表單編號:P-AD4201-08

AmiShield® Comprehensive Advanced Panel 18 (Plasma/Serum)

For Veterinary Use Only
For Professional Use Only

Product Part Number: 001-3IXF

----------Please follow the instructions before use----------

Intended use

The disposable AmiShield® Comprehensive Advanced Panel 18 (Plasma/Serum) in conjunction with the AmiShield® Veterinary Clinical Analyzer utilizes dry and liquid reagents to provide quantitative determinations of albumin (ALB), alkaline phosphatase (ALP), alanine aminotransferase (ALT), amylase (AMY), aspartate aminotransferase (AST), blood urea nitrogen (BUN), creatinine (CRE), glucose (GLU), phosphorus (PHOS), potassium (K^+), sodium (Na^+), total bilirubin (TBIL), total calcium (CA), and total protein (TP). At the same time through the calculation, can get the other four parameters (GLOB, ALB/ GLOB, BUN/CRE, and Na/K) information. After each test, biochemical test results can be obtained 18 to provide a basis for rapid diagnosis in lithium heparinized plasma or serum.

Clinical Significance

The disposable AmiShield® Comprehensive Advanced Panel 18 (Plasma/Serum) and the AmiShield® Veterinary Clinical Analyzer assist the veterinarian in diagnosing the following disorders:

Albumin (ALB): Hepatic and kidney diseases
Alkaline phosphatase (ALP): Hepatic, bone, parathyroid and intestinal diseases
Alanine aminotransferase (ALT): Hepatic diseases including hepatitis
Amylase (AMY): Kidney and pancreatic disease
Aspartate aminotransferase (AST): Hepatic diseases including hepatitis; cardiac diseases
Blood urea nitrogen (BUN): Hepatic and kidney diseases
Creatinine (CRE): Renal function
Glucose (GLU): Diabetes, hyperglycemia, hypoglycemia, hepatic disease
Phosphorus (PHOS): Nephrotic disease, hypoparathyroidism and nutritional disorders
Potassium (K^+): Renal glomerular or tubular disease, malnutrition, excessive intravenous potassium therapy and gastrointestinal bleeding
Sodium (Na^+): Dehydration, diabetes insipidus, toxemia, selective depression of sense of thirst, burns and trauma

Total bilirubin (TBIL): Hepatic disorders
Total calcium (CA): Parathyroid, bone and chronic renal disease, tetany
Total protein (TP): Dehydration, kidney, hepatic disease, metabolic and nutritional disorders

Globulin (GLOB) (calculated): Liver function and inflammation indicator
Albumin/Globulin (ALB/ GLOB) (calculated): indicator of inflammation and nutrition status
Blood Urea Nitrogen/Creatinine (BUN / CRE) (calculated): Kidney disease
Sodium / Potassium (Na / K) (calculated): Homeostasis of electrolytes and adrenal insufficiency

As with any diagnostic test procedure, the clinical samples or other test procedures should be considered prior to final diagnosis

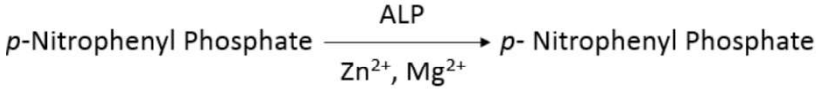
Principles of Procedures

(1) Albumin (ALB)

Dye-binding method is used to detect the quantity of albumin. Albumin is bound by the Bromcresol green (BCG) dye to produce an increase in the blue-green color measured at 620 nm. The color increase is proportional to the concentration of albumin present.

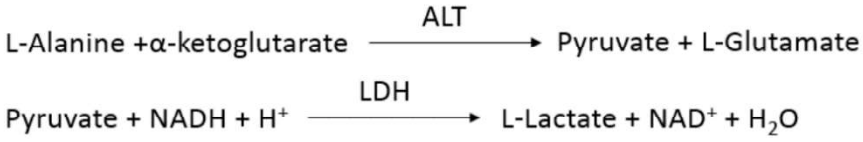
(2) Alkaline Phosphatase (ALP)

The detection method is based on the recommended method of AACC. The p-Nitrophenyl phosphate (p-NPP) is hydrolyzed to p-nitrophenol (p-NP) and inorganic phosphate by ALP catalyzation. The rate at which the p-NPP is hydrolyzed, measured at 405 nm, is directly proportional to the ALP activity.



