AmiShield® Equine Profile Panel

For Veterinary Use Only
For Professional Use Only

Catalog Number: **001-3GYD**

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

Intended use

The disposable AmiShield® Equine Profile Panel in conjunction with the AmiShield® Veterinary Clinical Analyzer utilizes dry and liquid reagents to provide quantitative determinations of albumin (ALB), alkaline phosphatase (ALP), aspartate aminotransferase (AST), blood urea nitrogen (BUN), creatinine (CRE), creatine kinase (CK), glucose (GLU), gamma glutamy transferase (GGT), lactate dehydrogenase (LDH), phosphorus (PHOS), total calcium (CA), total cholesterol (CHOL), and total protein (TP). At the same time through the calculation, can get the other three parameters (GLOB, ALB/ GLOB, BUN/CRE) information. After each test, biochemical test results can be obtained 16 to provide a basis for rapid diagnosis in lithium heparinized whole blood, lithium heparinized plasma or serum.

Clinical Significance

The disposable AmiShield® Equine Profile Panel 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
Aspartate aminotransferase (AST): Hepatic diseases, including viral hepatitis and cirrhosis; cardiac diseases
Blood urea nitrogen (BUN): Hepatic and kidney diseases
Creatinine (CRE): Renal disease
Creatine kinase (CK): Mainly used in clinical diagnosis of muscle damage and myocardial infarction
Glucose (GLU): Diabetes, hyperglycemia, hypoglycemia, hepatic disease
Gamma glutamyl transferase (GGT): Bile duct disease
Lactate dehydrogenase (LDH): Body parts are directly injured or used to diagnose myocardial infarction, liver disease.
Phosphorus (PHOS): Nephrotic disease, hypoparathyroidism and nutritional disorders
Total calcium (CA): Parathyroid, bone and chronic renal disease；tetany
Total cholesterol (CHOL): Risk factors for atherosclerosis, cardiovascular disease
Total protein (TP): Dehydration, kidney, hepatic disease, metabolic and nutritional

disorders

Globulin (GLOB) (calculated): Liver function

Albumin/Globulin (ALB/ GLOB) (calculated): an important indicator of viral hepatitis and cirrhosis

Blood urea Nitrogen/Creatinine (BUN / CRE) (calculated): Kidney disease

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

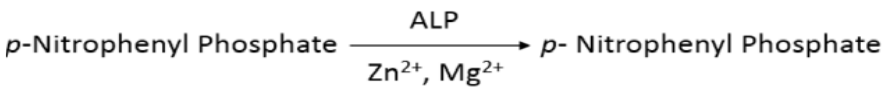
Principles of Procedures

(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.

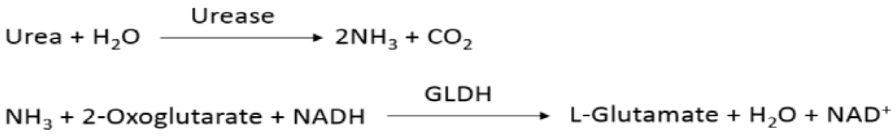


(3) Aspartate Aminotransferase (AST)

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.

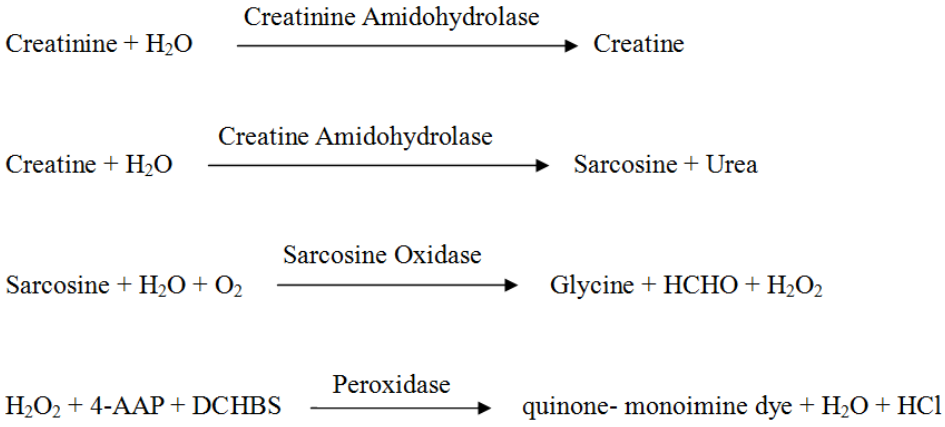
(4) Blood urea Nitrogen (BUN)

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.



