Healvet®

Thyroxine（T4）Rapid Quantitative Test

INTENDED USE

The Healvet™ Thyroxine（T4）Rapid Quantitative Test is a fluorescence immunoassay used along with Healvet™ FIA 3000 for quantitative determination of canine or feline T4 concentration in canine or feline serum or plasma specimen. The test is used to assist in the evaluation of thyroid function.

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

TEST PRINCIPLE

This test employs a quantitative competitive fluorescence immunoassay technique. A competitive binding assay is based upon the competition of labeled and unlabeled analyte for a limited number of antibody binding sites. Unbound antibodies and immunocomplexes migrate along the nitrocellulose membrane forward to the Test line. The unbound antibodies are then captured by antigens immobilized on the Test line. The more T4 in the patient specimen, the more immnocomplexes are formed, thus the less fluorescent-labeled antibodies captured on the test line. The fluorescent signal intensity reflects the amount of T4 captured and is processed in Healvet™ FIA 3000.The T4 concentration is expressed in nmol/L.

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.
11. Recommend the use of serum or plasma. Maybe there are some interfering substances in whole blood, which may affect the accuracy of test results.
12. Please do not use the serum separator tube for testing，which may affect the accuracy of test results.

MATERIAL

Material Provided

Each box contains:
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 testfor 30 minutes to attain room temperature before testing.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either serum or plasma.

For Serum or Plasma:

1.Following standard phlebotomy venipuncture procedure, collect whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended). If serum sample will be used, use a vessel without anticoagulant (do not use the serum separator tube).
2.Separate serum from blood within 2 hours after blood collection.If a specimen appears to be severely hemolyzed, another specimen should be obtained and tested.
3.Optimally, the test should be performed immediately after the specimen collection. If the test cannot be performed within 2 hour after blood collection, store the specimen at 2℃～8℃ for no longer than 48 hours. For long-term storage, specimens shall be kept below -20℃.

Bring all materials 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 75μl of prepared sample into the buffer and mix well.
4. Immediately pipette 75μl of mixed sample to add into the sample of the test device. The mixed sample must be added within 2 minutes.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 15 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 T4 test results automatically and displays the concentration of T4 on the screen right after correctly adding the sample to the sample well for 15 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™ T4 (Thyroxine) 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 meterwill display an error message, indicating that another test should be conducted.

LIMITATIONS OF PROCEDURE

1.This test is developed for testing canine or feline serum or plasma specimen.
2.The results of Healvet™ T4 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 false positive results include cross-reactions with some components of blood from individual to antibodies; and non-specific adhesion of some components in canine or feline blood that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of T4 antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The performance of the test is highly sensitive to the storage and handling conditions of kits and sample specimens at optimal conditions.
4.There is the possibility that factors such as technical or procedural errors, as well as additional substances in blood specimens that are not listed in the Cross-Reactivity section, may interfere the test and cause erroneous results.
5. T4 may decrease with a normal thyroid gland: ①older dogs and special breeds (such as hounds, greyhounds, wolfhounds, and east African hounds) have lower normal T4. ②In healthy dogs, the physiological mechanism of the body also decrease the total T4 concentration, which fluctuates throughout the day, sometimes below the reference level. ③Normal thyroid syndrome (ESS) may produce cytokines such as interleukin and TNF (tumor necrosis factor) and release them into the blood, which inhibited T4. ④Some drugs may alter the metabolism of thyroxine, they inhibits T4 concentrations, such as corticosteroids, barbiturates, nonsteroidal anti-inflammatory drugs (NSAIDs), and synergetic sulfanilamide. When test T4, these drugs need to be discontinued, and the withdrawal time should be determined according to the characteristics, dosage and duration of different drugs.
6. Causes of increased T4 in hypothyroidism: the blood's own thyroglobulin autoantibody (TgAA) can compete with antibodies used in immunology tests, which influences test results. When the circulating TSH value increases and the total T4 value is within the normal range, free T4 should be detected by balanced dialysis method to ensure that it will not be disturbed by antibodies.

INTERPRETATION

Reference range of Thyroxine in canine or feline blood:
1.Detection range: 6.4~120nmol/L　0.5~9.3ug/dL
　　1 ug/dL=12.87 nmol/L
2.Reference:

	Signification	nmol/L	μg/dL
Canine	low	<12.9	<1.0
	normal	12.9-50	1.0-3.9
	high	>50	>3.9
Feline	low	<10.3	<0.8
	normal	10.3-60	0.8-4.7
	high	>60	>4.7

Each Laboratory should establish a reference range that is representative of the population to be evaluated. The diagnosis must be made in conjunction with other clinical symptoms and tests.

MANUFACTURED BY

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