【Product Name】

Comprehensive Profile (24)

【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】

The Comprehensive Profile (24) 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), total bilirubin (TBIL), alanine aminotransferase (ALT), creatinine (CRE), amylase (AMY) , glucose (GLU), triglycerides (TG), total cholesterol (CHOL), calcium (Ca), phosphorus (P), aspartate aminotransferase (AST), total bile acid(TBA), gamma glutamyltransferase (GGT), total carbon dioxide (tCO_2),urea nitrogen(BUN), creatine kinase (CK), alkaline phosphatase (ALP) and magnesium (Mg) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Comprehensive Profile (24) measurements are used in the diagnosis of liver and gallbladder diseases, glucose metabolism and lipid metabolism disorders, pancreatic diseases, cardiovascular diseases, urinary system diseases.

【Principles of Testing】

The Comprehensive Profile (24) is used to quantitatively test the concentration of the nineteen 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.

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

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. 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.

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

4. 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.

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

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

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.

5. 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^+.

$$\text{Urea} + 2H_2O \xrightarrow{\text{Urease}} 2NH_4^+ + CO_3^{2-}$$

$$NH_4^+ + \alpha\text{-Oxoglutarate} + \text{NADH} \xrightarrow{GLDH} \text{L-Glutamate} + H_2O + NAD^+$$

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.

6. 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.

$$\text{Creatinine} + H_2O \xrightarrow{CAH} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{CRH} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + H_2O + O_2 \xrightarrow{SAO} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 + TBHBA + 4\text{-}AAP \xrightarrow{POD} \text{Red Quinoneimine Dye} + H_2O$$

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.

7. 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.

$$\text{Creatine phosphate} + ADP \xrightarrow{CK} \text{Creatine} + ATP$$

$$ATP + \text{D-glucose} \xrightarrow{HK} ADP + \text{G-6-P}$$

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

8. 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.

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

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

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.

9. Total Cholesterol (CHOL)

The reaction of CHOL is an enzymatic end-point method that uses cholesterol esterase (CE) and cholesterol dehydrogenase (CHDH). CE hydrolyzes cholesterol esters to form cholesterol and fatty acids. The CHDH reaction converts cholesterol to cholest-4-en-3-one. The NADH is measured bichromatically at 340 nm and 405 nm. NADH production is directly proportional to the amount of cholesterol present. An assay-specific blank is also monitored to ensure no extraneous reactions interfere with the calculations of CHOL levels.

$$\text{Cholesterol Esters} + H_2O \xrightarrow{CE} \text{Cholesterol} + \text{Fatty Acids}$$

$$\text{Cholesterol} + NAD^+ \xrightarrow{CHDH} \text{Cholest-4-en-3-one} + NADH + H^+$$

10. Alkaline Phosphatase (ALP)

Under the catalysis of ALP, the Phosphoric acid on nitrobenzene (4-NNP) was turned into Para nitro phenol (4-NP).4-NP shows a yellow color in alkaline solution. At the wavelength of 405/505nm, the ALP activity can be calculated by monitoring the absorbance change rate.

$$\text{4-NNP} \xrightarrow{\text{ALP}} \text{Acyl phosphate + 4-NP}$$

11. Triglycerides (TG)

The TRIG assay is an enzymatic end-point method that makes use of four enzymes. The reaction mechanism follows:

$$\text{Triglycerides} + 3H_2O \xrightarrow{LPL} \text{Glycerol + 3Fatty Acids}$$

$$\text{Glycerol + ATP} \xrightarrow{GK,\ Mg^{2+}} \text{G-3-P + ADP}$$

$$\text{G-3-P} + NAD^+ + O_2 \xrightarrow{G-3PDH} \text{DAP} + NADH + H^+$$

$$NADH + H^+ + \text{INT} \xrightarrow{\text{Diaphorase}} NAD^+ + \text{Formazan}$$

In the first step, the triglycerides are hydrolyzed into glycerol and fatty acids in a reaction catalyzed by lipoprotein lipase. Glycerol is then phosphorylated in an ATP-requiring reaction catalyzed by glycerol kinase (GK). The glycerolphosphate is then oxidized to dihydroxyacetone phosphate with the simultaneous reduction of NAD^+ to NADH in a reaction catalyzed by glycerol-3-phosphate dehydrogenase (G-3-PDH). 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 triglycerides in the sample

12. 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.

