

General Chemistry II Lyophilized Kit

【Product Name】

General Chemistry II 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】

Celcercare M or Pointcare M chemistry analyzer

【Intended Use】

The General Chemistry II Lyophilized Kit used with the Celcercare 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 (CO₂), glucose (GLU), creatinine (CRE), blood urea and amylase (AMY) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

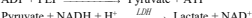
The General Chemistry II Lyophilized Kit measurements are used in the diagnosis of salt metabolism disorders, urinary system diseases, and pancreas diseases.

【Principles of Testing】

The General Chemistry II Lyophilized Kit is used to quantitatively test the concentration of the eight 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) phosphorylates 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.



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.



Chloride (CL⁻)

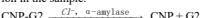
The method is based on the determination of chloride-dependent activation of α-amylase activity. Deactivated α-amylase is reactivated by addition of the chloride ion. The reactivation of α-amylase activity is proportional to the concentration of chloride ion in the sample. The reactivated α-amylase converts the substrate,

2-chloro-4-nitrophenyl-β-1,4-galactopyranosylmaltoside (CNP-G2) to

2-chloro-4-nitrophenol (CNP) producing color and

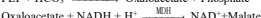
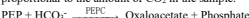
1,4-galactopyranosylmaltoside. The reaction is measured

bichromatically and the increase in absorbance is directly proportional to the reactivated α-amylase activity and the concentration of chloride ion in the sample.



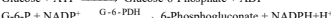
Carbon Dioxide (CO₂)

In the enzymatic method, the specimen is first made alkaline to convert all forms of carbon dioxide (CO₂) to bicarbonate (HCO₃⁻). Phosphoenolpyruvate (PEP) and HCO₃⁻ 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 CO₂ in the sample.



Glucose (GLU)

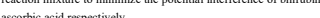
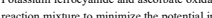
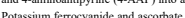
The reaction of glucose with adenosine triphosphate (ATP) catalyzed by hexokinase (HK), produces glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) catalyzes the reaction of G-6-P into 6-phosphogluconate and the reduction of nicotinamide adenine dinucleotide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



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)

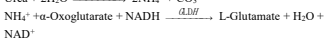
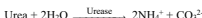
In the coupled enzyme reactions, creatiniamidohydrolase (CAH) hydrolyzes creatinine to creatine. A second enzyme, creatiniamidohydrolase (CRH), catalyzes the formation of sarcosine from creatine. Sarcosine oxidase (SAO) causes the oxidation of sarcosine to glycine, formaldehyde and hydrogen peroxide (H₂O₂). 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.



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.

Urea

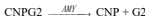
In the coupled-enzyme reaction, urease hydrolyzes urea into ammonia and carbon dioxide. Upon combining ammonia with-oxoglutarate and reduced nicotinamide adenine dinucleotide (NADH), the enzyme glutamate dehydrogenase (GLDH) oxidizes NADH to NAD⁺.



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.

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.



【Principle of Operation】

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

【Description of Reagents】

Each General Chemistry II Lyophilized Kit 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 component of each General Chemistry II 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 |
| Urea assay reagent | 13.5 μL |
| Amylase 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 Celcercare 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 Celcercare 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 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 | ammonium chloride mmol/L | Creatine μmol/L |
| K ⁺ | 16 | 150 | 50 | 75 | — | — |
| Na ⁺ | 10 | 150 | 50 | 75 | — | — |
| Cl ⁻ | 18 | 210 | 50 | 75 | — | — |
| CO ₂ | 45 | 525 | 250 | 75 | — | — |
| GLU | 40 | 600 | 1000 | 50 | — | — |
| CRE | 40 | 1050 | 500 | 25 | — | 600 |
| UREA | 25 | 600 | 1000 | — | 1 | — |
| AMY | 40 | 1000 | 400 | 100 | — | — |

【Procedure】

Materials Provided

General Chemistry II Lyophilized Kit

Celcercare 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 Celcercare M or the Pointcare M chemistry analyzer Operator's Manual.

Calibration

Each batch of reagent is calibrated using Rondox 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 analyzer at the time of scanning the code.

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

Quality Control

Refer to Operator's Manual of the Celcercare M or the Pointcare M

chemistry analyzer. Performance of the Celercare M or the Pointcare M 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 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 | |
|-----------------|---|---|---|---|
| | Whole blood and plasma: | Whole blood and plasma: | Whole blood and plasma: | Whole blood and plasma: |
| K ⁺ | Serum: 3.5 ~ 5.3 mmol/L 3.0 ~ 5.1 mmol/L | Serum: 3.5 ~ 5.3 mmol/L 3.0 ~ 5.1 mmol/L | Serum: 3.5 ~ 5.3 mmol/L 3.0 ~ 5.1 mmol/L | Serum: 3.5 ~ 5.3 mmol/L 3.0 ~ 5.1 mmol/L |
| Na ⁺ | 137 ~ 147 mmol/L | 137 ~ 147 mmol/L | 137 ~ 147 mmol/L | 137 ~ 147 mmol/L |
| Cl ⁻ | 99 ~ 110 mmol/L | 99 ~ 110 mmol/L | 99 ~ 110 mmol/L | 99 ~ 110 mmol/L |
| CO ₂ | 23 ~ 29 mmol/L | 23 ~ 29 mmol/L | 23 ~ 29 mmol/L | 23 ~ 29 mmol/L |
| GLU | 3.9 ~ 6.1 mmol/L | 70.2 ~ 109.8 mg/dL | 70.2 ~ 109.8 mg/dL | 70.2 ~ 109.8 mg/dL |
| CRE | Male: 54 ~ 109 μmol/L; | Male: 0.61 ~ 1.23 mg/dL; | Male: 0.61 ~ 1.23 mg/dL; | Male: 0.61 ~ 1.23 mg/dL; |
| | Female: 45 ~ 84 μmol/L | Female: 0.51 ~ 0.95 mg/dL | Female: 0.51 ~ 0.95 mg/dL | Female: 0.51 ~ 0.95 mg/dL |
| UREA | 2.9 ~ 8.2 mmol/L | 17.42 ~ 49.25 mg/dL | 17.42 ~ 49.25 mg/dL | 17.42 ~ 49.25 mg/dL |
| AMY | 0 ~ 220 U/L | 0 ~ 220 U/L | 0 ~ 220 U/L | 0 ~ 220 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 General Chemistry II Lyophilized Kit should be used with the Celercare M or the Pointcare M 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 |
|-----------------|---|
| 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% |
| UREA | B% ≤ 15.0% |
| AMY | B% ≤ 10.0% |

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% |
| UREA | 5.0% |
| AMY | 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% |
| UREA | 10.0% |
| AMY | 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 |
| UREA | 0.9 ~ 35.7 mmol/L |
| AMY | 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 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 |
|---|---|
|  | In vitro diagnostic medical device |
|  | Manufacturer |
|  | Authorized representative in the European Community |
|  | Use-by date |
|  | Batch code |
|  | Date of manufacture |
|  | CE MARK |
|  | Consult instructions for use |
|  | Limit of temperature |
|  | Unique device identifier |
|  | Do not re-use |

【Manufacturer】

 Tianjin MNCHIP Technologies Co., Ltd.
 Add.: 1-4F, Area, No.122 Dongting Rd, Development Zone,
 300457 Tianjin P.R. China
 SRN: CN-MF-000029863
 Technical support Telephone: +86-131-6318-8628
 Service email: service@mnchip.com
 Learn more about MNCHIP, other products can log in:
<http://www.mnchip.com>

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 SRN: NL-AR-000000444
 Email: ar@umedwings.eu