

TRUFORMA®

Free Thyroxine (fT4) Test

FOR THE QUANTITATIVE
DETECTION OF FREE THYROXINE
(fT4) LEVELS IN CANINE SERUM

For Veterinary Use Only

READ ALL INSTRUCTIONS
BEFORE BEGINNING THE ASSAY

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

Distributed by:
Zomedica
Ann Arbor, MI 48108 USA
www.zomedica.com

Manufactured by:
Qorvo Biotechnologies, LLC

INTENDED USE

The TRUFORMA® Free Thyroxine (fT4) Test is used for the quantitative detection of free thyroxine (fT4) levels in canine 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 serum: protein-bound T4 (inactive) and free, unbound T4, which is the biologically active form of the hormone. The TRUFORMA fT4 test measures free T4 levels.

This test employs a single-use cartridge containing assay-specific reagents for the detection of T4 in the unbound state in canine serum. The TRUFORMA fT4 Test works as a competitive immunoassay utilizing a T4 specific monoclonal antibody conjugated to a reporter enzyme, and a solid phase coated with a T4 analogue attached to a carrier protein. During the test, sample and anti-T4-antibody conjugate are mixed together and flow across the T4 analogue-coated bulk acoustic wave (BAW) biosensor. Free T4 present in the sample binds to the antibody-enzyme conjugate in solution and prevents that antibody from binding to the T4 analogue-coated BAW biosensor. After several wash steps, an enzyme substrate is exposed to the sensor surface. The enzyme converts the substrate to an insoluble product that accumulates on the 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 biosensor surface.

The change in frequency is used to calculate the concentration of fT4 present in the sample using the stored calibration curve. As a competitive immunoassay, a sample containing a low concentration of fT4 results in a higher amount of antibody-enzyme conjugate attached to the solid phase and a larger signal. Thus, concentrations of serum free T4 are inversely proportional to the anti-T4 antibody that is bound to the solid phase. Free T4 concentrations that fall outside of the normal reference range may be indicative of abnormal levels of T4 or T4 binding proteins 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 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. fT4 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 fT4 Test has been tested with red-top tubes 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, 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 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 BULB PIPETTE

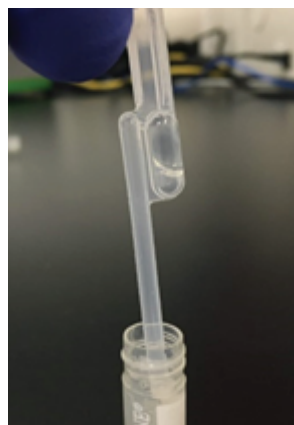


Figure 1

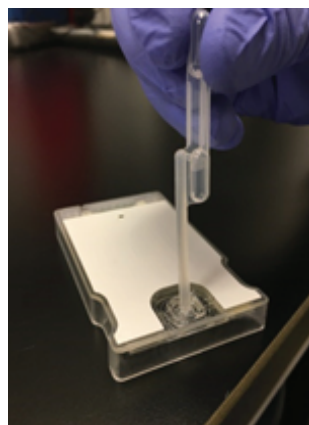


Figure 2

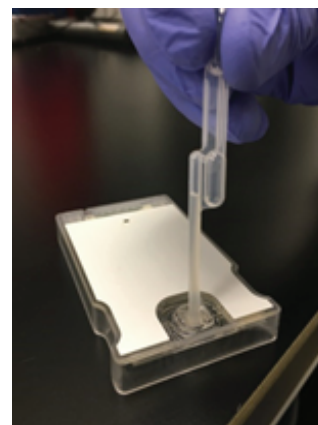


Figure 3

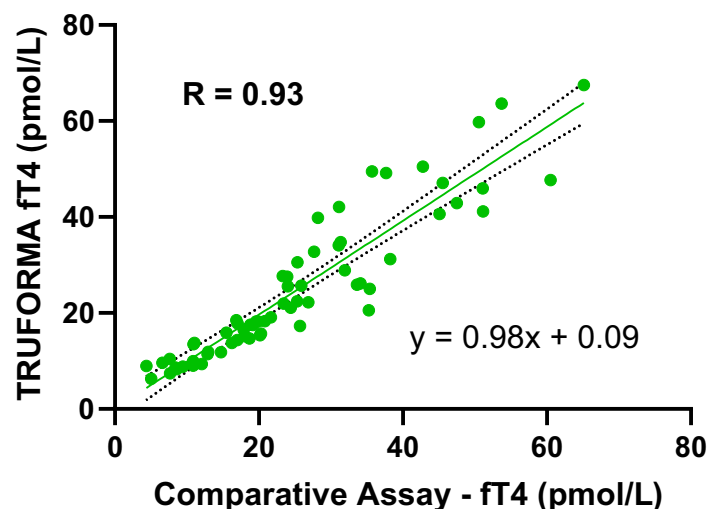
Table 1: Canine Reference Range

	TRUFORMA Canine fT4
Reference Range (pmol/L)	8.00-38.1

Table 2: fT4 Dynamic Range

	TRUFORMA Canine fT4
LLOQ, (pmol/L)	4.00
ULOQ, (pmol/L)	77.2

Figure 4: Correlation of TRUFORMA Canine fT4 with Comparative Method



*Correlation with 66 canine samples

EXPECTED VALUES

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

PERFORMANCE DATA

Results are reported in picomoles per liter (pmol/L). Unless otherwise noted, all data was generated on canine serum samples collected in tubes without gel barriers or other clotting additives. All performance data was generated on the TRUFORMA system. The reportable range for the TRUFORMA fT4 Test is found in **Table 2**.

CORRELATION

Correlation analysis evaluates the agreement and commutability of a new test method with a comparative or reference method. fT4 levels were measured in 66 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 in **Figure 4**.

The TRUFORMA System will display the fT4 serum concentration results. Interpretation of results are available on MyZomedica.com.

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