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

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

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.

13. Calcium (Ca)

Calcium in the patient sample binds with arsenazo III to form a calcium-dye complex.

$$Ca^{2+} + \text{Arsenazo III} \longrightarrow Ca^{2+}\text{-Arsenazo III Complex}$$

It is an endpoint reaction. The amount of total calcium in the sample is proportional to the absorbance.

14. Phosphorus (P)

The enzymatic method for the MNCHIP system uses maltose phosphorylase (MP) coupled through β -phosphoglucomutase (β -PGM) and glucose-6-phosphate dehydrogenase (G6PDH). The amount of

NADH formed can be measured as an endpoint at 340/405 nm.

$$\text{Maltose + Pi} \xrightarrow{MP} \text{Glucose-1-Phosphate (G-1-P) + Glucose}$$

$$\text{Glucose-1-Phosphate (G-1-P)} \xrightarrow{\beta\text{-PGM}} \text{Glucose-6-Phosphate (G-6-P)}$$

$$\text{Glucose-6-Phosphate (G-6-P) + } NAD^+ \xrightarrow{\text{G6PDH}} \text{NADH+ 6-Phosphogluconate+} H^+$$

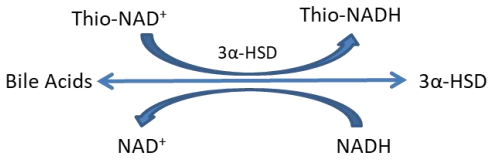
15. Amylase (AMY)

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 405nm and 505 nm.

$$\text{CNP-G2} \xrightarrow{\text{AMY}} \text{CNP + G2}$$

16. Total Bile Acid (TBA)

In the presence of the thio-derivative of nicotinamide adenine dinucleotide (Thio-NAD+) the enzyme 3-α-Hydroxysteroid Dehydrogenase (3-α-HSD) reversibly oxidizes bile acids to oxidized bile acids (3-α-keto forms) with the concomitant conversion of Thio-NAD^+ to its reduced form Thio-NADH. In a cycling reaction, the oxidized bile acids are returned to their reduced state when excess NADH is present. The NADH is converted to NAD+. The rate of increase in absorbance at 405nm (Thio-NADH) is measured and is proportional to the concentration of bile acids in the sample. The rate is measured bichromatically at 405 and 500nm.



17. Total Carbon Dioxide (tCO_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.

$$\text{PEP + } HCO_3^- \xrightarrow{\text{PEPC}} \text{Oxaloacetate + Phosphate}$$

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

18. 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.

$$\text{L-γ-glutamyl-3-carboxy-4-nitroanilide+ glycylglycine} \xrightarrow{\text{GGT}}$$

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.

19. Magnesium (Mg)

The hexokinase (HK) activation method is described as:

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK, } Mg^{2+}} \text{G-6-P} + \text{ADP}$$

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

The rate limiting reaction is the HK reaction. Magnesium from the sample activates HK, which in turn catalyzes the breaking down of glucose to form glucose-6-phosphate (G-6-P) and ADP. G-6-P reacts with nicotinamide adenine dinucleotide phosphate ($NADP^{+}$) to form reduced nicotinamide adenine dinucleotide phosphate (NADPH) and 6-phosphogluconate in the presence of glucose-6-phosphate-dehydrogenase (G-6-PDH). This is a first-order rate reaction. The rate of production of NADPH is directly proportional to the amount of magnesium present in the sample. Absorbance is measured bichromatically at 340 nm and 405 nm.

