

**TRUFORMA**

## Total Thyroxine (tT4) Test

FOR THE QUANTITATIVE  
DETECTION OF TOTAL  
THYROXINE (tT4) LEVELS  
IN CANINE OR FELINE SERUM

**For Veterinary Use Only**

READ ALL INSTRUCTIONS  
BEFORE BEGINNING THE ASSAY

For Customer Assistance:  
734-369-2555 (Option 1)

Distributed and manufactured by:  
Zomedica  
Plymouth, MN 55447 USA  
[www.zomedica.com](http://www.zomedica.com)

### INTENDED USE

The TRUFORMA® Total Thyroxine (tT4) Test is used for the quantitative detection of total thyroxine (tT4) levels in canine and feline serum in the assessment of thyroid function.

### OVERVIEW

Thyroxine (T4) is a major hormone produced by the thyroid gland. T4 takes two forms when found in canine or feline serum: protein-bound T4 (inactive) and unbound free T4, which is the biologically active form of the hormone. The TRUFORMA tT4 Test measures total concentration of both T4 forms.

This test employs a single-use cartridge containing assay-specific reagents for the detection of total thyroxine (T4) in canine or feline serum. The TRUFORMA tT4 Test works as a competitive immunoassay utilizing a biotin labeled T4 specific monoclonal antibody, a releasing agent to release T4 bound to serum binding proteins, and a solid phase coated with T4 attached to a carrier protein. During the test, sample, releasing agent, and anti-T4-antibody are mixed together and flow across the T4-coated bulk acoustic wave (BAW) biosensor. T4 bound to T4 binding proteins is released into solution, and all T4 present in the sample is available to bind to the antibody in solution, preventing that antibody from binding to the T4-coated biosensor. After a wash step, the sensor is exposed to a streptavidin enzyme conjugate, which attaches to the biotinylated anti-T4 bound to the surface.

The enzyme converts the substrate to an insoluble product that accumulates on the BAW biosensor surface and is measured as a shift in frequency by the BAW biosensor. This signal is proportional to the amount of enzyme present on the BAW biosensor surface. The change in frequency is used to calculate the concentration of T4 present in the sample using the stored calibration curve. As a competitive immunoassay, a sample containing a low concentration of T4 results in a higher amount of antibody-enzyme conjugate attached to the solid phase and a larger signal. Thus, concentrations of serum T4 are inversely proportional to the amount of anti-T4 antibody that is bound to the solid phase. Total T4 concentrations that fall outside of the normal reference range may be indicative of abnormal levels of total T4 as a result of a thyroid condition.

### PRECAUTIONS & WARNINGS

- Do not use a cartridge after the expiration date printed on the cartridge pouch.
- Do not remove the cartridge from pouch until ready for use.
- Use a new disposable bulb pipette for each test.
- Do not use a cartridge from a pouch that appears to be tampered with, torn or damaged.
- Do not use a cartridge if it appears to be cracked, broken, leaking liquid or otherwise damaged.
- For veterinary in vitro diagnostic use of feline and canine serum samples only.
- As with any diagnostic test procedure, all other test procedures including the clinical status of the patient should be considered prior to final diagnosis.

### STORAGE & HANDLING

- Store cartridges at refrigerated temperature (2–8 °C/35–46 °F).
- Do not freeze cartridges.
- Serum samples may be stored under refrigerated conditions (2–8 °C/35–46 °F) for up to 4 days prior to testing.
- Cartridges may be left at room temperature (20–25 °C/68–77 °F) for up to 24 hours in the protective pouch, and up to 4 hours out of the protective pouch prior to use. If not used in this time period, dispose of the cartridge.

### COMPONENTS

1. tT4 Cartridge(s)
2. Disposable Bulb Pipette(s)
3. Instructions for Use

### SERUM COLLECTION

Collect blood in blood collection tubes without anticoagulant. After complete clotting has occurred, separate serum by centrifugation.

The TRUFORMA tT4 Test has been tested with red-top tubes with no additives and has not been evaluated with all types of blood collection tubes. Results may vary depending on the tube used due to the presence of additives such as clot activators, serum-separator gels, or preservatives.