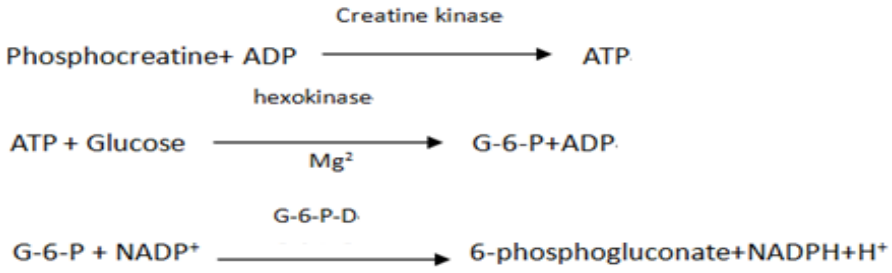
(5) Creatinine (CRE)

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.



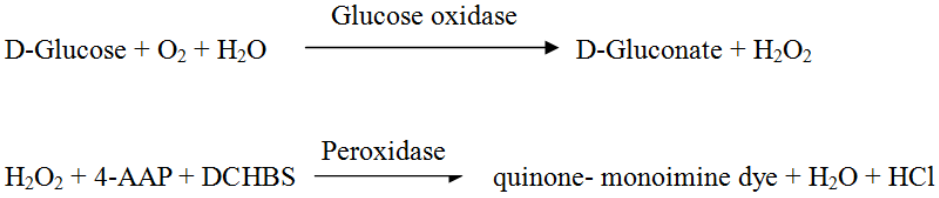
(6) Creatine kinase (CK)

Phosphocreatine in serum or plasma generates adenylamine triphosphate (ATP) by creatine kinase (CK), which phosphorylates glucose by hexokinase to generate glucose-6-phosphate, Glucose-6-phosphate dehydrogenase and NADH can be detected after oxidation of NADPH. The absorption of NADPH at 340nm, which can calculate the blood or plasma creatine kinase (CK) levels.



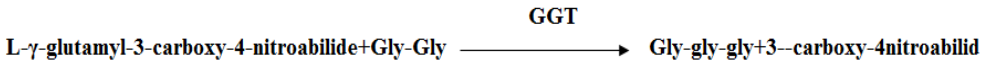
(7) Glucose (GLU)

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.



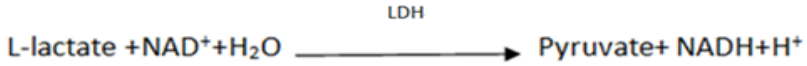
(8) Gamma glutamyl transferase (GGT)

The detection method is a modification method based on IFCC Method. The addition of sample containing gamma glutamyl transferase to the substrates L-γ-glutamyl-3-carboxy-4-nitroabilide and glycylglycine(gly-gly) causes the formation of L-γ-glutamyl-glycylglycine(gly-gly-gly) and 3-carboxy-4-nitroabilid. The production of 3-carboxy-4-nitroabilid is proportional to the GGT activity in the sample.



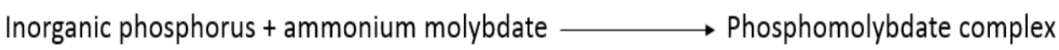
(9) Lactate dehydrogenase (LDH)

Lactate dehydrogenase in serum or plasma reacts with L-lactate and nicotine amine purine dinucleotide (NAD+) generates pyruvate and detectable NADH, which color intensity is directly proportional to lactate dehydrogenase activity in serum or plasma.



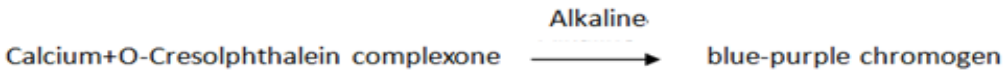
(10) Phosphorus (PHOS)

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.



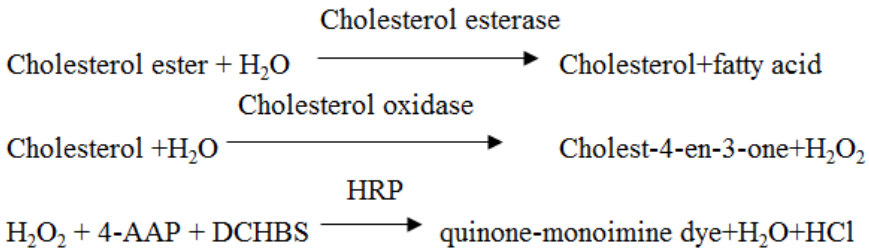
(11) Total calcium (CA)

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.



