

【Product Name】

Large Animal Diagnostics

【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 V or Pointcare V chemistry analyzer

【Intended Use】

The Large Animal Diagnostics 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 whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

The Large Animal Diagnostics measurements are used in the diagnosis of hepatobiliary system diseases, urinary system diseases, glucose metabolism and lipid metabolism diseases, pancreatic diseases, cardiovascular diseases.

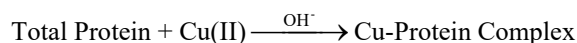
【Principles of Testing】

The Large Animal Diagnostics is used to quantitatively test the concentration of the ten biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:

1. Total Protein (TP)

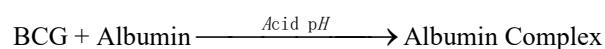
The total protein method is a Biuret reaction, the protein solution is treated with cupric [Cu(II)] ions in a strong alkaline medium. The Cu(II) ions react with peptide bonds between the carbonyl oxygen and amide nitrogen atoms to form a colored Cu-protein complex.

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.



2. Albumin (ALB)

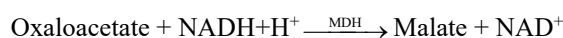
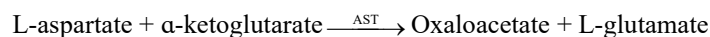
Bromocresol green (BCG), when bound with albumin, changes color from a yellow to green color. The absorbance maximum changes with the color shift.



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)

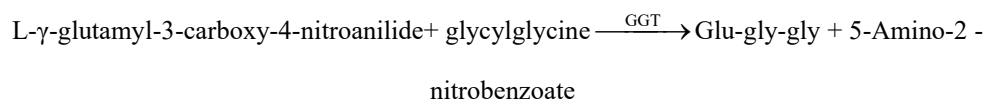
AST catalyzes the reaction of L-aspartate and α -ketoglutarate into oxaloacetate and L-glutamate. Oxaloacetate is converted to malate and NADH is oxidized to NAD^+ by the catalyst MDH.



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)

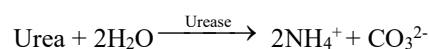
The addition of sample containing gammaglutamyltransferase to the substrates L- γ -glutamyl-3-carboxy-4-nitroanilide and glycylglycine causes the formation of L- γ -glutamyl-glycylglycine (glu-gly-gly) and 5-Amino-2-nitrobenzoate.



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 with α -oxoglutarate and reduced nicotinamide adenine dinucleotide (NADH), the enzyme glutamate dehydrogenase (GLDH) oxidizes NADH to NAD^+ .

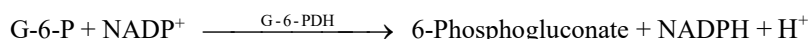
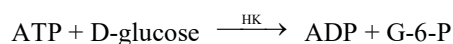


The rate of change of the absorbance difference between 340 nm and 405 nm is caused by the conversion of NADH to NAD^+ and is directly proportional to the amount of urea present in the sample.

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.



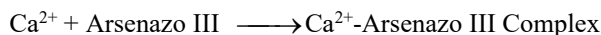
7. Alkaline Phosphatase (ALP)

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.



8. Calcium (Ca)

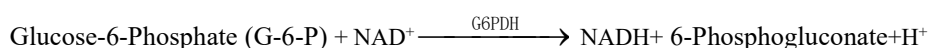
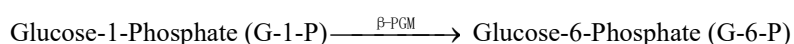
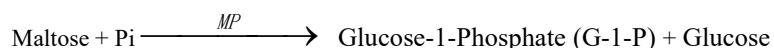
Calcium in the patient sample binds with arsenazo III to form a calcium-dye complex.



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

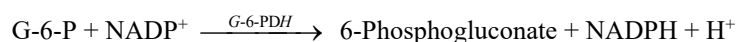
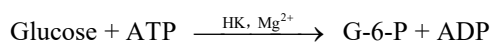
9. Phosphorus (P)

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.



10. Magnesium (Mg)

The hexokinase (HK) activation method is described as:



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 Diagnostics 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 componen of each Large Animal Diagnostics is as follows (after redissolution):

Component	Quantity
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Total protein assay reagent	13.5 µL
Albumin 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
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 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. 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.

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 ₄ Cl 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 Diagnostics

Celercare V or Pointcare V 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 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-dimensional 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 distributors 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	Equine: 57 ~ 80g/L; Bovine: 66 ~ 93g/L	Equine: 5.7 ~ 8.0g/dL; Bovine: 6.6 ~ 9.3g/dL
ALB	Equine: 22 ~ 37g/L; Bovine: 25~38g/L	Equine: 2.2 ~ 3.7 g/dL; Bovine: 2.5 ~ 3.8 g/dL
AST	Equine: 175~ 340U/L; Bovine:66 ~ 211U/L	Equine: 175 ~ 340U/L; Bovine: 66 ~ 211U/L
GGT	Equine: 5~24U/L; Bovine: 12 ~ 48U/L	Equine: 5~24U/L; Bovine:12~ 48U/L
BUN	Equine: 2.5 ~ 8.9mmol/L Bovine: 2.4 ~ 7.14mmol/L	Equine: 7 ~ 25mg/dL Bovine: 6 ~ 20mg/dL
CK	Equine: 120 ~ 470U/L; Bovine: 833 ~ 688U/L	Equine: 120 ~ 470U/L; Bovine: 833 ~ 688U/L
ALP	Equine: 50 ~ 170U/L; Bovine: 23 ~ 135U/L	Equine: 50 ~ 170U/L; Bovine: 23 ~ 135U/L
Ca	Equine: 2.9 ~ 3.6mmol/L; Bovine: 1.97 ~ 2.39mmol/L	Equine:11.5 ~ 14.2mg/dL; Bovine:7.9 ~ 9.6mg/dL
P	Equine: 0.61 ~ 1.39mmol/L; Bovine: 1.3 ~ 3.0 mmol/L	Equine: 1.9 ~ 4.3mg/dL; Bovine: 4.1 ~ 9.2mg/dL
Mg	Equine: 0.74 ~1.2mmol/L; Bovine: 0.7 ~ 1.19 mmol/L	Equine: 1.8~2.9 mg/dL; Bovine: 1.7 ~ 2.9 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 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 Diagnostics 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】



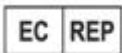
Used reagent discs contain animal body fluids. Follow good laboratory safety practices when handling and disposing of used discs. See the Celercare V or the Pointcare V chemistry analyzer Operator's Manual for instructions on cleaning biohazardous spills.





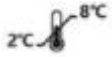

The reagent discs are plastic and may crack or chip if dropped. Never use a dropped disc as it may spray biohazardous material throughout the interior of the analyzer.

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 °C) 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】



Tianjin MNCHIP Technologies Co., Ltd.

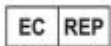
Add.: 1-4F, Area, No.122 Dongting Rd, Development Zone, 300457 Tianjin P.R. China

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Learn more about MNCHIP, other products can log in: <http://www.mnchip.com>



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