AmiShield® Bile acid Disc

For Veterinary Use Only
For Professional Use Only

Product Part Number: **001-21LN**

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

Intended use

The disposable AmiShield® Bile acid Disc in conjunction with the AmiShield® Veterinary Clinical Analyzer utilizes dry and liquid reagents to provide quantitative determinations of Bile acid in lithium heparinized plasma or serum.

Clinical Significance

The disposable AmiShield® Bile acid Disc and the AmiShield® Veterinary Clinical Analyzer assist the veterinarian in diagnosing the following disorders:

Bile acid (TBA): Hepatobiliary disease; portosystemic vascular anomaly (PSVA); extrahepatic shunting.

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

Principles of Procedures

Bile acid (TBA)

In the presence of the Thio-NAD^+ (thio-derivative of nicotinamide adenine dinucleotide), the enzyme 3-α-HSD (3-α-Hydroxysteroid Dehydrogenase) reversibly oxidizes bile acids to oxidized bile acids (3-α-keto forms) with the concomitant conversion of Thio-NAD^+ to 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 cycling reaction amplifies the levels of bile acids from the sample. The rate of increase per minute in absorbance at 405 nm (Thio-NADH) is measured and is proportional to the concentration of total bile acids in the sample. The rate is measured bichromatically at 405 nm.

$$\text{Bile Acids} + \text{Thio-NAD}^+ \xrightarrow{3\alpha\text{-HSD}} \text{Thio-NADH} + \text{H}^+$$

$$\text{3-α-keto steroids} + \text{NADH} + \text{H}^+ \xrightarrow{3\alpha\text{-HSD}} \text{Bile Acids} + \text{NAD}^+$$

Storage

1. Store the disc 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 expiration date which printed on the disc foil pouch.

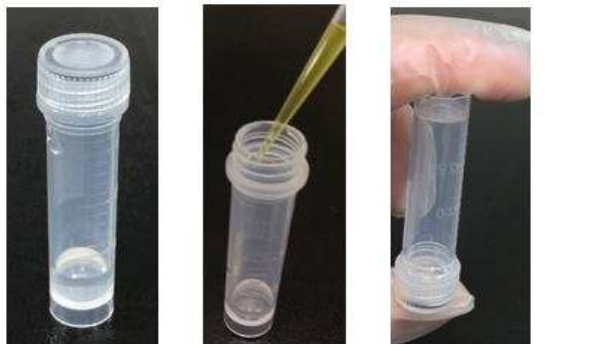
2. Do not expose opened or unopened disc to direct sunlight or temperatures above 30 ℃ (86 ℉).
3. Do not use a disc after the expiration date.
4. Do not use a disc from a damaged foil pouch. Because, a torn or otherwise damaged foil pouch may lead moisture to reach the unused disc and adversely affect 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.



Diluents tube Add sample Invert three 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 ℃ 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 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 ℃ (36 – 46 ℉) for no longer than 48 hours.

Precautions

- Wear a laboratory coat and gloves to avoid the bioharzard 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 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® Bile acid Disc.
2. 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	
Bile acid (TBA)	Canine	1-25	µmo/L	1-25	µmo/L
	Feline	1-11	µmo/L	1-11	µmo/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	
Bile acid (TBA)	1-150	µmo/L	1-150	µmo/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	
Bile acid (TBA)	0.9917	1.0383	0.4896	20	1-102	µmol/L

Bibliography

- 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.
- O'Leary CA, Parslow A, Malik R, et al. The inheritance of extra-hepatic portosystemic shunts and elevated bile acid concentrations in Maltese dogs. J Small Anim Pract 2014; 55: 14-21.
- Bridger N, Glanemann B, Neiger R. Comparison of postprandial and ceruletide serum bile acid stimulation in dogs. J Vet Intern Med 2008; 22: 873-8.
- Gerritzen-Bruning MJ, van den Ingh TS, Rothuizen J. Diagnostic value of fasting plasma ammonia and bile acid concentrations in the identification of portosystemic shunting in dogs. J Vet Intern Med 2006; 20: 13-9.

Symbols

	Consult Instructions for use	⚠	Caution
	Temperature Limitation	REF	Reference Number

LOT	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.co