InSight™ V-IA

Thyroxine（T4）Rapid Quantitative Test

INTENDED USE

The InSight V-IA Thyroxine（T4）Rapid Quantitative Test is a fluorescence immunoassay used with the InSight V-IA Veterinary Immunoassay Analyser for quantitative determination of canine or feline T4 concentration in canine or feline serum or plasma. The test is used to assist in the evaluation of thyroid function.

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

TEST PRINCIPLE

This test employs a quantitative competitive fluorescence immunoassay technique. A competitive binding assay is based upon the competition of labelled and unlabelled analytes for a limited number of antibody binding sites. Unbound antibodies and immunocomplexes migrate along the nitrocellulose membrane towards the test line. The unbound antibodies are then captured by antigens immobilised on the test line. The more T4 in the patient specimen, the more immunocomplexes are formed, thus the less fluorescent-labelled antibodies captured on the test line. The fluorescent signal intensity reflects the amount of T4 captured and is processed in InSight V-IA Veterinary Immunoassay Analyser. The T4 concentration is expressed in nmol/L or μg/dl.

WARNINGS AND PRECAUTIONS

1.This kit is for in vitro diagnostic use only.
2.The Lot No. 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, unsealed or the cartridge/buffer is damaged.
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 unsealed.
6.A buffer tube should be used for processing one sample only.
7.One pipette tip should be used for one sample only.
8.Do not touch the test area of the test device.
9.All samples and used test materials are considered 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.
10. Serum or plasma samples must be used. Do NOT use whole blood as inaccurate results may report.
11. Do NOT use a serum separator tube as inaccurate results may report.

MATERIAL

Materials Provided

Each box contains:

- 10 individual sealed test cartridges
- One test device ID Chip
- Instructions for use
- 10 buffer tubes

Materials Required but Not Provided

- InSight V-IA Veterinary Immunoassay Analyser
- Pipette
- Timer
- Centrifuge

STORAGE AND STABILITY

1.Store the test kit at 4～30℃ up to the expiration date.
2.Once the pouch has been opened, the test should be performed within an hour.
3.If removed from the refrigerator, allow 30 minutes for the test to attain room temperature before testing.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either serum or plasma.
1.Following standard phlebotomy venipuncture procedure, collect whole blood sample using a blood collection tube. If a plasma sample will be used, use a blood collection tube containing lithium heparin anticoagulant. If a serum sample will be used, use a plain serum tube.
2.Separate serum or plasma from blood within 2 hours after blood collection. If a sample appears to be severely haemolysed, another sample should be obtained and tested.
3.The test should be performed immediately after the specimen collection. If the test cannot be performed within 2 hours after blood collection, store the sample at 2℃～8℃ for no longer than 48 hours. For long-term storage, samples should be kept below -20℃.
Bring all materials to room temperature before use. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly. Only clear, non-haemolysed specimens should be used.

TEST PROCEDURE

Refer to InSight V-IA Veterinary Immunoassay Analyser User Manual for complete instructions for use of the analyser.
1.Set the test cartridge on a clean, level horizontal surface.
2.Make sure that the cartridge Lot No. matches with the ID Chip No. Insert the ID Chip into the analyser. Be aware not to touch the insertion tip of the ID Chip. Press “Read ID Card” on the test screen.
3.Pipette 75μl of prepared sample into the buffer tube, gently mix well. Vigorous agitation and foaming should be avoided.
4.Pipette 75μl of mixed sample dilution to the sample well of the test cartridge. Avoid forming bubbles.
5.Please refer to Section V in the InSight V-IA Veterinary Immunoassay Analyser User Manual for details.
a) **Quick Test Mode:** Set the timer for 15 minutes, start the timer immediately after adding the sample mixture to the sample well. Once the timer has counted down, insert the test device immediately into the cartridge holder of the analyser 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 cartridge holder of the analyser immediately after adding the sample to the sample well, click ‘Test’. The analyser will start to countdown and read the test results automatically.
6.Results are displayed on the main screen and printed automatically.

INTERPRETATION OF RESULTS

The InSight V-IA Veterinary Immunoassay Analyser calculates T4 test results automatically and displays the concentration of T4 on the screen. For further information, refer to the User Manual for the InSight V-IA Veterinary Immunoassay Analyser.

Reference range of Thyroxine in canine or feline blood:
1.Detection range: 8~100 nmol/L / 0.62~7.77 μg/dL
Reference Ranges:

		nmol/L	μg/dL
Canine	low	<15	<1.2
	normal	15-50	1.2-3.9
	high	>50	>3.9
Feline	low	<15	<1.2
	normal	15-60	1.2-4.7
	high	>60	>4.7

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

QUALITY CONTROL

Each InSight V-IA T4 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 analyser will display an error message, indicating that another test should be performed
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LIMITATIONS OF PROCEDURE

1.This test is developed for testing canine or feline serum or plasma only.
2.The results of InSight V-IA 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 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.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 decreases 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 (tumour necrosis factor) and release into the blood, which inhibits T4. ④Some drugs may alter the metabolism of thyroxine, they inhibit T4 concentrations, such as corticosteroids, barbiturates, nonsteroidal anti-inflammatory drugs (NSAIDs) and synergetic sulfanilamide.
6.Sample interference (haemolysis/icterus/lipaemia) may cause abnormal results.
7. Causes of increased T4 in hypothyroidism: the blood's 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 antibodies are not causing interference of the T4 result.

MANUFACTURED BY

Woodley Equipment Company Ltd.
Old Station Park Buildings, St. John Street, Horwich, Bolton, BL6 7NY, UK
Tel: +44 (0) 1204 669033
Email: sales@woodleyequipment.com
Web: www.woodleyequipment.com