【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 Comprehensive Profile (24) 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.
Calibration information is included in barcode code. Please check it on the label.
The component of each Comprehensive Profile (24) is as follows (after redissolution):

Component	Quantity
Total protein assay reagent	12.6μL
Albumin assay reagent	12.6μL
Total Bilirubin assay reagent	12.6μL
Alanine Aminotransferase assay reagent	12.6μL
Urea assay reagent	12.6μL
Creatinine assay reagent	12.6μL
Creatine Kinase assay reagent	12.6μL
Glucose assay reagent	6.6μL
Total Cholesterol assay reagent	12.6μL
Alkaline Phosphatase assay reagent	12.6μL

Triglycerides assay reagent	12.6μL
Gamma Glutamyltransferase assay reagent	12.6μL
Phosphorus assay reagent	12.6μL
Calcium assay reagent	9.7μL
Amylase assay reagent	12.6μL
Aspartate Aminotransferase assay reagent	12.6μL
Total bile acid assay reagent	12.6μL
Magnesium assay reagent	12.6μL
Total 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 V or the Pointcare V 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 V or the Pointcare V chemistry analyzer Operator’s Manual.

The required sample usage is 100 μL of lithium heparin whole blood, lithium heparin plasma, serum or quality controls.

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.

Analyte	Interfering substances concentration （≤）								
	Bilirubin mg/dL	Intralipid mg/dL	Hemoglobin mg/dL	Vitamin C mg/dL	Pyruvate mmol/L	NH_4Cl mmol/L	Creatine μ mol/L	Ca^{2+} mmol/L	Mg^{2+} mmol/L
TP	25	1050	200	——	——	——	——	——	——
ALB	40	600	1000	——	——	——	——	——	——
AST	40	600	50	25	1	——	——	——	——
GGT	40	1050	200	——	——	——	——	——	——
BUN	25	600	1000	——	——	1	——	——	——
CK	40	1000	400	100	——	——	——	——	——
ALP	40	1050	400	——	——	——	——	——	——
Ca	180	210	200	75	——	——	——	——	3
P	45	525	100	27	——	——	——	——	——
ALT	40	600	50	50	1	——	——	——	——
TBIL	——	1050	1000	75	——	——	——	——	——
CRE	40	1050	500	25	——	——	600	——	——
GLU	40	600	1000	50	——	——	——	——	——
CHOL	40	1000	800	40	——	——	——	——	——
AMY	40	1000	400	100	——	——	——	——	——
TBA	50	600	500	50	——	——	——	——	——
Mg	120	140	50	——	——	——	——	2	——
TG	40	——	1000	50	——	——	——	——	——
tCO_2	45	525	250	75	——	——	——	——	——

【Procedure】

■ Materials Provided

Comprehensive Profile (24)
Celercare V or Pointcare V chemistry analyzer
please tear off the aluminum strip before using for 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 Celercare V or the Pointcare V 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-dimentional code printed on the sealed pouch are provided to analyzer at the time of scanning the code.
Refer to the Celercare V or the Pointcare V chemistry analyzer Operator’s Manual for the 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.

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 of the endpoint and rate reaction calculations are 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
ALP	Dog: 20 ~ 150U/L; Cat:10 ~ 90U/L	Dog: 20 ~ 150U/L; Cat:10 ~ 90U/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
CHOL	Dog: 2.84 ~ 8.26mmol/L Cat: 1.68 ~ 5.81mmol/L	Dog: 110 ~ 320mg/dL Cat: 65 ~ 225mg/dL
CK	Dog: 20 ~ 200U/L; Cat: 50 ~ 450U/L	Dog: 20 ~ 200U/L; Cat: 50 ~ 450U/L
AMY	Dog: 400 ~ 3500U/L; Cat: 400 ~ 3500U/L	Dog: 400 ~ 3500U/L; Cat: 400 ~ 3500U/L
Ca	Dog: 1.98 ~ 2.95mmol/L; Cat: 1.95 ~ 2.95mmol/L	Dog: 7.9 ~ 11.8mg/dL; Cat: 7.8 ~ 11.8mg/dL
P	Dog: 0.81 ~ 2.2mmol/L; Cat: 1 ~ 2.74mmol/L	Dog: 2.5 ~ 6.8mg/dL; Cat: 3.1 ~ 8.5mg/dL
TG	Dog:0.1~0.9mmol/L	Dog: 8.8 ~79.7mg/dL