## TEST PROCEDURE

1. Confirm that the cartridge has not expired by reviewing the expiration date on the pouch label.
2. While wearing gloves, remove the cartridge from pouch and place on a flat surface. The pouch contains a desiccant that can be disposed of as normal waste.
3. Using supplied bulb pipette, dispense the sample into sample port (approximately 150 µL). Recommended technique for adding sample: With sample-filled bulb pipette (**Figure 1**), wet the sample port filter by placing the bulb pipette tip on top of the sample port filter and lightly squeeze the pipette (**Figure 2**), dispensing a small amount of sample. Lift bulb pipette tip off sample port filter and dispense remaining sample into sample port as shown in **Figure 3**.
4. Ensure all of the sample has been absorbed into the sample port with no pooling. Sample pooling in the port may be an indicator that the port has been overfilled. Do NOT overfill the sample port.
5. Place the cartridge into the instrument by holding the sample port end with the cartridge label facing up and following the arrow indicated insert direction displayed on the cartridge label. Gently push the cartridge into the cartridge receiver until the instrument accepts and draws in the cartridge.
6. After the test is completed, the results will be displayed on the TRUFORMA system results screen and will also be electronically sent to myZomedica.com.
7. Dispose of the used cartridges and bulb pipettes in a biohazardous waste container.

## USING DISPOSABLE BULB PIPETTE



Figure 1

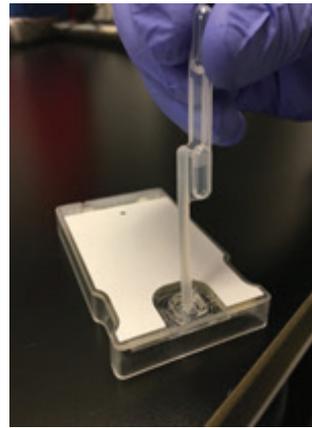


Figure 2

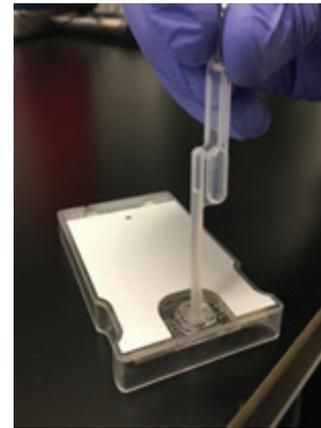


Figure 3

Table 1: Canine and Feline Reference Range

	TRUFORMA Canine	TRUFORMA Feline
Reference Range (µg/dL)	1.11-4.03	0.90-3.82

Table 2: tT4 Dynamic Range

	TRUFORMA Canine	TRUFORMA Feline
Lower Limit of Quantitation (µg/dL)	0.45	0.47
Upper Limit of Quantitation (µg/dL)	30.0	30.0

Figure 4: Correlation of Canine TRUFORMA tT4 with Comparative Method

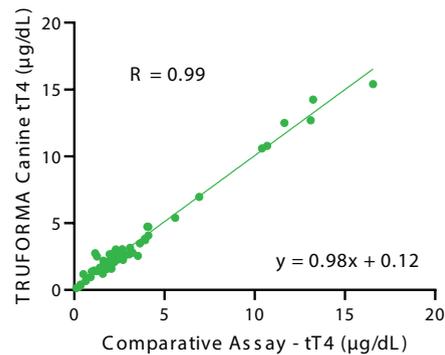
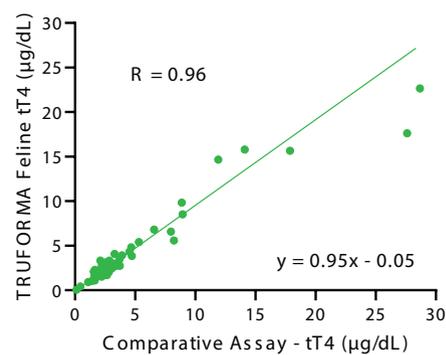


Figure 5: Correlation of Feline TRUFORMA tT4 with Comparative Method



## EXPECTED VALUES

The normal ranges listed in **Table 1** are those established for canine and feline patient populations. Test results should be interpreted in conjunction with patient's clinical signs.

## PERFORMANCE DATA

Results are reported in micrograms per deciliter (µg/dL). Unless otherwise noted, all data was generated using canine or feline serum samples collected in tubes without gel barriers or other clotting additives. All performance data was generated on the TRUFORMA system. The reportable ranges for the TRUFORMA tT4 Test are found in **Table 2**.

## CORRELATION

Correlation analysis evaluates the agreement and commutability of a new test method with a comparative or reference method. Total T4 levels were measured in 65 canine and 65 feline serum samples using TRUFORMA and a comparative method. All samples were analyzed on the same freeze-thaw cycle for both methods, and results were used to generate correlation statistics for canine samples (**Figure 4**) and feline samples (**Figure 5**).

The TRUFORMA System will display the tT4 serum concentration results. Interpretation guidelines for results are available on myZomedica.com.

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