【Product Name】

Liver & Kidney Profile (9+4)

【Packing Specification】

Type B: 1 Test / Disc, 10 Discs / Box.
Type B with diluent container.

【Testing Instrument】

Celercare V or Pointcare V chemistry analyzer

【Intended Use】

Liver & Kidney Profile (9+4) used with the Celercare V or the Pointcare V chemistry analyzer, is intended to be used for the in vitro quantitative determination of total protein (TP), albumin (ALB), alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma glutamyltransferase (GGT), total bilirubin (TBIL), creatinine (CRE), urea nitrogen(BUN), glucose (GLU) in heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Liver & Kidney Profile (9+4) measurements are used in the diagnosis of liver and gall bladder diseases, urinary system diseases, glucose metabolism disorders.

【Principles of Testing】

The Liver & Kidney Profile (9+4) is used to quantitatively test the concentration of the 9 biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:

1. 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.

$$\text{Total Protein} + \text{Cu(II)} \xrightarrow{OH^-} \text{Cu-Protein Complex}$$

2. 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.

$$\text{BCG} + \text{Albumin} \xrightarrow{Acid\ pH} \text{Albumin Complex}$$

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.

3. 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.

$$\text{L-Alanine} + \text{α-Ketoglutarate} \xrightarrow{ALT} \text{L-Glutamate} + \text{Pyruvate}$$

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

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.

4. 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.

$$\text{L-aspartate} + \text{α-ketoglutarate} \xrightarrow{AST} \text{Oxaloacetate} + \text{L-glutamate}$$

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

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.

5. Gamma Glutamyltransferase (GGT)

The addition of sample containing gammaglutamyltranferase to the substrates L-γ-glutamyl-3-carboxy-4-nitroanilide and glycylglycinecauses the formation of L-γ-glutamyl- glycylglycine(glu-gly-gly) and 5-Amino-2-nitrobenzoate.

$$\text{L-γ-glutamyl-3-carboxy-4-nitroanilide+ glycylglycine} \xrightarrow{GGT} \text{Glu-gly-gly + 5-Amino-2 - nitrobenzoate}$$

The absorbance of this rate reaction is measured at 405/505 nm. The production is directly proportional to the GGT activity in the sample.

6. 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.

$$\text{Bilirubin} + O_2 \xrightarrow{BOD} \text{Biliverdin} + H_2O$$

7. 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.

8. 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.

9. 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.

$$Glucose + ATP \xrightarrow{HK} Glucose\text{-}6\text{-}Phosphate + ADP$$

$$G\text{-}6\text{-}P + NADP^+ \xrightarrow{G\text{-}6\text{-}PDH} 6\text{-}Phosphogluconate + NADPH + H^+$$

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 V or the Pointcare V chemistry analyzer Operator's Manual, for the Principles and Limitations of the Procedure.

【Description of Reagents】

Each Liver & Kidney Profile (9+4) contains lyophilized test-specific reagent beads. A lyophilized blank reagent bead includes in each disc for a judgment of error 0233.
Type B is the reagent disc with diluent container.
Calibration information is included in barcode code. Please check it on the label.
The componen of each Liver & Kidney Profile (9+4) is as follows (after redissolution):

Component	Quantity
Total protein assay reagent	13.5 μL
Albumin assay reagent	13.5 μL
Alanine Aminotransferase assay reagent	13.5 μL
Aspartate Aminotransferase assay reagent	13.5 μL

Gamma Glutamyltransferaseassay reagent	13.5 μL
Total Bilirubin assay reagent	13.5 μL
Creatinine assay reagent	13.5 μL
Urea assay reagent	13.5 μL
Glucose assay reagent	6.6 μL
Stabilizer	Appropriate amount

【Storage】

Store reagent discs in their sealed pouches at a temperature of 2-8°C (36-46°F). Do not expose opened or unopened discs to direct sunlight or temperatures exceeding 32°C (90°F). Reagent discs may be used until the expiration date indicated on the package, which is also encoded in the unique code printed on the sealing pouch.

A torn or damaged pouch may allow moisture to reach the unused disc, adversely affecting its performance. Therefore, do not use any 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 plasma, serum or quality controls.

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.

