

# AmiShield<sup>®</sup> Total T4/CHOL Panel

For Veterinary Use Only

For Professional Use Only

Product Part Number: 001-21KA

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

## Intended use

The disposable AmiShield<sup>®</sup> Total T4/CHOL Panel in conjunction with the AmiShield<sup>®</sup> Veterinary Clinical Analyzer utilizes dry and liquid reagents to provide quantitative determinations of Total T4 in lithium heparinized plasma or serum.

## Clinical Significance

The disposable AmiShield<sup>®</sup> Total T4/CHOL Panel and the AmiShield<sup>®</sup> Veterinary Clinical Analyzer assist the veterinarian in diagnosing the following disorders:

Total T4: hyperthyroidism and hypothyroidism

Total Cholesterol (CHOL): hypercholesterolemia and hypercholesterolemia

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

## Principles of Procedures

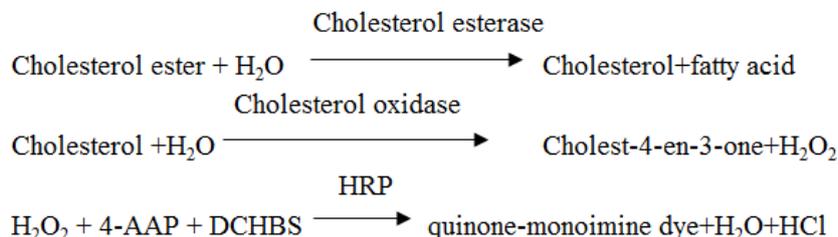
### (1) Total T4

The 8-anilino-1-naphthalene sulfonic acid (ANS) dissociates endogenous T4 from the plasma binding proteins. The released endogenous T4 competes for antibody (Ab) binding sites with T4 labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH-T4 conjugate). G6PDH-T4 conjugate bound to antibody has lower activity than does unbound conjugate. In the absence of thyroxine from the sample, the G6PDH labeled thyroxine is bound by the specific antibody and the enzyme activity is inhibited. The rate of change of the absorbance at 340 nm is due to the conversion of NAD<sup>+</sup> to NADH and is directly proportional to the amount of endogenous T4 in the sample.

### (2) Total 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 (H<sub>2</sub>O<sub>2</sub>) 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.



### Storage

1. Store the discs that sealed in their foil pouches at 2 – 8 °C (36 – 46 °F). When stored as described above, all reagents in the disc are stable until the expiration date which printed on the disc foil pouch.
2. Do not expose opened or unopened discs to direct sunlight or temperatures above 30 °C (86 °F).
3. Do not use the discs after the expiration date.
4. 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.

### Materials Required but not Provided

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

### Instructions for Reagent Handling

1. Each foil pouch contains a disc and one diluents tube with transparent top. The disc should be used for assay immediately following take out from refrigerator.
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 (60 µL) sample to diluents tube by pipette and screw the lid on tightly. Gently invert the tube several times.
7. Transfer 0.06 mL (60 µL) the diluted sample to disc inlet through the sample port by pipette. The undiluted sample will cause erroneous results.
8. Use only lithium heparinized plasma or serum.
9. The analyzer maintains the disc 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.

### **Sample Collection and Preparation**

1. The minimum required sample size is 0.06 mL (60 µL) of heparinized 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 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 disc. 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 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 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 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 Analyzer is lithium heparin. Sodium heparin must not be used when collecting blood sample for use with this disc. EDTA, fluoride, oxalate, and any anticoagulant containing ammonium ions will interfere with at least one reagent in the AmiShield® Total T4/CHOL Panel.

- Physiological 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.

## 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		
Total T4	Canine	1.1-4.0	µg/dL	14.2-51.5	nmol/L
	Feline	0.8-4.7	µg/dL	10.3-60.5	nmol/L
	Rabbit	1.7-2.4	µg/dL	21.9-30.9	nmol/L
Total Cholesterol (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

## 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	
Total T4	0.3 – 10.0	µg/dL	3.9 – 128.7	nmol/L
Total Cholesterol (CHOL)	20 – 500	mg/dL	0.52-13.00	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. Representative correlation statistics are shown in below.

Analyte	Correlation Coefficient	Slope	Intercept	Sample No.	Sample Range	
Total T4	0.992	1.092	-0.158	20	0.8-11.0	µg/dL
Total Cholesterol (CHOL)	0.948	0.968	-3.260	20	44-360	mg/dL

## Bibliography

- Carmel T. Mooney, Mark Peterson. BSAVA Manual of canine and feline endocrinology. 4th ed. 2012.
- Chen I-W, et al. Thyroxine: In:LA Kaplan and AJ Pesce, eds., Clinical Chemistry: Theory, Analysis and Correlation, 2nd ed. St. Louis: The C.V.

Mosby Company; 1989:956-959.

- Kaneko JJ, Harvey JW, Bruss ML. Clinical Biochemistry of Domestic Animals, 6th ed. San Diego, CA: Academic Press; 2008

## 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](http://www.protectlife-intl.com)