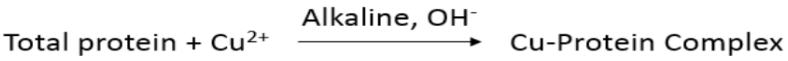
(12) Total cholesterol (CHOL)

Esterase (COE) hydrolyzes esters in blood or serum and generates cholesterol, which is oxidized by cholesterol oxidase (COD) to produce ketones and generate hydrogen peroxide. 3,5-Dichloro-2-hydroxybenzenesulfonic acid (DCHBS), 4-aminoantipyrine (4-AAP) and hydrogen peroxide catalyzed hydrogen peroxide via catalase to form a quinone- monoimine dye. The absorbance at 510 nm is proportional to total cholesterol (TC) concentration, from which the level of total cholesterol (TC) can be calculated. Potassium ferrocyanide and ascorbate oxidase are added to the reaction to reduce the interference of bilirubin and ascorbic acid.



(13) 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 0.14 mL (140 μL) sample to rotor inlet through the sample port by pipette.
6. **Use only lithium heparinized whole blood, 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 0.14 mL (140 μL) of lithium heparinized whole blood/plasma/serum or control.
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 whole blood/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. Lithium heparinized whole blood samples should be run within 60 minutes of collection; if this is not possible, separate the sample 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 biohazard 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® Equine Profile Panel.
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. Hematocrit (Hct)> 60% of whole blood samples may affect the test results.
7. 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	Equine	1.9 - 3.6	g/dL	19 – 36	g/L
ALP	Equine	10 - 326	U/L	10 – 326	U/L
AST	Equine	100 - 600	U/L	100 – 600	U/L
BUN	Equine	8 - 27	mg/dL	2.8 – 9.6	mmol/L
CA	Equine	10.4 - 13.4	mg/dL	2.59 – 3.34	mmol/L
CHOL	Equine	50 - 110	mg/dL	1.30 – 2.86	mmol/L
CRE	Equine	0.6 - 2.2	mg/dL	53 – 194	μmol/L
CK	Equine	10 - 350	U/L	10 – 350	U/L
GGT	Equine	1 - 87	U/L	1 – 87	U/L
GLU	Equine	64 - 150	mg/dL	3.55 – 8.33	mmol/L
LDH	Equine	25 - 1500	U/L	25 – 1500	U/L
PHOS	Equine	1.8 - 5.6	mg/dL	0.58 – 1.81	mmol/L
TP	Equine	5.6 - 7.9	g/dL	56 – 79	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 – 5	g/dL	10 – 50	g/L
ALP	4 – 2000	U/L	4 – 2000	U/L
AST	5 – 1500	U/L	5 – 1500	U/L
BUN	2 – 200	mg/dL	0.7 – 71	mmol/L
CA	4 – 40	mg/dL	1 – 10	mmol/L
CHOL	20 – 500	mg/dL	0.5 – 13	mmol/L
CRE	0.1 – 20	mg/dL	8.8 – 1768	μmol/L
CK	50 – 2000	U/L	50 – 2000	U/L
GGT	1 – 2000	U/L	1 – 2000	U/L
GLU	10 – 500	mg/dL	0.56 – 27.75	mmol/L
LDH	50 – 1500	U/L	50 – 1500	U/L
PHOS	2 – 15	mg/dL	0.65 – 4.85	mmol/L
TP	3 – 10	g/dL	30 – 100	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 (R2)	Slope	Intercept	Sample No.	Sample Range	
ALB	0.89	0.92	0.13	40	2.4 – 4.0	g/dL
ALP	0.97	0.98	-4.36	40	105 – 956	U/L
AST	0.98	0.96	6.64	40	18 – 935	U/L
BUN	0.91	1.00	-0.74	40	8 – 49	mg/dL
CA	0.93	1.11	-1.72	40	4 – 32	mg/dL
CHOL	0.90	0.93	11.75	40	51 – 273	mg/dL
CRE	0.99	0.99	-0.01	40	0.2 - 18.2	mg/dL
CK	0.95	0.97	6.79	40	26 – 587	U/L
GGT	0.99	1.11	-0.76	40	3 – 1452	U/L
GLU	0.98	1.00	5.52	40	30 – 357	mg/dL
LDH	0.95	0.86	52	40	56 – 923	U/L
PHOS	0.96	0.92	0.43	40	2.1 – 10.8	mg/dL
TP	0.86	0.99	0.19	40	1.5 – 7.6	g/dL

Bibliography

- Guder WG, Narayanan S, Wisser H, et al. List of analytes-preanalytical variables.

Annex In: Samples: From the Patient to the Laboratory. Darmstadt, Germany: GITVerlag, 1996:Annex 22-3.

- National Committee for Clinical Laboratory Standards (NCCLS). Evaluation of precision performance of clinical chemistry devices; approved guideline NCCLS Document EP5-A. Wayne, PA: NCCLS, 1999.
- 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