AmiShield®Diabetes Disc

For Veterinary Use Only
For Professional Use Only

Catalog Number: **001-21LR**

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

Intended use

The disposable AmiShield® HbA1c Disc in conjunction with the AmiShield® Veterinary Clinical Analyzer utilizes dry and liquid reagents to provide quantitative determinations of HbA1c in EDTA whole blood.

Clinical Significance

The disposable AmiShield® HbA1c Disc and the AmiShield Veterinary Clinical Analyzer assist the veterinarian in diagnosing the following disorders:

HbA1c

Monitoring blood glucose status of diabetics over a period (2–3 months).

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

Principles of Procedures

HbA1c

HbA1c in the sample specifically combines with the HbA1c antibodies to form a precipitate that causes increased turbidity. The degree of turbidity can be measured optically and is proportional to the concentration of HbA1c 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.

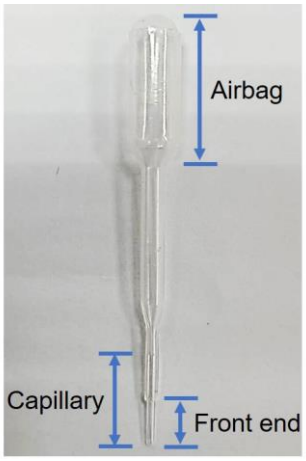
Materials Required but not Provided

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 with blue 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. Use EDTA whole blood for HbA1c detection. Open the foil pouch to get diluents tube(blue top), use front end of capillary-dropper (Fig. 1) to transfer EDTA whole blood (about 30 seconds). 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 EDTA whole blood is completely lysed (The inside and outside of the capillary are the same color).

Fig. 1 Capillary-dropper



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. 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°C and 30°C.

Sample Collection and Preparation

1. The minimum required sample size is 0.01 mL (10 μL) of EDTA whole blood.
2. Use only EDTA (purple stopper) evacuated specimen collection tubes for whole blood 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 diluted sample is transferred into the disc. A long delay time may affect the analytical performance.

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 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

Test Item	Substance concentration with interferences of less than ±10%		
	Conjugated bilirubin(mg/dL)	Unconjugated bilirubin(mg/dL)	Intralipid (mg/dL)
HbA1c	<35 no significant impact	<35 no significant impact	<1500 no significant impact

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	
HbA1c	Canine	<4.0	%	<4.0	%

Attention: Hemophilin-poor anemia patients (eg, hemolytic anemis, pernicious anemia, chronic loss of blood, chronic renal failure, pregnancy, etc.) may be measured pseudo-low HbA1c value. If patients's hemoglobin (Hb) is between 8.5~19 g/dL ,accurate results can be provided, out of this range can be assisted with fructosamine to track the effects of diabetes treatment.

Reference ranges for treated diabetic animals

Canine HbA1c (%)	
4-6.5%	Pre- Diabetic
>6.5%	(Fasting Glucose >300mg/dL) Diabetic
Treated diabetic dogs:	
4 –4.9%	excellent control
5 –5.9%	good control
>=6%	fair control

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	
HbA1c	3-13.0	%	3-13.0	%

Performance characteristics

Accuracy (Method Comparison):

The same clinical samples were tested on the AmiShield Clinical Chemistry Analyzer and the comparison machine, and the results of the tests were correlated using statistical methods base on CLSI EP9-A3.

Analyte	Correlation Coefficient	Slope	Intercept	Sample No.	Sample Range
HbA1c	0.973	0.962	+0.2468	47	3.9~12.6%

Reference

- Braatvedt GD, Drury PL, Cundy T.Assessing glycaemic control in diabetes: relat ionships between fructosamine and HbA1C. N Z Med J. 1997 Dec 12;110(1057):45962.

- Goemans AF, Spence SJ, Ramsey IK. Validation and determination of a reference interval for canine HbA1c using an immunoturbidimetric assay. Vet Clin Pathol. 2017 Jun;46(2):227-237.
- Elliott DA, Nelson RW, Reusch CE, Feldman EC, Neal LA. Comparison of serum fructosamine and blood glycosylated hemoglobin concentrations for assessment of glycemic control in cats with diabetes mellitus. J Am Vet Med Assoc. 1999 Jun 15;214(12):1794-8.
- Loste A, Marca MC Fructosamine and glycated hemoglobin in the assessment of glycaemic control in dogs Vet. Res. 32 (2001) 55–62
- Yu-Hsin Lien, Hui-Pi Huang, Glycosylated Hemoglobin Concentrations in Dogs with Hyperadrenocorticism and/or Diabetes Mellitus Compared to Clinically Healthy Dogs. JVCS. 2009 April Vol. 2, No. 2

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
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