【Product Name】

Canine Inflammation Profile (7+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】

The Canine Inflammation Profile (7+2) used with the Celercare V or the Pointcare V chemistry analyzer, is intended to be used for the in vitro quantitative determination of canine C-reactive protein(cCRP), total Protein (TP), albumin (ALB), calcium (Ca), glucose (GLU), amylase (AMY),lipase (LPS) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Canine Inflammation Profile (7+2) measurements are used in the diagnosis of inflammatory diseases.

【Principles of Testing】

The Canine Inflammation Profile (7+2) is used to quantitatively test the concentration of the 7 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. 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.

4. 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.

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

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

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.

5. Amylase (AMY)

In the coupled-enzyme reaction, amylase in the sample hydrolyzes 2-chloro-*p*-nitrophenyl-α-D-maltotrioside (CNP -G3) to 2 -chloro-4-nitrophenol (CNP) producing color and D -maltotrioside. The change in absorbance of the CNP is directly proportional to the amylase activity in the sample at 405nm and 505 nm.

$$\text{CNP-G3} \xrightarrow{\text{AMY}} \text{CNP} + \text{G3}$$

6. Lipase (LPS)

The chromogenic lipase substrate 1, 2-o-dilauryl-rac-glycerol-3-glutaric acid-(6'-methylresorufin) ester is cleaved by the catalytic action of lipase to form 1, 2-o-dilauryl-rac-glycerol and an unstable intermediate, glutaric acid -(6-methylresorufin) ester. This decomposes spontaneously in alkaline solution to form glutaric acid and methylesorufin.

1, 2-o-dilauryl-rac-glycerol-3-glutaric acid-(6'-methylresorufin) ester

$$\xrightarrow{\text{lipase}} \text{1, 2-o-dilauryl-rac-glycerol} + \text{glutaric acid -(6-methylresorufin) ester}$$

$$\text{glutaric acid -(6-methylresorufin) ester} \xrightarrow{\text{decomposes}} \text{glutaric acid} + \text{methylesorufin}$$

The lipase activity in the specimen is proportional to the production of methylresorufin in the reaction at 546nm and 700 nm.

7. Canine C-reactive protein (cCRP)

The cCRP antigen in the sample agglutinates with the high-specific anti-cCRP antibody latex particles in the reagent, and forms the antigen-antibody complex to produce turbidity, and the turbidity is proportional to the cCRP concentration in the blood. The concentration of cCRP in the sample was calculated by measuring the absorbance at 600nm.

$$\text{Canine C-reactive protein} + \text{Latex particles conjugated by cCRP antibody} \longrightarrow \text{cCRP+cCRP antibody latex particle complex}$$

【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 Canine Inflammation Profile (7+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 Canine Inflammation Profile (7+2) is as follows(after redissolution):

Component	Quantity
Canine C-reactive protein assay reagent	13.5 μL
Total protein assay reagent	13.5 μL
Albumin assay reagent	13.5 μL
Calcium assay reagent	9.7 μL
Glucose assay reagent	6.6 μL
Amylase assay reagent	13.5 μL
Lipase assay reagent	13.5μL
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 Vchemistry 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 lipase to decompose, causing deviations in the test results.
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	Mg^{2+} mmol/L
TP	25	1050	200	——	——
ALB	40	600	1000	——	——
Ca	180	210	200	75	3
GLU	40	600	1000	50	——
AMY	40	1000	400	100	——
LPS	50	1000	50	30	——
cCRP	35	750	750	——	——

【Procedure】

■ Materials Provided

Canine Inflammation Profile (7+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;	Dog: 5.2 ~ 8.2g/dL;
ALB	Dog: 22 ~ 44g/L;	Dog: 2.2 ~ 4.4 g/dL;
Ca	Dog: 1.98 ~ 2.95mmol/L;	Dog: 7.9 ~ 11.8mg/dL;
GLU	Dog:3.89 ~ 7.95mmol/L	Dog:70 ~ 143mg/dL
AMY	Dog: 200 ~ 1800U/L;	Dog: 200 ~ 1800U/L;
LPS	Dog: 0 ~ 258 U/L ;	Dog:0 ~258 U/L ;
cCRP	Dog: 0 ~ 10 mg/L	0 ~ 10 mg/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 Canine Inflammation Profile (7+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%
ALB	B% ≤ 6.0%
Ca	B% ≤ 5.0%
GLU	B% ≤ 20.0%

AMY	B% ≤ 10.0%
LPS	B% ⩽ 15%
cCRP	B% ⩽ 15%

Batch precision

Analyte	Coefficient of variation (≤ *)
TP	2.0%
ALB	2.0%
Ca	3.0%
GLU	5.0%
AMY	5.0%
LPS	5.0%
cCRP	6.0%

Inter batch precision

Analyte	Relative Range (≤ *)
TP	5.0%
ALB	5.0%
Ca	5.0%
GLU	10.0%
AMY	10.0%
LPS	10.0%
cCRP	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
TP	20 ~100g/L
ALB	10~60g/L
Ca	0.5 ~ 4mmol/L
GLU	1 ~ 35 mmol/L
AMY	5~ 3500 U/L
LPS	0 ~ 350 U/L
cCRP	0~100mg/L

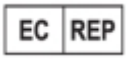
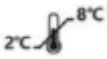
【Notes】

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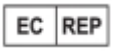
Learn more about MNCHIP, other products can log in: http://www.mnchip.com



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