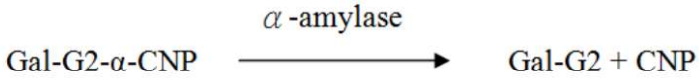
(3) Alanine Aminotransferase (ALT)

The detection procedure is based on IFCC Method. Alanine aminotransferase (ALT) catalyzes the transfer of the amino group from L-alaine to α-Ketoglutarate to yield pyruvate and L-glutamate. The pyruvate undergoes reduction with simultaneous oxidation of NADH to NAD in the LDH catalyzed indicator reaction. The resulting rate of decrease in absorbance at 340 nm is directly proportional to the ALT activity.



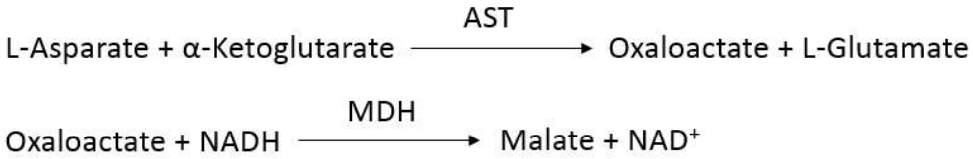
(4) Amylase (AMY)

α-Amylase hydrolyzes the 2-chloro-4-nitrophenyl-α-galactosylmaltoside (Gal-G2-α-CNP) to release 2-chloro-nitrophenol. The rate of increase in absorbance is measured at 405 nm and proportional to the α-amylase activity in the sample.



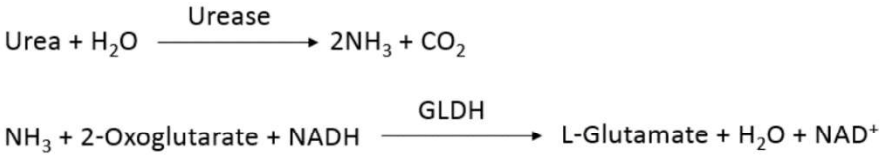
(5) Aspartate Aminotransferase (AST)

The detection method is a modification method based on IFCC Method. Aspartate aminotransferase (AST) catalyzes the transfer of the amino group from L-aspartate and α-ketoglutarate to yield oxalacetate and L-glutamate. The oxalacetate undergoes reduction with simultaneous oxidation of NADH to NAD in the malate dehydrogenase (MDH) catalyzed indicator reaction. The resulting rate of decrease in absorbance at 340 nm is directly proportional to the AST activity. Lactate dehydrogenase (LDH) is added to the reaction to prevent the interference from endogenous pyruvate which is normally present in serum.



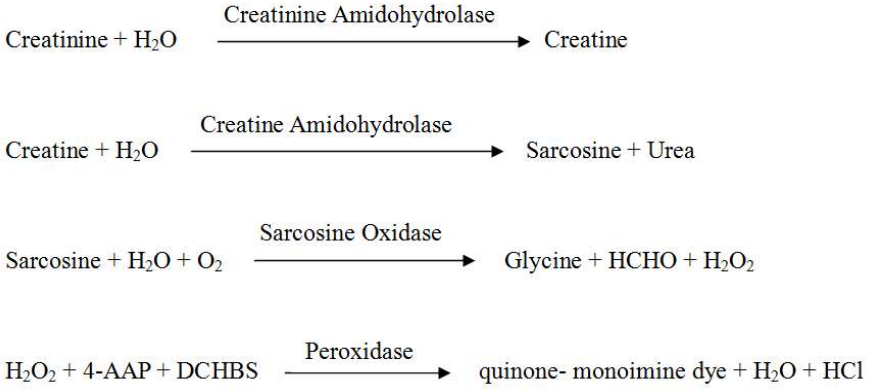
(6) Blood Urea Nitrogen (BUN)

Urea is hydrolyzed by urease to produce ammonia and carbon dioxide. The liberated ammonia reacts with α-ketoglutarate and NADH in the presence of enzyme glutamate dehydrogenase to yield glutamate and NAD. NADH undergoes oxidation during the reaction resulting in a decrease in absorbance at 340 nm that is directly proportional to the urea nitrogen concentration in the sample.



