**【Product Name】**

Large Animal Profile (10+3)

**【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 Large Animal Profile (10+3) 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), aspartate aminotransferase (AST), gamma glutamyltransferase (GGT), urea nitrogen(BUN), creatine kinase (CK), alkaline phosphatase (ALP), calcium (Ca), phosphorus (P), magnesium (Mg) in heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Large Animal Profile (10+3) measurements are used in the diagnosis of hepatobiliary system diseases, urinary system diseases, glucose metabolism and lipid metabolism diseases, pancreatic diseases, cardiovascular diseases.

**【Principles of Testing】**

The Large Animal Profile (10+3) is used to quantitatively test the concentration of the 10 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. 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.

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

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

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. 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.

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

$$\text{Glu-gly-gly} + \text{5-Amino-2 - nitrobenzoate}$$

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

**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 $NAD^+$.

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

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

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. 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.

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

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

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

**7. 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.

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

**8. 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.

**9. 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.

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

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

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

**10. Magnesium (Mg)**

The hexokinase (HK) activation method is described as:

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

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

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 Large Animal Profile (10+3) 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 Large Animal Profile (10+3) is as follows (after redissolution):

| Component | Quantity |
|---|---|
| Total protein assay reagent | 13.5 μL |

| | |
|---|---|
| Albumin assay reagent | 13.5 μL |
| Aspartate Aminotransferase assay reagent | 13.5 μL |
| Gamma Glutamyltransferaseassay reagent | 13.5 μL |
| Urea assay reagent | 13.5 μL |
| Creatine Kinase assay reagent | 13.5 μL |
| Alkaline Phosphatase assay reagent | 13.5 μL |
| Calcium assay reagent | 9.7 μL |
| Phosphorus assay reagent | 13.5 μL |
| Magnesium 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.

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 | $NH_4Cl$ mmol/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 | —— | —— | —— | —— |
| Mg | 120 | 140 | 50 | —— | —— | —— | 2 | —— |

## 【Procedure】

### ■ Materials Provided

Large Animal Profile (10+3)
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 | Equine: 57 ~ 80g/L;<br>Bovine: 66 ~ 93g/L | Equine: 5.7 ~ 8.0g/dL;<br>Bovine: 6.6 ~ 9.3g/dL |

| | | |
|---|---|---|
| ALB | Equine: 22 ~ 37g/L;<br>Bovine: 25~38g/L | Equine: 2.2 ~ 3.7 g/dL;<br>Bovine: 2.5 ~ 3.8 g/dL |
| AST | Equine: 175~ 340U/L;<br>Bovine:66 ~ 211U/L | Equine: 175 ~ 340U/L;<br>Bovine: 66 ~ 211U/L |
| GGT | Equine: 5~24U/L;<br>Bovine: 12 ~ 48U/L | Equine: 5~24U/L;<br>Bovine:12~ 48U/L |
| BUN | Equine: 2.5 ~ 8.9mmol/L<br>Bovine: 2.4 ~ 7.14mmol/L | Equine: 7 ~ 25mg/dL<br>Bovine: 6 ~ 20mg/dL |
| CK | Equine: 120 ~ 470U/L;<br>Bovine: 833 ~ 688U/L | Equine: 120 ~ 470U/L;<br>Bovine: 833 ~ 688U/L |
| ALP | Equine: 50 ~ 170U/L;<br>Bovine: 23 ~ 135U/L | Equine: 50 ~ 170U/L;<br>Bovine: 23 ~ 135U/L |
| Ca | Equine: 2.9 ~ 3.6mmol/L;<br>Bovine: 1.97 ~ 2.39mmol/L | Equine:11.5 ~ 14.2mg/dL;<br>Bovine:7.9 ~ 9.6mg/dL |
| P | Equine: 0.61 ~ 1.39mmol/L;<br>Bovine: 1.3 ~ 3.0 mmol/L | Equine: 1.9 ~ 4.3mg/dL;<br>Bovine: 4.1 ~ 9.2mg/dL |
| Mg | Equine: 0.74 ~1.2mmol/L;<br>Bovine: 0.7 ~ 1.19 mmol/L | Equine: 1.8~2.9 mg/dL;<br>Bovine: 1.7 ~ 2.9 mg/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 Large Animal Profile（10+3） 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% |
| AST | B% ≤ 15.0% |
| GGT | B% ≤ 15.0% |
| BUN | B% ≤ 15.0% |
| CK | B% ≤ 10.0% |
| ALP | B% ≤ 10.0% |
| Ca | B% ≤ 5.0% |
| P | B% ≤ 10.0% |
| Mg | B% ≤ 15.0% or Absolute deviation ≤ 0.2mmol/L |

**Batch precision**

| Analyte | Coefficient of variation (≤ *) |
|---|---|
| TP | 2.0% |
| ALB | 2.0% |
| AST | 5.0% |
| GGT | 5.0% |
| BUN | 5.0% |
| CK | 5.0% |
| ALP | 5.0% |
| Ca | 3.0% |
| P | 5.0% |
| Mg | 5.0% |

**Inter batch precision**

| Analyte | Relative Range (≤ *) |
|---|---|
| TP | 5.0% |
| ALB | 5.0% |
| AST | 10.0% |
| GGT | 10.0% |
| BUN | 10.0% |
| CK | 10.0% |
| ALP | 10.0% |
| Ca | 5.0% |
| P | 10.0% |
| Mg | 10.0% |

**Dynamic Ranges**

| Analyte | Dynamic Ranges |
|---|---|

| | |
|---|---|
| TP | 20~100g/L |
| ALB | 10~60g/L |
| AST | 5 ~ 1600U/L |
| GGT | 5 ~ 1500U/L |
| BUN | 0.9~35.7 mmol/L |
| CK | 5 ~ 3000 U/L |
| ALP | 5 ~ 2000U/L |
| Ca | 0.5 ~ 4mmol/L |
| P | 0.2 ~ 7mmol/L |
| Mg | 0.2 ~ 1.6mmol/L |

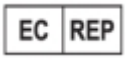
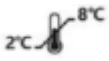
**【Notes】**

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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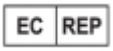


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