【Product Name】

Preanesthetic Plus Profile (9+2)

【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】

Preanesthetic Plus Profile (9+2) 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), alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), creatinine (CRE),urea nitrogen(BUN),, glucose (GLU), creatine kinase (CK), lactate dehydrogenase (LDH) in heparinized plasma or serum in a clinical laboratory setting or point-of-care location.
The Preanesthetic Plus Profile (9+2) measurements are used in the diagnosis of liver and gallbladder diseases, urinary system diseases, glucose metabolism disorders, cardiovascular diseases.

【Principles of Testing】

The Preanesthetic Plus Profile (9+2) 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. 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.

3. 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.

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

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

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.

4. 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.

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

5. 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.

6. 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.

7. 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.

8. 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.

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

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

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

9. 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 reactioncatalyzed 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.

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

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

【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 Preanesthetic Plus Profile (9+2) 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 Preanesthetic Plus Profile (9+2) is as follows (after redissolution):

Component	Quantity

Total protein assay reagent	13.5 μL
Alanine aminotransferase assay reagent	13.5 μL
Aspartate aminotransferase assay reagent	13.5 μL
Alkaline phosphatase assay reagent	13.5 μL
Creatinine assay reagent	13.5 μL
Urea assay reagent	13.5 μL
Glucose assay reagent	6.6 μL
Creatine kinase assay reagent	13.5 μL
Lactate dehydrogenase assay reagent	13.5 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.

Use only lithium heparin evacuated specimen collection tubes for 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	NH_4Cl	Creatine
	mg/dL	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	μmol/L
TP	25	1050	200	——	——	——	——

ALT	40	600	50	50	1	——	——
AST	40	600	50	25	1	——	——
ALP	40	1050	400	——	——	——	——
CRE	40	1050	500	25	——	——	600
BUN	25	600	1000	——	——	1	——
GLU	40	600	1000	50	——	——	——
CK	40	1000	400	100	——	——	——
LDH	40	1000	50	100	——	——	——

【Procedure】

■ Materials Provided

Preanesthetic Plus Profile (9+2)
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
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
ALP	Dog: 20 ~ 150U/L; Cat: 10 ~ 90U/L	Dog: 20 ~ 150U/L; Cat: 10 ~ 90U/L
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
CK	Dog: 20 ~ 200U/L; Cat: 50 ~ 450U/L	Dog: 20 ~ 200U/L; Cat: 50 ~ 450U/L
LDH	Dog: 40 ~ 400U/L; Cat: 0 ~ 800U/L	Dog: 40 ~ 400U/L; Cat: 0 ~ 800U/L

【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 Preanesthetic Plus Profile (9+2) 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%
ALT	B% ≤ 15.0%

AST	B% ≤ 15.0%
ALP	B% ≤ 10.0%
CRE	B% ≤ 10.0%
BUN	B% ≤ 15.0%
GLU	B% ≤ 20.0%
CK	B% ≤ 10.0%
LDH	B% ≤ 10.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
TP	2.0%
ALT	5.0%
AST	5.0%
ALP	5.0%
CRE	5.0%
BUN	5.0%
GLU	5.0%
CK	5.0%
LDH	5.0%

Inter batch precision

Analyte	Relative Range (≤ *)
TP	5.0%
ALT	10.0%
AST	10.0%
ALP	10.0%
CRE	10.0%
BUN	10.0%
GLU	10.0%
CK	10.0%
LDH	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
TP	20 ~ 100g/L
ALT	5 ~ 1500U/L
AST	5 ~ 1600U/L
ALP	5 ~ 2000U/L
CRE	20 ~ 2000μmol/L

BUN	0.9 ~ 35.7mmol/L
GLU	1 ~ 35mmol/L
CK	5 ~ 3000U/L
LDH	25 ~ 3000U/L

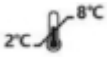
【Notes】

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	Veterinary use only
	Manufacturer
UDI	Unique device identifier
EC REP	Authorized representative in the European Community
	Use-by date
LOT	Batch code
	Date of manufacture
	Consult instructions for use
	Limit of temperature
	Do not re-use

【Manufacturer】

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