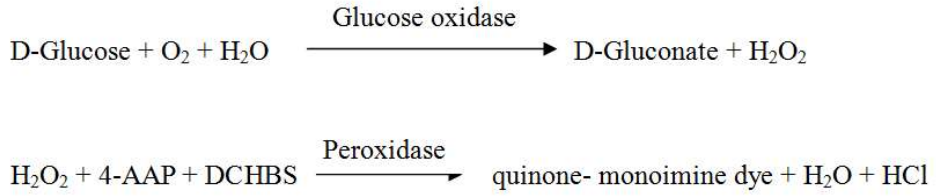
(7) Creatinine (CRE)

Creatinine is catalyzed to creatine by creatinine amidohydrolase. Under the catalyzation of creatine amidohydrolase, sarcosine and urea is produced from creatine. Sarcosine is oxidized to glycine and hydrogen peroxide (H_2O_2) in the presence of sarcosine oxidase. Hydrogen peroxide reacts with the substrates 3,5-Dichloro-2-hydroxybenzenesulfonic acid (DCHBS) and 4-aminoantipyrine (4-AAP) to form the color complex quinone- monoimine dye that absorbs at 510 nm. The rate of formation of color is proportional to the creatinine in the sample. Potassium ferrocyanide and ascorbate oxidase are added to the reaction to minimize the interference from bilirubin and ascorbic acid.



(8) Glucose (GLU)

Glucose is oxidized by glucose oxidase to gluconate and hydrogen peroxide. DCHBS, 4-AAP and hydrogen peroxide, in the presence of peroxidase, produces a quinoneimine dye that is measured at 510 nm. The absorbance at 510 nm is proportional to the concentration of glucose in the sample. Potassium ferrocyanide and ascorbate oxidase are added to the reaction to minimize the interference from bilirubin and ascorbic acid.

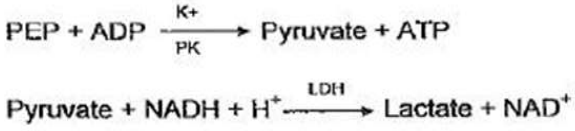


(9) Phosphorus (PHOS)

Inorganic phosphorus reacts with ammonium molybdate in a strongly acid solution to form a phosphomolybdate complex that absorbs light at 340 nm. The absorbance at this wavelength is directly proportional to the amount of inorganic phosphorus present in the sample.

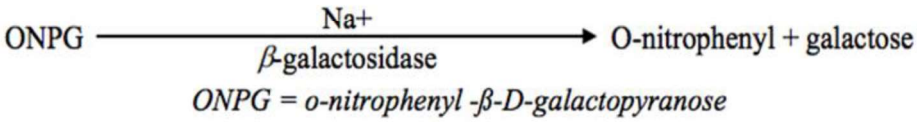
(10) Potassium (K^+)

The activation of pyruvate kinase with potassium shows excellent linearity and negligible susceptibility to endogenous substances. In the coupled-enzyme reaction, the activated pyruvate kinase (PK) dephosphorylates phosphoenolpyruvate (PEP) to form pyruvate. Subsequently, the lactate dehydrogenase (LDH) catalyzes conversion of pyruvate to lactate and the NADH is concomitantly oxidized to NAD^+. The rate of change in absorbance at 340 nm is directly proportional to the amount of potassium in the sample.



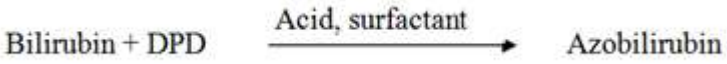
(11) Sodium (Na^+)

The β-galactosidase is activated by the sodium in the sample. The activated enzyme catalyzes the reaction of o-nitrophenyl-β-D-galactopyranoside (ONPG) to galactose ando-nitrophenol that is measured at 405 nm. The absorbance at 405 nm is proportional to the concentration of sodium in the sample.



