AmiShield® SAA Disc

For Veterinary Use Only
For Professional Use Only

Catalog Number: **001-21PE**

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

Intended use

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

Clinical Significance

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

Serum Amyloid A（SAA）

Infectious, inflammatory diseases, tissue injury, malignant tumors, tissue necrosis, and surgery.

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

Principles of Procedures

Serum Amyloid A（SAA）

SAA in the sample specifically combines with the SAA antibodies to form a precipitate that causes increased turbidity. The degree of turbidity can be measured optically and is proportional to the concentration of serum amyloid A in the sample.

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.

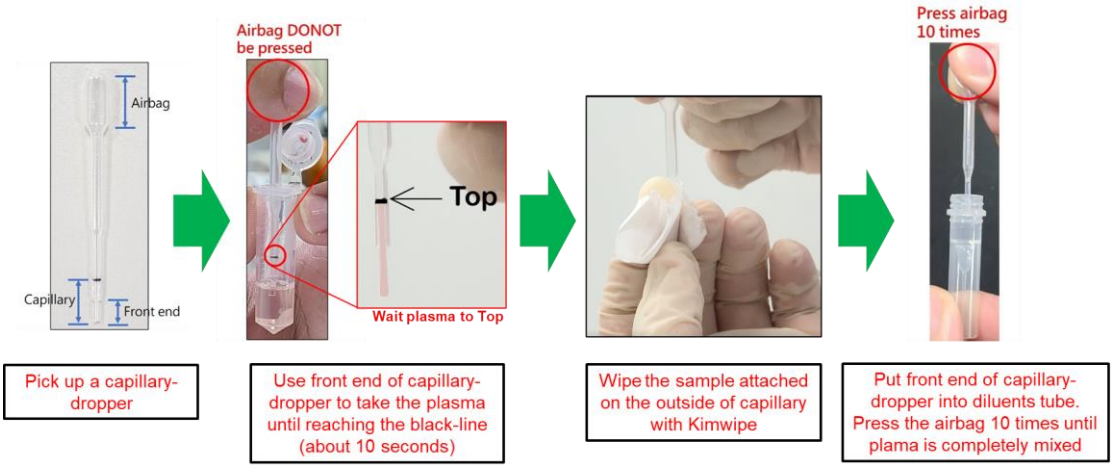
Materials Required but not Provided

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. 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. Use Lithium Heparinized Plasma for SAA detection. Before operating, centrifuge whole blood by 5,000 rpm for 5 minutes, then supernatant is plasma.
7. Use front end of capillary-dropper to capillary the plasma until reaching the black-line (about 10 seconds)(Fig.1). Wipe the sample attached on the outside of capillary with Kimwipe, and put front end of capillary-dropper into diluents tube. Then, press the airbag 10 times until plasma is completely mixed.

(Fig.1)



8. 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.
9. Use only lithium heparinized plasma or serum.
10. 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. 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. Run the separated plasma or serum sample within 5 hours after centrifugation. **Please invert the dilution tube of plasma 5 times before injecting to SAA disc.** Plasma sample can be stored at 2–8°C (36–46°F) for no longer than 48 hours, or be frozen at -20°C (-4°F) for up to two months (Avoid repeating freeze and thaw).

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® SAA 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 Unis	
SAA	Feline	0.1-5.0	μg/mL	0.1-5.0	mg/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 Unis	
SAA	0.1-200.0	μg/mL	0.1-200.0	μg/mL

Bibliography

- Jose Joaquin Ceron et al., Acute phase proteins in dogs and cats: current knowledge and future perspectives. Vet Clin Pathol. 2005 Jun;34(2):85-99.
- Kajikawa et al., Changes in concentrations of serum amyloid A protein, alpha 1-acid glycoprotein, haptoglobin, and C-reactive protein in feline sera due to induced inflammation and surgery. Vet Immunol Immunopathol. 1999 Mar 29;68(1):91-8.
- Takashi Tamamoto et al., Verification of measurement of the feline serum amyloid A (SAA) concentration by human SAA turbidimetric immunoassay and its clinical application. J Vet Med Sci. 2008 Nov;70(11):1247-52.
- A Giordano et al., Changes in some acute phase protein and immunoglobulin concentrations in cats affected by feline infectious peritonitis or exposed to feline coronavirus infection. Vet J. 2004 Jan;167(1):38-44.
- Takashi Tamamoto et al., Serum amyloid A as a prognostic marker in cats with various diseases.J Vet Diagn Invest. 2013 May;25(3):428-32.

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