MNCHIP

Clinical Emergency Lyophilized Kit

【Product Name】
Clinical Emergency 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 Clinical Emergency 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 potassium (K^+), sodium (Na^+), chloride (CL^-), carbon dioxide (CO_2), glucose (GLU), creatinine (CRE), uric acid (UA), amylase (AMY), creatine kinase (CK), creatine kinase-MB isoenzyme (CK-MB), lactate dehydrogenase (LDH), a-hydroxybutyrate dehydrogenase (α-HBDH) and aspartate aminotransferase (AST) in heparinised plasma or serum in a clinical laboratory setting or point-of-care location.
The Clinical Emergency Lyophilized Kit measurements are used in the diagnosis of salt metabolism disorders, cardiovascular disease, urinary system diseases, and pancreas diseases.
【Principles of Testing】
The Clinical Emergency Lyophilized Kit is used to quantitatively test the concentration of the thirteen biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:
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^+
Sodium (Na^+)
In the enzymatic reaction, β-D-galactosidase is activated by the sodium in the sample. The activated enzyme catalyzes the reaction of o-nitrophenyl-β-D-galactopyranoside (ONPG) to o-nitrophenol and galactose.
ONPG $\xrightarrow{Na^+,\ \beta-D-galactosidase}$ o-Nitrophenol + Galactose
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.
CNP-G2 $\xrightarrow{Cl^-,\ \alpha-amylase}$ CNP + G2
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
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.
Glucose + ATP $\xrightarrow{HK}$ Glucose-6-Phosphate + ADP
G-6-P + $NADP^+$ $\xrightarrow{G-6-PDH}$ 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.
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 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 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.
Amylase (AMY)
In the coupled-enzyme reaction, amylase in the sample hydrolyzes 2-chloro-4-nitrophenyl-β-1,4-galactopyranosylmaltoside (CNP-G2) to 2-chloro-4-nitrophenol (CNP) producing color and 1,4-galactopyranosylmaltoside. The change in absorbance of the CNP is directly proportional to the amylase activity in the sample at 405 nm and 505 nm.
CNP-G2 $\xrightarrow{AMY}$ CNP + G2
Creatine Kinase (CK)
Creatine kinase catalyzes the formation of creatine and adenosine triphosphate (ATP) from creatine phosphate and adenosine diphosphate (ADP). With hexokinase (HK) as a catalyst, ATP reacts with D-glucose to form ADP and D-glucose-6-phosphate (G-6-P), which is reacted with nicotinamide adenine dinucleotide phosphate ($NADP^+$) in the presence of glucose-6-phosphate dehydrogenase (G-6-PDH) to produce 6-Phosphogluconate (6-PG) and NADPH. The formation of NADPH is measured as a change in absorbance at 340 nm relative to 405 nm. This absorbance change is directly proportional to creatine kinase activity in the sample.
