Healvet®

Canine Glycosylated hemoglobin(cHbA1c) Rapid Quantitative Test

INTENDED USE

The Healvet™ HbA1c Rapid Quantitative Test is a fluorescence immunoassay used along with Healvet™ FIA 3000 for quantitative determination of canine HbA1c concentration in canine whole blood. The test is used as an aid to Diabetes diagnostic testing.

For *in vitro* diagnostic use only. For professional use only.

TEST PRINCIPLE

1.This test employs a quantitative Double antibody sandwich fluorescence immunoassay technique.

2.The fluorescent signal intensity reflects the amount of HbA1c captured and is processed in Healvet™ FIA 3000. The HbA1c concentration is expressed in %.

WARNINGS AND PRECAUTIONS

1.This kit is for in vitro diagnostic use only. Do not swallow.

2.Lot Number of all the test components (test device, ID chip and buffer) must match each other. Do not mix components from different kit lots.

3.Inspect the packaging and labels before use. Do not use if the pouch is broken, torn or not well sealed, or the vial looks damaged or leaked.

4.Carefully follow the instructions and procedures described in this insert.

5.Do not use the test device beyond the expiration date. The test device must remain in its original sealed pouch until ready to use. Do not use if the pouch or the device itself is damaged, torn or not fully sealed.

6.A buffer tube should be used for processing one sample only.

7.The operation shall be conducted away from vibration and magnetic field. Healvet™ FIA 3000 may generate minute vibration during use, which should be regarded as normal.

8.One pipette tip should be used for one specimen only.

9.Do not touch the test area of the test device

10.All specimens and used test materials are considered as potentially infectious. The used pipette tips, buffer tubes, test devices and specimens must be handled carefully and disposed of in accordance with local regulations and procedures.

MATERIAL

Material Provided

1.10 individual sealed pouches, each containing:

■ a test Device

■ a desiccant pouch

2.One Test Device ID Chip

3.Instructions for Use

4.10 tubes of Tris-HCl buffer

5. Pipette Tips

Material Required But Not Provided

1.Healvet™ FIA 3000

2.Transfer Pipette

3.Timer

4.Centrifuge

STORAGE AND STABILITY

1.Store the test kit at 4～30℃ up to the expiration date.

2.Once the pouch is opened, the test should be performed within an hour.

3.If removed from refrigerator, allow the test for 30 minutes to attain room temperature before testing.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed on whole blood

For Whole Blood:

1.Following standard phlebotomy venipuncture procedure, collect whole blood specimen containing anticoagulants (EDTA recommended).

2.It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.

3.It's not suitable to test the whole blood samples which have been stored at 2℃～8℃ for more than 48 hours.

Bring all meterials to room temperature before use. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

Refer to Healvet™ FIA 3000 Operation Manual for complete instructions for use of the Test device.

1.Set a Test Device on a clean, level horizontal place.

2.Make sure that the Test Device lot No. matches with ID Chip No. Insert ID Chip into the meter. Be aware not to touch the insertion tip of the ID chip.

3.Pipette 10μl of prepared whole blood sample into the buffer, gently mix well 1min. Vigorous agitation and foaming should be avoided.

4.Pipette 75μl of mixed sample to add into the sample of the test device. Avoid forming bubbles.

5.Please refer to the Section V Operation in Operation Manual for details.

a) Quick Test mode: start the timer right after adding the sample mixture to the sample well. Leave the Test Device at room temperature for 5 minutes. Then insert test device immediately onto the holder of the meter and click Test. The instrument will scan the Test Device automatically and show the test result.

b) Standard Test mode: insert the Test Device into the device holder of the Meter right after adding the sample to the sample well, click Test. The meter will start to countdown and read the test result automatically.

6.Results are displayed on the main screen or be printed by click Print.

INTERPRETATION OF RESULTS

1.The Healvet™ FIA 3000 calculates HbA1c test results automatically and displays the concentration of HbA1c on the screen right after correctly adding the sample to the sample well for 5 minutes. For further information, refer to the Operation Manual for the Healvet™ FIA 3000.

2.Healvet™ FIA 3000 will prompt "Abnormal C-line" when insufficient sample volume or liquid is not fully crawled across the test line, then recommends adding sample again.

QUALITY CONTROL

Each Healvet™ HbA1c Rapid Quantitative Test contains an internal control for routine quality control requirements. This internal quality control is performed each time a patient sample is tested, If an invalid result from the internal control occurs, the meter will display an error message, indicating that another test should be conducted.

LIMITATIONS OF PROCEDURE

1.This test is developed for testing canine whole blood.

2.The results of Healvet™ HbA1c Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If test results do not agree with the clinical evaluation, additional tests should be performed accordingly.

3.The performance of the test is highly sensitive to the storage and handling conditions of kits and samples.

4.There is the possibility that factors such as technical or procedural errors may interfere with the test and cause erroneous results.

5.Sample interference (haemolysis/icterus/lipaemia) may cause abnormal results.

6.Vitamin C and vitamin E can inhibit glycosylation of glycosylated hemoglobin, which make the HbA1c test value was low.High doses of salicylate, erythropoietin, antiretrovirals, and ribavirin can shorten the life of red blood cells, which make the HbA1c test value was low

7.Other diseases：Hypertriglyceridemia and hyperbilirubinemia can increase HbA1c levels, while chronic liver disease can reduce HbA1c levels by interfering with red blood cell production and reducing its lifespan.

8.The HbA1c life span is consistent with that of red blood cells, so any factors that alter the life span of red blood cells in the blood(such as hemolytic anemia, aplastic anemia, massive blood loss or transfusion, and chronic malaria)，can effect HbA1c measurement results.In hemolytic anemia, immature red blood cells increase and their binding sites for glucose decrease;The number of reticulocyte increased in patients with active bleeding and uremia treated with dialysis, but the red blood cells life span was shortened, and the HbA1c measured at this time was low.Factors that can also increase the life span of red blood cells, such as splenectomy, red blood cell clearance disorder, decreased reticulogenesis, and aplastic anemia, can increase the level of HbA1c in the blood.

INTERPRETATION

Reference range of HbA1c in canine blood:

1.Detection range : 4%-14.5%

2.Reference:

Test Result	Significance
4.0%-6.0%	normal
6.0%-8.0%	Subclinical stage
>8.0%	diabetes

Each Laboratory should establish a reference range that is representative of the population to be evaluated.

MANUFACTURED BY

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Version No : HbA1c20201201-A03EN