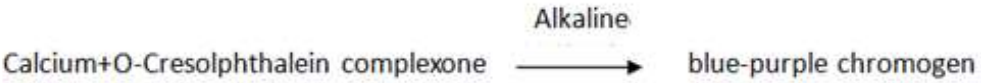
(12) Total Bilirubin (TBIL)

Total Bilirubin is coupled with a diazonium salt (DPD) in a strongly acid medium. The intensity of the color of the azobilirubin produced is proportional to the TBIL concentration and can be measured photometrically.



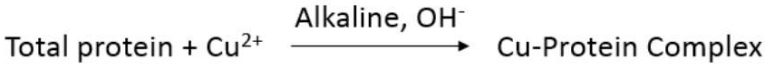
(13) Total calcium (CA)

Total calcium is coupled with o-Cresolphthalein complexone (Phthalein purple) in a alkaline solution to form blue-purple color complex. The amount of Calcium in the sample is proportional to the absorbance. For calcium determination, 8-hydroxyquinoline was added to the reagent to eliminate the interference of magnesium ions in the sample.



(14) Total Protein (TP)

The detection method is based on biuret reaction. Protein is coupled with cupric ions Cu (II) in a strongly alkaline solution to form a violet colored complex. The intensity of the color is proportional to the protein concentration.



Storage

1. Store the rotor that sealed in their foil pouches at 2 – 8 °C (36 – 46 °F). When stored as described above, all reagents in the rotor are stable until the expiration date which printed on the rotor foil pouch.
2. Do not expose opened or unopened rotor to direct sunlight or temperatures above 30 °C (86 °F).
3. Do not use a rotor after the expiration date.
4. Do not use a rotor from a damaged foil pouch. Because, a torn or otherwise damaged foil pouch may lead moisture to reach the unused rotor and adversely affect reagent performance.

Materials Required but not Provided

1. AmiShield® Veterinary Clinical Analyzer
2. Sample collector
3. Pipette and tip
4. Controls

Instructions for Reagent Handling

1. The rotor should be used for assay immediately following take out from refrigerator.
2. Open the sealed foil pouch and remove carefully the rotor. Don't touch the barcode located on the top of the rotor. The contaminated or scratched barcode will not be scanned by analyzer.
3. The rotor should be used within 20 minutes after opening the pouch. The rotor in opened pouches can't be placed back into the refrigerator for reuse.
4. The rotor would be firmly pressed onto the spindle of AmiShield® Veterinary Clinical Analyzer.
5. Transfer 0.06 mL (60 μL) sample to rotor inlet through the sample port by pipette.
6. **Use only lithium heparinized plasma or serum.**
7. The analyzer maintains the rotor at a temperature of 37 °C over the measurement interval. The analysis time is about 13-15 minutes. In addition, the AmiShield® System operates at ambient temperatures between 15°C and 30°C.

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Sample Collection and Preparation

1. The minimum required sample size is 0.06 mL (60 μL) of lithium heparinized plasma, serum or controls.
2. Use no-additive (red stopper) evacuated specimen collection tubes or serum separator tubes (yellow or red/yellow stopper) for serum samples. Use only lithium heparin (green stopper) evacuated specimen collection tubes for plasma samples.
3. Whole blood samples obtained by venipuncture must be homogenous. Gently invert the collection tubes several times just prior to sample transfer. Do not shake the collection tube. Shaking may cause hemolysis.
4. Release both the needle of syringe and the stopper of collection tube before transferring whole blood sample to collection tube.
5. The test must be started once sample is transferred into the rotor. A long delay time may affect the analytical performance.
6. Samples in the collection tubes should be separated into plasma or serum and transfer it into a clean test tube. Run the separated plasma or serum sample within 5 hours of centrifugation. If this is not possible, refrigerate the sample in a stoppered test tube at 2 – 8 °C (36 – 46 °F) for no longer than 48 hours.

Precautions

- Wear a laboratory coat and gloves to avoid the bio-hazard and puncture injury.
- The medical waste should be disposed following the local regulations.
- See the AmiShield® Veterinary Clinical Analyzer Operator's Manual for complete information on using the analyzer.

