

AmiShield® Fructosamine Disc

For Veterinary Use Only

For Professional Use Only

Product Part Number: 001-21LQ

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

Intended use

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

Clinical Significance

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

Fructosamine

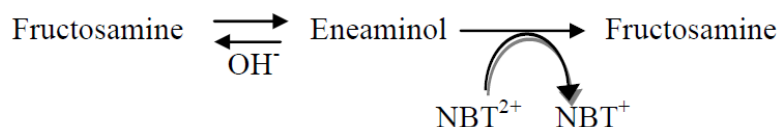
Monitoring blood glucose status of diabetics over a period (1-3 weeks).

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

Principles of Procedures

Fructosamine

The colorimetric assay is based on the ability of ketoamines to reduce nitrotetrazolium-blue (NBT) to formazan in an alkaline solution. The rate of formazan is directly proportional to the concentration of fructosamine. The rate of reaction is measured photometrically at 552 nm.



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. 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".
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) the sample to disc inlet through the sample port by pipette.
7. Use only lithium heparinized whole blood, plasma or serum.
8. 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 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 disc. 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. 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® Fructosamine 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.

Fructosamine values for		Common Units		SI Unis	
Normal non-diabetic animal	Canine	260–378	µmol/L	260–378	µmol/L
	Feline	191–349	µmol/L	191–349	µmol/L
Newly diagnosed diabetic animal	Canine	> 320	µmol/L	> 320	µmol/L
	Feline	> 350	µmol/L	> 350	µmol/L

Attention : Vomiting, diarrhea, and gastrointestinal problems will cause the diseases of albumin loss, and affect the accuracy of fructosamine. Therefore, the hypoalbuminemia, hypoglobulinemia and feline hyperthyroidism will cause a pseudo-low concentration of fructosamine.

Reference range for treated diabetic animals

Control level	Canine Fructosamine (µmol/L)	Feline Fructosamine (µmol/L)
Poor control	>450	>550
Fair control	400–450	450–550
Good control	350–400	350–450
Excellent control	<350	<350

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	
Fructosamine	100 – 1000	µmol/L	100 – 1000	µmol/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	
Fructosamine	0.981	0.962	15.394	20	5-700	µmol/L

Precision data

Test Item	N	Sample	Mean	Between-run	
				SD	% CV
Fructosamine	12	Level 1	168.4	12.9	7.7
		Level 2	316.6	27.6	8.7

Expiration date

Please see the information printed on the disc foil pouch.

Reference

- Armbruster DA, et al. Fructosamine: Structure, analysis, and clinical usefulness. Clin Chem. 1987; 33(12):2153-63.
- Reusch CE, et al. Evaluation of fructosamine in dogs and cats with hypo- or hyperproteinaemia, azotaemia, hyperlipidaemia and hyperbilirubinaemia. Vet Rec. 2001; 148(12):370-6.
- Reusch CE, et al. Fructosamine. A new parameter for diagnosis and metabolic control in diabetic dogs and cats. J Vet Intern Med. 1993; 7(3):177-82.
- Loste A, Marca MC Fructosamine and glycated hemoglobin in the assessment of glycaemic control in dogs Vet. Res. 32 (2001) 55–62.

- ISFM Consensus Guidelines on the Practical Management of Diabetes Mellitus in Cats. Journal of Feline Medicine and Surgery (2015) 17, 235–250
- Ellen Behrend, Amy Holford, Patty Lathan, Renee Rucinsky, Rhonda Schulman, AAHA Diabetes Management Guidelines for Dogs and Cats. 2018 Jan/Feb JAAHA 54:1

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