Creatine phosphate + ADP $\xrightarrow{CK}$ Creatine + ATP
ATP + D-glucose $\xrightarrow{HK}$ ADP + G-6-P
G-6-P + $NADP^+$ $\xrightarrow{G-6-PDH}$ 6-Phosphogluconate + NADPH + H^+
Creatine Kinase-MB isoenzyme (CK-MB)
The sample is incubated in the CK-MB reagent which includes the anti-CK-M antibody. The activity of the non-inhibited CK-B is then determined using the following series of reactions:
Creatine phosphate + ADP $\xrightarrow{CK-B}$ Creatine + ATP
ATP + D-glucose $\xrightarrow{HK}$ ADP + G-6-P
G-6-P + $NADP^+$ $\xrightarrow{G-6-PDH}$ 6-Phosphogluconate + NADPH + H^+
CK-B catalyzes the formation of creatine and adenosine triphosphate (ATP) from creatine phosphate and adenosine diphosphate (ADP). The auxiliary enzyme hexokinase (HK) catalyzes the phosphorylation of glucose by the ATP format, to produce ADP and glucose-6-phosphate (G-6-P) is oxidized to 6-phosphogluconate with the concomitant production of NADH. The rate of NADH formation, measured at 340 /405 nm, is directly proportional to serum CK-B activity. Multiplying the obtained test result by 2 is CK-MB activity.
Lactate Dehydrogenase (LDH)
Lactate dehydrogenase (LDH) catalyzes the oxidation of L-lactate to pyruvate with the concurrent reduction of nicotinamide adenine dinucleotide (NAD^+) to reduced nicotinamide adenine dinucleotide (NADH). The NADH is then oxidized with the simultaneous reduction of INT in a reaction catalyzed by diaphorase. The intensity of the highly colored formazan is measured bichromatically at 505/800 nm and is directly proportional to the concentration of lactate dehydrogenase (LDH) in the sample.
L-Lactate + NAD^+ $\xrightarrow{LDH}$ Pyruvate + NADH + H^+
NADH + H^+ + INT $\xrightarrow{Diaphorase}$ NAD^+ + Formazan
α-Hydroxybutyrate Dehydrogenase (α-HBDH)
LDH isoenzyme in the presence of NADH and H^+ converts a-oxobutyrate substrate into α-hydroxybutyrate while NAD^+ is formed. The rate of decrease in absorbance is proportional to the α-hydroxybutyrate dehydrogenase (α-HBDH) activity at 340/405 nm.
α-oxobutyrate + NADH + H^+ $\xrightarrow{\alpha-HBDH}$ α-hydroxybutyrate + NAD^+
Aspartate Aminotransferase (AST)
AST catalyzes the reaction of L-aspartate and α-ketoglutarate into oxaloacetate and L-glutamate. Oxaloacetate is converted to malate and NADH is oxidized to NAD^+ by the catalyst MDH.
L-aspartate + α-ketoglutarate $\xrightarrow{AST}$ Oxaloacetate + L-glutamate
Oxaloacetate + NADH+ H^+ $\xrightarrow{MDH}$ Malate + NAD^+
The rate of absorbance change at 340 /405 nm caused by the conversion of NADH to NAD^+ is directly proportional to the amount of AST present in the sample.
【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 Clinical Emergency 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 Clinical Emergency Lyophilized Kit is as follows (after redissolution):