Warnings

1. When rotor embeds onto the spindle the diluent container is open. A rotor with an opened diluent container can't be reused. Ensure that the sample or control has been placed into the rotor before running the test.
2. The AmiShield® products used only with the AmiShield® Veterinary Clinical Analyzer, vice versa. Before START the test, please confirm the rotor is properly and evenly embedded into the spindle, in addition, the assembled holder should be well placed on the spindle in the Analyzer.
3. Please avoid colliding or falling damages. In this case, the rotor can't be used.
4. Reagents in the rotor may contain acids or caustic substances. The operator does not come into contact with the reagents when following the recommended procedures. In the event that the reagents are handled (e.g., cleaning up after dropping and cracking a rotor), avoid ingestion, skin contact, or inhalation of the reagents.
5. Some reagents contain sodium azide, which may react with lead and copper

plumbing to form highly explosive metal azides. Reagents will not come into contact with lead and copper plumbing when following recommended procedures. However, if the reagents do come into contact with such plumbing, flush with a large volume of water to prevent azide buildup.

Quality Control and Calibration

1. The AmiShield® Veterinary Clinical Analyzer is calibrated by the manufacturer before shipment.
2. The barcode printed on the upper cover provides the analyzer with ═ rotor-specific calibration data.
3. Controls may be run periodically on the AmiShield® Veterinary Clinical Analyzer to verify the accuracy of the analyzer by user.
4. A control is only available from producer. Run controls on the rotor in the same manner as for patient samples. See the AmiShield® Veterinary Clinical Analyzer Operator's Manual to run controls.
5. The QA/QC should be conducted following the local regulations or the laboratory guideline.

Known Interference Substances

1. The only anticoagulant recommended for the AmiShield® Veterinary Clinical Analyzer is **lithium heparin**. Sodium heparin must not be used when collecting blood sample for use with this rotor. The EDTA, fluoride, oxalate, and any anticoagulant containing ammonium ions will interfere with at least one chemistry in the AmiShield® Comprehensive Advanced Panel 18 (Plasma/Serum).
2. Physical interferents (hemolysis, icterus, and lipemia) may cause changes in the reported concentrations of some analytes. The sample indices are printed on the bottom of each result card to inform the operator about the levels of interferents present in each sample.
3. Bilirubin may interfere with the peroxidase used in the creatinine reaction. Creatinine results are lowered when bilirubin levels are > 10 mg/dL.
4. Glucose concentrations are affected by the length of time since the patient has eaten and by the type of sample collected from the patient. To accurately interpret glucose results, samples should be obtained from a patient that has been fasted for at least 12 hours.
5. Interference may be seen in the total protein test when analyzing samples with a lipemic index. Samples with a triglyceride concentration >400 mg/dL may show an increased total protein level.
6. Hemolysis samples will release some substrate to the serum or plasma, may cause AST, LDH, K and other biochemical markers increased significantly, ALT, UA,

CHOL, ALP, CK light to moderate the degree of increase. Severe hemolysis samples recommended not to use.

Reference Intervals

These normal intervals are provided only as a guideline. The most definitive reference intervals are established for your patient population. Test results should be interpreted in conjunction with the patient's clinical signs.

