】－ Analytical Sensitivity

The analytical sensitivity parameters listed below, including Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantification (LoQ), were established during method validation in accordance with applicable international guidelines.

These performance characteristics are provided to support regulatory requirements in Thailand and are intended for information purposes only. They do not alter the intended use, test principle, calibration procedure, or interpretation of results as described in the main Instructions for Use (IFU).

Limit of Blank(LoB); Limit of Detection(LoD); Limit of Quantification(LoQ)

Analyte	Unit	LoB	LoD	LoQ
ALB	g/L	0.716	1.196	6.049
UREA	mmol/L	0.23	0.262	0.508
CRE	μmol/L	0.869	1.051	4.227
UA	μmol/L	4.606	5.279	8.19
Ca^{2+}	mmol/L	0.226	0.265	0.505
P	mmol/L	0.048	0.057	0.127
CO_2	mmol/L	0.638	0.829	3.013

Notes

LoB is the highest apparent analyte concentration expected to be found when replicates of a blank sample containing no analyte are tested.

LoD is the lowest analyte concentration that can be reliably distinguished from the LoB and at which detection is feasible.

LoQ is the lowest analyte concentration that can be quantitatively determined with acceptable precision and accuracy under stated conditions.

These values were determined using representative reagent lots and instruments under controlled laboratory conditions. Actual performance may vary depending on laboratory conditions, calibration status, and operator technique.