Amishield® CHOL/TRIG/GLU Panel

In Veterinary use only

For Professional Use Only

Product Part Number: **001-23JC**

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

Intended use

The disposable Amishield® CHOL/TRIG/GLU Panel in conjunction with the Amishield® Veterinary Clinical Chemistry Analyzer utilizes dry and liquid reagents to provide quantitative determinations of total cholesterol (CHOL), triglycerides (TRIG) and glucose (GLU) in lithium heparinized whole blood, lithium heparinized plasma or serum.

Clinical Significance

The disposable Amishield® CHOL/TRIG/GLU Panel and the Amishield® Veterinary Clinical Chemistry Analyzer assist the veterinarian in diagnosing the following disorders:

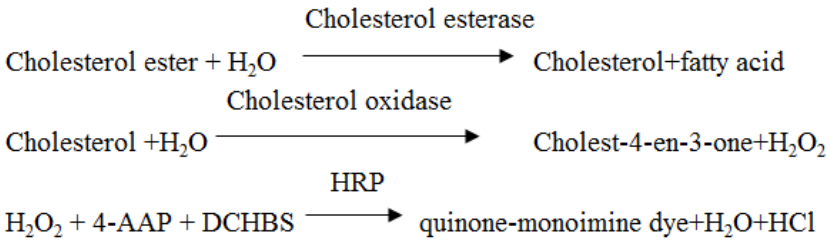
Total cholesterol (TC) : Risk factors for arteriosclerosis, cardiovascular disease.
Triglycerides (TG) : Risk factors for arteriosclerosis, cardiovascular disease.
Glucose (GLU) : Diabetes, hyperglycemia, hypoglycemia, hepatic disease.

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

Principles of Procedures

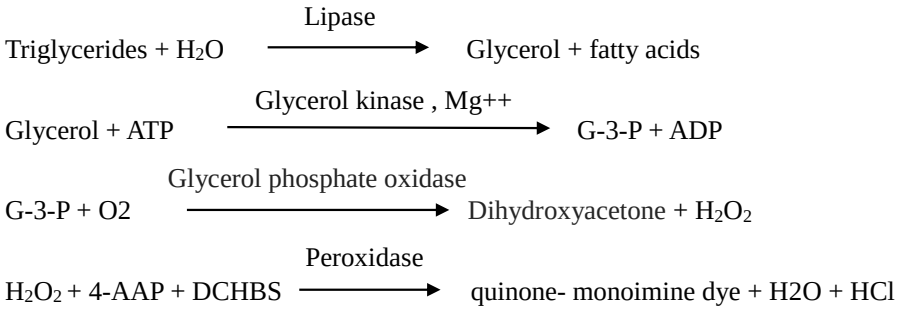
Cholesterol (CHOL)：

The common test procedures typically employ cholesterol esterase and cholesterol oxidase. Cholesterol is oxidized to cholest-4-en-3-one and hydrogen peroxide (H2O2) in the presence of cholesterol 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.



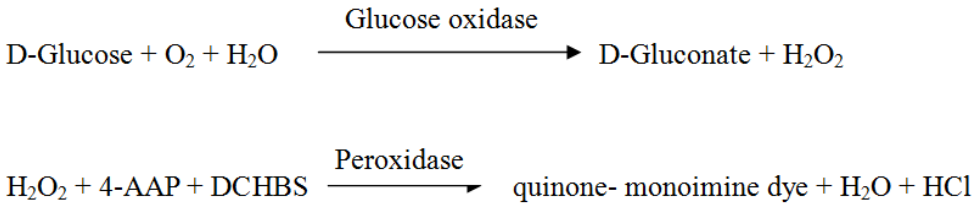
Triglycerides (TRIG)：

Triglycerides is hydrolyzed by lipase to produce glycerol and fatty acid. Under the catalyzation of glycerol kinase and magnesium ion, Glyceraldehyde 3-phosphate (G-3-P) and ADP is produced from glycerol and ATP. G-3-P is oxidized to dihydroxyacetone and hydrogen peroxide (H2O2) in the presence of glycerol phosphate 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 triglycerides in the sample. Potassium ferrocyanide and ascorbate oxidase are added to the reaction to minimize the interference from bilirubin and ascorbic acid.



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.



Storage

1. The expiration date is printed on the foil pouch. Do not use the discs after the expiration date.
2. Store the discs that sealed in their foil pouches at 2 – 8 ℃ (36 – 46 ℉). When stored as described above, all reagents in the disc are stable until the date of use by which printed on the disc foil pouch.
3. Open the pouch and remove the disc just prior to use. Do not expose opened or unopened discs to direct sunlight or temperatures above 30 ℃ (86 ℉).
4. Do not use the discs after the date of use by. The date of use by is printed on the disc foil pouch.
5. Do not use the discs from a damaged foil pouch. Because, a torn or otherwise damaged foil pouch may lead moisture to reach the unused disc and adversely affect reagent performance.
6. Notice：After removing the pouch at 2 – 8 °C, please use it immediately, do not return to room temperature. Disc which is return to the room temperature may 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. Use directly Reagent disc from the refrigerator without warming.
2. Open the sealed foil pouch and remove carefully the disc. Don’t touch the barcode located on the top of the disc. The contaminated or scratched barcode will not be scanned by analyzer.
3. The disc should be used within 20 minutes after opening the pouch. The disc in opened pouches can’t be placed back into the refrigerator for reuse.
4. Reverse the disc buckle press firmly into the disc till hearing “click”. After clicking the buckles, please avoid reversing the disc to effuse the reagent.
5. Embed the disc on the holder (Note: three discs should be assembled into the holder before analysis) and ensure the balance (Note: the dummy disc could be used for balance). The holder assembling three discs would be firmly pressed onto the spindle of AmiShield® Veterinary Clinical Analyzer.
6. Transfer 0.06 mL (60μL) the sample to disc inlet through the sample port by

pipette.