Use only lithium heparin evacuated specimen collection tubes for 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	Pyruvate mmol/L	Creatine μmol/L	NH_4Cl mmol/L
TP	25	1050	200	——	——	——	——
ALB	40	600	1000	——	——	——	——
ALT	40	600	50	50	1	——	——
AST	40	600	50	25	1	——	——
GGT	40	1050	200	——	——	——	——

TBIL	——	1050	1000	75	——	——	——
CRE	40	1050	500	25	——	600	——
BUN	25	600	1000	——	——	——	1
GLU	40	600	1000	50	——	——	——

【Procedure】

■ **Materials Provided**

Liver & Kidney Profile (9+4)
Celercare V or Pointcare V chemistry analyzer
Please tear off the aluminum strip before using Type B.
Transfer pipettes (fixed volume 100 μL for sample) and tips

■ **Test Procedure**

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

■ **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 Operator's Manual for 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, please consult the manual.
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 regarding endpoint and rate reaction calculations can be 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
TP	Dog: 52 ~ 82g/L; Cat: 54 ~ 89g/L	Dog: 5.2 ~ 8.2g/dL; Cat: 5.4 ~ 8.9g/dL
ALB	Dog: 22 ~ 44g/L; Cat: 22 ~ 45g/L	Dog: 2.2 ~ 4.4 g/dL; Cat: 2.2 ~ 4.5 g/dL
ALT	Dog: 10 ~ 140U/L; Cat: 8.2 ~ 123U/L	Dog: 10 ~ 140U/L; Cat: 8.2 ~ 123U/L

AST	Dog: 8.9 ~ 55U/L; Cat: 9.2 ~ 60U/L	Dog: 8.9 ~ 55U/L; Cat:9.2 ~ 60U/L
GGT	Dog: 0 ~ 7U/L; Cat: 0 ~ 2U/L	Dog: 0 ~ 7U/L; Cat: 0 ~ 2U/L
TBIL	Dog: 2 ~ 15μmol/L; Cat: 2 ~ 15μmol/L	Dog: 0.1 ~ 0.9mg/dL; Cat: 0.1 ~ 0.9mg/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
GLU	Dog: 3.89 ~ 7.95mmol/L Cat: 4.11 ~ 8.84mmol/L	Dog: 70 ~ 143mg/dL Cat: 74 ~ 159mg/dL

【Interpretation of Results】

Physiological interferents, such as hemolysis, icterus, and lipemia, can cause changes in the reported concentrations of certain analytes. Sample indices are printed at the bottom of each printout to inform the operator about any abnormalities in the sample. The operator should take care to avoid hemolysis caused by improper blood collection techniques.

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.

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 Liver & Kidney Profile (9+4) 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
TP	B% ≤ 5.0%
ALB	B% ≤ 6.0%
ALT	B% ≤ 15.0%
AST	B% ≤ 15.0%
GGT	B% ≤ 15.0%
TBIL	B% ≤ 10.0%
CRE	B% ≤ 10.0%
BUN	B% ≤ 15.0%

GLU	B% ≤ 20.0%

Batch precision

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

Inter batch precision

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

Dynamic Ranges

Analyte	Dynamic Ranges
TP	20 ~ 100g/L
ALB	10 ~ 60g/L
ALT	5 ~ 1500U/L
AST	5 ~ 1600U/L
GGT	5 ~ 1500U/L
TBIL	2~800μmol/L
CRE	20 ~ 2000 μmol/L
BUN	0.9~35.7mmol/L
GLU	1 ~ 35mmol/L

【Notes】

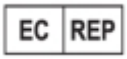
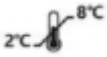
Used reagent discs contain animal body fluids. It is essential to follow good laboratory safety practices

when handling and disposing of these used discs. For instructions on cleaning biohazardous spills, refer to the Celercare V or Pointcare V chemistry analyzer Operator's Manual.

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

Reagent beads may contain acids or caustic substances. Operators do not come into contact with the reagent beads when following the recommended procedures. It is important to avoid ingestion, skin contact, or inhalation of the reagent beads.

【Symbols Used in Labelling】

Symbol	Explanation
	Veterinary use only
	Manufacturer
	Unique device identifier
	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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Ver1.1