【Product Name】

Feline Inflammation 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】

Feline Inflammation 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 feline serum amyloid A(fSAA), total Protein (TP), albumin (ALB), creatinine (CRE), urea nitrogen(BUN), total bile acids (TBA), alkaline phosphatase (ALP), gammaglutamyltransferase (GGT), amylase (AMY), lipase (LPS) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Feline Inflammation Profile(10+3) measurements are used in the diagnosis of inflammatory diseases.

【Principles of Testing】

The Feline Inflammation 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. 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 acidrespectively.

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

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

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

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

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.

4. 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^+.

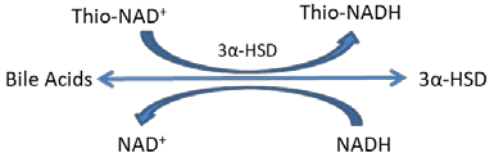
$$\text{Urea} + 2H_2O \xrightarrow{\text{Urease}} 2NH_4^+ + CO_3^{2-}$$

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

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.

5. Total Bile Acids (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 from 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.



6. 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.

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

7. 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.

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

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

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

8. 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.

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

9. 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.

$$\text{1, 2-o-dilauryl-rac-glycerol-3-glutaric acid-(6'-methylresorufin) ester} \xrightarrow{\text{lipase}} \text{1, 2-o-dilauryl-rac-glycerol + glutaric acid -(6-methylresorufin) ester}$$

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

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

10. Feline serum amyloid A(fSAA)

The fSAA antigen in the sample agglutinates with the high-specific anti-fSAA antibody latex particles in the reagent, and forms the antigen-antibody complex to produce turbidity, and the turbidity is proportional to the fSAA concentration in the blood. The concentration of fSAA in the sample was calculated by measuring the absorbance at 546nm.

$$\text{Feline serum amyloid A + Latex particles conjugated by fSAA antibody} \longrightarrow \text{fSAA+ fSAA antibody latex particle complex}$$

【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 Feline Inflammation 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 Feline Inflammation Profile(10+3) is as follows(after redissolution):

Component	Quantity
Feline serum amyloid A assay reagent	13.5 μL
Total protein assay reagent	13.5 μL
Albumin assay reagent	13.5 μL
Creatinine assay reagent	13.5 μL
Urea assay reagent	13.5 μL
Total bile acids assay reagent	13.5 μL
Alkaline Phosphatase assay reagent	13.5 μL
Gamma glutamyltransferase assay reagent	13.5 μL
Amylase assay reagent	13.5 μL
Lipase 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 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.
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	Creatine μmol/L	NH_4Cl mmol/L
TP	25	1050	200	——	——	——
ALB	40	600	1000	——	——	——
CRE	40	1050	500	25	600	——
BUN	25	600	1000	——	——	1
TBA	50	600	500	50	——	——
ALP	40	1050	400	——	——	——
GGT	40	1050	200	——	——	——
AMY	40	1000	400	100	——	——
LPS	50	1000	50	30	——	——
fSAA	35	750	750	——	——	——

【Procedure】

■ **Materials Provided**

Feline Inflammation 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	Cat:54 ~ 89g/L	Cat:5.4 ~ 8.9g/dL
ALB	Cat:22 ~ 45g/L	Cat:2.2 ~ 4.5 g/dL
CRE	Cat:27 ~ 223μmol/L	Cat:0.3 ~ 2.5mg/dL
BUN	Cat:3.6 ~ 15.5mmol/L	Cat:10 ~ 43mg/dL
TBA	Cat:0~15μmol/L	Cat:0~15μmol/L
ALP	Cat:10 ~ 90U/L	Cat:10 ~ 90U/L
GGT	Cat:0 ~ 2U/L	Cat:0 ~ 2U/L
AMY	Cat:200 ~ 1800U/L	Cat:200 ~ 1800U/L
LPS	Cat:0 ~ 143 U/L	Cat:0 ~143U/L
fSAA	Cat:0 ~ 10 mg/L	Cat: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 Feline Inflammation 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%
CRE	B% ⩽ 10.0%
BUN	B%⩽15.0%
TBA	B%⩽15.0%
ALP	B% ⩽ 10.0%
GGT	B% ⩽ 15.0%
AMY	B% ⩽ 10.0%
LPS	B% ⩽ 15%
fSAA	B% ⩽ 15%

Batch precision

Analyte	Coefficient of variation (≤ *)
TP	2.0%
ALB	2.0%
CRE	5.0%
BUN	5.0%
TBA	5.0%
ALP	5.0%
GGT	5.0%
AMY	5.0%
LPS	5.0%
fSAA	6.0%

Inter batch precision

Analyte	Relative Range (≤ *)
TP	5.0%
ALB	5.0%
CRE	10.0%
BUN	10.0%
TBA	10.0%
ALP	10.0%
GGT	10.0%
AMY	10.0%
LPS	10.0%
fSAA	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
TP	20 ~100g/L
ALB	10~60g/L
CRE	20 ~ 2000μmol/L
BUN	0.9 ~35.7mmol/L
TBA	0-150μmol/L
ALP	5 ~ 2000U/L
GGT	5 ~ 1500U/L
AMY	5~ 3500 U/L
LPS	0 ~ 350 U/L
fSAA	0~100mg/L

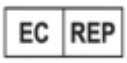
【Notes】

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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