MNCHIP

Liver and Renal Function Lyophilized Kit

【Product Name】
Liver and Renal Function 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 Liver and Renal Function 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 total Protein (TP), albumin (ALB), total bilirubin (TBIL), alanine aminotransferase (ALT), aspartate aminotransferase (AST),gamma glutamyltransferase (GGT), blood urea, creatinine (CRE) and glucose (GLU)in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Liver and Renal Function Lyophilized Kit measurements are used in the diagnosis of liver and gall bladder diseases, urinary system diseases, carbohydrate metabolism disorders.
【Principles of Testing】
The Liver and Renal Function Lyophilized Kit is used to quantitatively test the concentration of the nine biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:
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.
Total Protein + Cu(II) $\xrightarrow{OH^-}$ Cu-Protein Complex
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.
BCG + Albumin $\xrightarrow{pH4.2}$ 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.
Total Bilirubin (TBIL)
In the enzyme procedure, bilirubin is oxidized by bilirubin oxidase (BOD) into biliverdin. Bilirubin is quantitated as the difference in absorbance between 450nm and 546 nm. The initial absorbance of this endpoint reaction is determined from the bilirubin blank cuvette and the final absorbance is obtained from the bilirubin test cuvette. The amount of bilirubin in the sample is proportional to the difference between the initial and final absorbance measurements.
Bilirubin + O_2 $\xrightarrow{BOD}$ Biliverdin + H_2O
Alanine Aminotransferase (ALT)
ALT catalyzes the transfer of an amino group from L-alanine to α-ketoglutarate to form L-glutamate and pyruvate. Lactate dehydrogenase catalyzes the conversion of pyruvate to lactate. Concomitantly, NADH is oxidized to NAD^+, as illustrated in the following reaction scheme.
L-Alanine + α-Ketoglutarate $\xrightarrow{ALT}$ L-Glutamate + Pyruvate
Pyruvate + NADH + H^+ $\xrightarrow{LDH}$ Lactate + NAD^+
The rate of change of the absorbance difference between 340 nm and 405 nm is due to the conversion of NADH to NAD^+ and is directly proportional to the amount of ALT present in the sample.
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 $\xrightarrow{MDH}$ 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.
Gamma Glutamyltransferase (GGT)
The addition of sample containing gammaglutamyltranferase to the substrates L-γ-glutamyl-3-carboxy-4-nitroanilide and glycylglycine causes the formation of L-γ-glutamyl-glycylglycine(glu-gly-gly) and 5-Amino-2-nitrobenzoate.
L-γ-glutamyl-3-carboxy-4-nitroanilide+ glycylglycine $\xrightarrow{GGT}$ Glu-gly-gly +5-Amino-2-nitrobenzoate
The absorbance of this rate reaction is measured at 405/505 nm. The production is directly proportional to the GGT activity in the sample.
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 + H_2O $\xrightarrow{Urease}$ NH_3 + CO_2
NH_3 +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, 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.
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.
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 $\xrightarrow{G\text{-}6\text{-}PDH}$ 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.
【Principle of Operation】
Refer to the Celercare Mor the Pointcare M chemistry analyzer Operator's Manual, for the Principles and Limitations of the Procedure.
【Description of Reagents】
Each Liver and Renal Function 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 eachLiver and Renal Function Lyophilized Kit is as follows (after redissolution):

Component	Quantity
Total protein assay reagent	13.5 μL
Albumin assay reagent	13.5 μL
Total Bilirubin assay reagent	13.5 μL
Alanine Aminotransferase assay reagent	13.5 μL
Aspartate Aminotransferase assay reagent	13.5 μL
Gamma Glutamyltransferase assay reagent	13.5 μL
Urea assay reagent	13.5 μL
Creatinine assay reagent	13.5 μL
Glucose assay reagent	6.6 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 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.
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.

Interfering substances concentration （≤）

Analyte	Bilirubin	Intralipid	Hemoglobin	Vitamin C	Pyruvate	Ammonium chloride	Creatine
	mg/dL	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	μmol/L
TP	25	1050	200	——	——	——	——
ALB	40	600	1000	——	——	——	——
GLU	40	600	1000	50	——	——	——
ALT	40	600	50	50	1	——	——
AST	40	600	50	25	1	——	——
GGT	40	1050	200	——	——	——	——
UREA	25	600	1000	——	——	1	——
CRE	40	1050	500	25	——	——	600
TBIL	—	1050	1000	75	——	——	——

【Procedure】
Materials Provided
Liver and Renal Function Lyophilized Kit
Celercare Mor 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 Rondox 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 M or the Pointcare M chemistry analyzer Operator's Manual for the specific information.

Quality Control

Refer to 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. 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 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 Unit	Common Units
TP	65 ~ 85 g/L	6.5 ~ 8.5 g/dL
ALB	40 ~ 55 g/L	4.0 ~ 5.5 g/dL
TBIL	3.4 ~ 20 μmol/L	0.20 ~ 1.17 mg/dL
ALT	Male: 9 ~ 50 U/L; Female: 7 ~ 40 U/L	Male: 9 ~ 50 U/L; Female: 7 ~ 40 U/L
AST	Male: 15 ~ 40 U/L; Female: 13 ~ 35 U/L	Male: 15 ~ 40 U/L; Female: 13 ~ 35 U/L
GGT	Male: 10 ~ 60 U/L; Female: 7 ~ 45 U/L	Male: 10 ~ 60 U/L; Female: 7 ~ 45 U/L
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
GLU	3.9 ~ 6.1 mmol/L	70.2 ~ 109.8 mg/dL

【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 Liver and Renal Function 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
TP	B% ≤ 5.0%
ALB	B% ≤ 6.0%
TBIL	B% ≤ 10.0%
ALT	B% ≤ 15.0%
AST	B% ≤ 15.0%
GGT	B% ≤ 15.0%
UREA	B% ≤ 15.0%
CRE	B% ≤ 10.0%
GLU	B% ≤ 20.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
TP	2.0%
ALB	2.0%
TBIL	5.0%
ALT	5.0%
AST	5.0%
GGT	5.0%
UREA	5.0%
CRE	5.0%
GLU	5.0%

Inter batch precision

Analyte	Relative Range (≤ *)
TP	5.0%
ALB	5.0%
TBIL	10.0%
ALT	10.0%
AST	10.0%
GGT	10.0%
UREA	10.0%
CRE	10.0%
GLU	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
TP	30~100 g/L
ALB	10~60 g/L
TBIL	2~800 μmol/L
ALT	5~1100 U/L
AST	5~1100 U/L
GGT	5~1100 U/L
UREA	0.9~35.7 mmol/L
CRE	20~1500 μmol/L
GLU	1~30 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 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
IVD	In vitro diagnostic medical device
	Manufacturer
EC REP	Authorized representative in the European Community
	Use-by date
LOT	Batch code
	Date of manufacture
CE	CE MARK
	Consult instructions for use
2℃ 4℃	Limit of temperature
UDI	Unique device identifier
	Do not re-use

【Manufacturer】

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