7. Use only lithium heparinized whole blood, lithium heparinized plasma (green stopper evacuated specimen collection tubes) or serum (red or red/black stopper evacuated specimen collection tubes).
8. The analyzer maintains the disc at a temperature of 37 ℃ over the measurement interval. The analysis time is about 13-15 minutes. In addition, the AmiShield® System operates at ambient temperatures between 15℃ and 30℃.

Sample Collection and Preparation

1. The minimum required sample size is 60 μL of lithium heparinized whole blood, lithium heparinized plasma, serum or control. The reagent disc inlet can contain up to 60 μL of sample.
2. Collected specimens should be dispensed into the reagent disc immediately.
3. Use no-additive (red stopper) evacuated specimen collection tubes or serum separator tubes (red or red/black stopper) for serum samples. Use only lithium heparin (green stopper) evacuated specimen collection tubes for whole blood or plasma samples.
4. Whole blood samples obtained by venipuncture must be homogenous before transferring a sample to the reagent disc. Gently invert the collection tubes several times just prior to sample transfer. Do not shake the collection tube. Shaking may cause hemolysis.
5. Release both the needle of syringe and the stopper of collection tube before transferring whole blood sample to collection tube. Wear a laboratory coat and gloves to avoid the bioharzard and puncture injury.
6. The test must be started once sample is transferred into the reagent disc. A long delay time may affect the analytical performance.
7. Whole blood venipuncture 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 ℃ (36–46 ℉) for no longer than 48 hours.
8. A plasma or serum sample can be stored at -10℃ (14℉) for up to 5 weeks in a freezer that does not have a self-defrost cycle.

⚠ ***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. ***The diluent container in the disc should be manually opened by reversing the buckle in the disc and firmly pressing it before embeds into the spindle. A disc with an opened diluent container can't be reused. Ensure that the sample or control has been placed into the disc before running the test.***
2. ***The AmiShield® products used only with the AmiShield® Veterinary Clinical Chemistry Analyzer, vice versa. Before START the test, please confirm the disc 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 disc can't be used.***
4. ***Reagents in the disc 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 reagent disc), 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 disc-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 serum-based control is only available from producer. Run controls on the disc 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 Chemistry Analyzer is lithium heparin. Sodium heparin must not be used when

collecting blood sample for use with this panel. The EDTA, fluoride, oxalate, and any anticoagulant containing ammonium ions will interfere with at least one chemistry in the Amishield CHOL/TRIG/GLU 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. Whole blood samples with a hematocrit (Hct) greater than 60% may affect the test results.

Test Item	Substance concentraion with interferences of less than ±10%			
	Conjugated bilirubin(mg/dL)	Unconjugated bilirubin(mg/dL)	Intralipid(mg/dL)	Hemoglobin(mg/dL)
TRIG	4.3	4.3	*—	<500 no significant impact
CHOL	5.1	5.1	345.1	<500 no significant impact
GLU	7.0	7.0	547.8	<500 no significant impact

*Intralipid does not interfere with TG measurement.

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	
CHOL	Canine	110–320	mg/dL	2.86–8.32	mmol/L
	Feline	82–220	mg/dL	2.13–5.72	mmol/L
	Rabbit	35–60	mg/dL	0.91–1.56	mmol/L
TRIG	Canine	22–125	mg/dL	0.24–1.38	mmol/L
	Feline	25–133	mg/dL	0.28–1.46	mmol/L
	Rabbit	124–156	mg/dL	1.36–1.72	mmol/L
GLU	Canine	70–140	mg/dL	3.89–7.77	mmol/L
	Feline	75–166	mg/dL	4.16–9.21	mmol/L
	Rabbit	75–150	mg/dL	4.16–8.33	mmol/L

Performance characteristics

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
CHOL	20-500 mg/dL	0.52-13.00 mmol/L
TRIG	20-500 mg/dL	0.22-5.50 mmol/L
GLU	50-500 mg/dL	2.78-27.75 mmol/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 (IDEXX Catalyst Dx). Representative correlation statistics are shown in below.

Analyte	Correlation Coefficient	Slope	Intercept	Sample No.	Sample Range
CHOL	0.968	0.963	+4.528	19	77-340 mg/dL
TRIG	0.973	0.902	+12.845	19	27-427 mg/dL
GLU	0.991	1.025	- 4.201	23	80-308 mg/dL

Bibliography

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Symbols

 Consult Instructions for use  Caution

IVD	In vitro Diagnostic	REF	Reference Number
	Temperature Limitation		Manufacturer
LOT	Batch code	CE	Denotes conformity to specified European directives
	Use by		Do Not Reuse
EC REP	Authorised Representative in the EU		Biological Risks

ProtectLife international Biomedical Inc.
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Official Website：www.protectlife-intl.com
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Borkstrasse 10, 48163 Muenster, Germany