GGT	Cat: 0.1~0.9mmol/L Dog: 0 ~ 7U/L; Cat: 0 ~ 2U/L	Cat: 8.8 ~79.7mg/dL Dog: 0 ~ 7U/L; Cat: 0 ~ 2U/L
TBA	Dog: 0 ~ 15μmol/L; Cat: 0 ~ 15μmol/L	Dog: 0 ~ 15μmol/L; Cat: 0 ~ 15μmol/L
Mg	Dog: 0.6 ~ 1.09mmol/L; Cat: 0.7 ~ 1.21mmol/L	Dog: 1.5 ~ 2.6mg/dL; Cat: 1.7 ~ 2.9mg/dL
AST	Dog: 8.9 ~ 48.5U/L; Cat: 9.2 ~ 39.5U/L	Dog: 8.9 ~ 48.5U/L; Cat: 9.2 ~ 39.5U/L
tCO_2	Dog: 12 ~ 27mmol/L; Cat: 15 ~ 24mmol/L	Dog: 12 ~ 27mmol/L; Cat: 15 ~ 24mmol/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 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 Comprehensive Profile (24) 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% ≤ 6.0%
ALB	B% ≤ 6.0%
ALT	B% ≤ 15.0%
ALP	B% ≤ 10.0%
TBIL	B%≤10.0%
CRE	B% ≤ 10.0%
BUN	B%≤15.0%
GLU	B% ≤ 20.0%
CHOL	B%≤10.0%

AST	B% ≤ 15.0%
CK	B% ≤ 10.0%
AMY	B% ≤ 10.0%
Ca	B% ≤ 5.0%
P	B% ≤ 10.0%
TBA	B% ≤ 15.0%
GGT	B% ≤ 15.0%
Mg	B% ≤ 15.0% or Absolute deviation ≤ 0.2mmol/L
TG	B%≤15.0%
tCO_2	B% ≤ 10.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
TP	5.0%
ALB	2.0%
ALT	8.0%
ALP	5.0%
TBIL	5.0%
CRE	6.0%
BUN	5.0%
GLU	5.0%
CHOL	4.0%
AST	8.0%
CK	5.0%
AMY	5.0%
Ca	5.0%
P	5.0%
Mg	5.0%
TBA	5.0%
GGT	5.0%
TG	5.0%
tCO_2	6.0%

Inter batch precision

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

GLU	10.0%
CHOL	6.0%
AST	10.0%
CK	10.0%
AMY	10.0%
Ca	10.0%
P	10.0%
TBA	10.0%
Mg	10.0%
GGT	10.0%
TG	10.0%
tCO_2	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
TP	20 ~100g/L
ALB	10~60g/L
ALT	5 ~ 1500U/L
ALP	5 ~ 2000U/L
TBIL	2~800μmol/L
CRE	20 ~2000μmol/L
BUN	0.9 ~35.7mmol/L
GLU	1 ~35mmol/L
CHOL	0.5 ~14mmol/L
AST	5 ~ 1600U/L
GGT	5 ~ 1500U/L
AMY	5~ 3500 U/L
CK	5 ~ 3000 U/L
Ca	0.5 ~ 4mmol/L
P	0.2 ~ 7mmol/L
TBA	0 ~ 150μmol/L
Mg	0.2 ~ 1.6mmol/L
TG	0 ~9.04mmol/L
tCO_2	10 ~ 35mmol/L

【Notes】

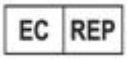
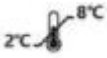
Used reagent discs contain animal body fluids. Follow good laboratory safety practices when handling and disposing of used discs. See the Celercare V or the Pointcare V chemistry analyzer Operator's Manual for instructions on cleaning biohazardous spills.

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
	Veterinary use only
	Manufacturer
	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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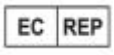

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