Component	Quantity
Potassium assay reagent	13.5 μL
Sodium assay reagent	13.5 μL
Chloride assay reagent	13.5 μL
Carbon dioxide assay reagent	5.3 μL
Glucose assay reagent	6.6 μL
Creatinine assay reagent	13.5 μL
Uric acid assay reagent	13.5 μL
Amylase assay reagent	13.5 μL
Creatine kinase assay reagent	13.5 μL
Creatine kinase-MB isoenzyme assay reagent	13.5 μL
Lactate dehydrogenase assay reagent	13.5 μL
a-hydroxybutyrate dehydrogenase assay reagent	13.5 μL
Aspartate Aminotransferase assay reagent	13.5 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 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 starting the test, shake the lithium heparin blood collection tube gently upside down several times.

Glucose concentration in a patient's sample can be significantly influenced by both the timing of the sample collection and the conditions under which the sample is stored. To ensure accurate measurement of glucose, it is recommended that the sample be collected after the patient has fasted for at least 12 hours. Additionally, if the sample is not centrifuged and is stored at room temperature, glucose levels can decrease by approximately 5 – 12 mg/dL within the first hour post-collection.

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 mg/dL	Intralipid mg/dL	Hemoglobin mg/dL	Vitamin C mg/dL	Pyruvate mmol/L	Creatine µmol/L
AST	40	600	50	25	1	——
CK	40	1000	400	100	——	——
CK-MB	10	125	100	100	——	——
LDH	40	1000	50	100	——	——
α-HBDH	40	250	50	100	——	——
GLU	40	600	1000	50	1	——
AMY	40	1000	400	100	——	——
UA	22.5	120	800	10	——	——
CRE	40	1050	500	25	——	600
K^+	16	150	50	75	——	——
Na^+	10	150	50	75	——	——
Cl^-	18	210	50	75	——	——
CO_2	45	525	250	75	——	——

【Procedure】

Materials Provided

Clinical Emergency 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 430µL 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
K^+	Serum: 3.5 ~ 5.3 mmol/L Whole blood and plasma: 3.0-5.1 mmol/L	Serum: 3.5 ~ 5.3 mmol/L Whole blood and plasma: 3.0-5.1 mmol/L
Na^+	137 ~ 147 mmol/L	137 ~ 147 mmol/L
Cl^-	99 ~ 110 mmol/L	99 ~ 110 mmol/L
CO_2	23 ~ 29 mmol/L	23 ~ 29 mmol/L
GLU	3.9 ~ 6.1 mmol/L	70.2 ~ 109.8 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
AMY	0 ~ 220 U/L	0 ~ 220 U/L
CK	Male: 38 ~ 174 U/L; Female: 26 ~ 140 U/L	Male: 38 ~ 174 U/L; Female: 26 ~ 140 U/L
CK-MB	0 ~ 25 U/L	0 ~ 25 U/L
LDH	109 ~ 245 U/L	109 ~ 245 U/L
α-HBDH	72 ~ 182 U/L	72 ~ 182 U/L
AST	Male: 15 ~ 40 U/L; Female: 13 ~ 35 U/L	Male: 15 ~ 40 U/L; Female: 13 ~ 35 U/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 Clinical Emergency 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
K^+	B% ≤ 15.0%
Na^+	B% ≤ 15.0%
Cl^-	B% ≤ 15.0%
CO_2	B% ≤ 10.0%
GLU	B% ≤ 20.0%
CRE	B% ≤ 10.0%
UA	B% ≤ 10.0%
AMY	B% ≤ 10.0%
CK	B% ≤ 10.0%
CK-MB	B% ≤ 10.0%
LDH	B% ≤ 10.0%
α-HBDH	B% ≤ 10.0%
AST	B% ≤ 15.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
K^+	5.0%
Na^+	5.0%
Cl^-	5.0%
CO_2	5.0%
GLU	5.0%
CRE	5.0%
UA	4.0%
AMY	5.0%
CK	5.0%
CK-MB	6.0%
LDH	5.0%
α-HBDH	5.0%
AST	5.0%

Inter batch precision

Analyte	Relative Range (≤ *)
K^+	10.0%
Na^+	10.0%
Cl^-	10.0%
CO_2	10.0%
GLU	10.0%
CRE	10.0%
UA	6.0%
AMY	10.0%
CK	10.0%
CK-MB	10.0%
LDH	10.0%
α-HBDH	10.0%
AST	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
K^+	1 ~ 8 mmol/L
Na^+	90 ~ 170 mmol/L
Cl^-	60 ~ 140 mmol/L
CO_2	10 ~ 35 mmol/L
GLU	1 ~ 30 mmol/L
CRE	20 ~ 1500 µmol/L
UA	150-900 µmol/L
AMY	5~ 1100 U/L
CK	20 ~ 1000 U/L
CK-MB	5 ~ 200 U/L
LDH	25 ~ 800 U/L
α-HBDH	25 ~ 800 U/L
AST	5 ~ 1100 U/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°C) 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
K^+	mmol/L	0.225	0.267	0.516
Na^+	mmol/L	4.109	4.468	50.775
Cl^-	mmol/L	2.177	3.219	32.336
CO_2	mmol/L	0.605	0.77	3.006
GLU	mmol/L	0.244	0.277	0.3
CRE	μmol/L	0.865	1.062	4.264
UA	μmol/L	4.723	5.365	8.909
AMY	U/L	0.626	0.835	3.122
CK	U/L	0.616	0.757	5.008
CK-MB	U/L	0.55	0.689	2.884
LDH	U/L	1.069	1.245	6.319
α-HBDH	U/L	0.971	1.168	4.218
AST	U/L	0.504	0.623	3.128

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.