Analyte		Common Units		SI Units	
ALB	Canine	2.4–3.9	g/dL	24-39	g/L
	Feline	2.2–4.0	g/dL	22–40	g/L
ALP	Canine	20–212	U/L	20–212	U/L
	Feline	20–111	U/L	20-111	U/L
ALT	Canine	5–125	U/L	5–125	U/L
	Feline	5–130	U/L	5–130	U/L
AMY	Canine	500–1500	U/L	500–1500	U/L
	Feline	500–1500	U/L	500–1500	U/L
AST	Canine	5–60	U/L	5–60	U/L
	Feline	5–48	U/L	5–48	U/L
BUN	Canine	6–27	mg/dL	2.14-9.64	mmol/L
	Feline	6–36	mg/dL	2.14–12.85	mmol/L
CA	Canine	7.9-12.0	mg/dL	1.97-2.99	mmol/L
	Feline	7.8-11.3	mg/dL	1.95-2.82	mmol/L
CRE	Canine	0.3–1.5	mg/dL	27–133	μmol/L
	Feline	0.3–2.4	mg/dL	27–212	μmol/L
GLU	Canine	70–140	mg/dL	3.89–7.77	mmol/L
	Feline	75–166	mg/dL	4.2–9.2	mmol/L
K	Canine	3.5–5.8	mmol/L	3.5–5.8	mmol/L
	Feline	3.5–5.8	mmol/L	3.5–5.8	mmol/L
Na	Canine	138–160	mmol/L	138–160	mmol/L
	Feline	142–164	mmol/L	142–164	mmol/L
PHOS	Canine	2.1–6.5	mg/dL	0.68–2.1	mmol/L
	Feline	3.1–7.5	mg/dL	1–2.42	mmol/L
TBIL	Canine	0.1–0.9	mg/dL	1.7–15.4	μmol/L
	Feline	0.1–0.9	mg/dL	1.7–15.4	μmol/L
TP	Canine	5.1–8.0	g/dL	51–80	g/L

	Feline	5.7–8.9	g/dL	57–89	g/L

Dynamic range

The chemistry for each analyte is linear over the dynamic range listed below. The intervals below do not represent normal ranges.

Analyte	Common Units		SI Units	
ALB	1.0–5.0	g/dL	10.0–50.0	g/L
ALP	4–2000	U/L	4–2000	U/L
ALT	5–1500	U/L	5–1500	U/L
AMY	50–3000	U/L	50–3000	U/L
AST	5–1500	U/L	5–1500	U/L
BUN	2–200	mg/dL	0.71–71.4	mmol/L
CA	4.0 – 40.0	mg/dL	1.00 – 9.98	mmol/L
CRE	0.1–20.0	mg/dL	9–1768	μmol/L
GLU	10–500	mg/dL	0.56–27.7	mmol/L
K	2–10	mmol/L	2–10	mmol/L
Na	80–200	mmol/L	80–200	mmol/L
PHOS	2.0–15.0	mg/dL	0.68–4.85	mmol/L
TBIL	0.1–20.0	mg/dL	1.7-342	μmol/L
TP	3.0–10.0	g/dL	30.0–100.0	g/L

Method Comparison

Field studies were conducted at a veterinary teaching hospital. The same serum samples were analyzed by the AmiShield® Veterinary Clinical Analyzer and a comparative method. Representative correlation statistics are shown in below.

Analyte	Correlation Coefficient	Slope	Intercept	Sample No.	Sample Range	
ALB	0.84	0.53	1.36	83	1.5-4	g/dL
ALP	0.93	1.02	11.09	81	23-3016	U/L
ALT	0.99	0.88	7.73	83	10-704	U/L
AMY	0.93	0.73	264.36	77	323-2450	U/L
AST	0.99	0.91	4.46	83	9-259	U/L
BUN	0.97	0.89	3.34	83	8-124	mg/dL
CA	0.95	0.69	3.43	86	5.3-11.6	mg/dL
CRE	0.97	0.92	0.09	83	0.4-9.1	mg/dL
GLU	0.98	1.01	-3.23	83	77-434	mg/dL
K	0.94	0.89	0.81	20	3.0-8.5	mmol/L

Na	0.91	0.91	12.35	20	125-188	mmol/L
PHOS	0.93	0.87	0.52	83	2.2-10.5	mg/dL
TBIL	0.95	1.06	0.03	83	0.1-2.2	mg/dL
TP	0.93	0.92	0.47	83	3-7.9	g/dL

Bibliography

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- Wu AHB, ed. Tietz clinical guide to laboratory tests, 4th edition, p.880. W.B. Saunders Company, St. Louis, 2006.
- Abaxis. VetScan Operator's Manual. 2012.

Symbols

	Consult Instructions for use		Caution
	Temperature Limitation		Reference Number
	Batch code		Manufacturer
	Use by		Do Not Reuse

Manufacturer：ProtectLife international Biomedical Inc.
Address：4F., No.8, Xinghua Rd., Taoyuan Dist., Taoyuan City 33068, Taiwan
Customer and Technical Service：886 3 3775599
Official Website：www.protectlife-intl.com