TRUFORMA®

Thyroid-Stimulating Hormone (TSH) Test

FOR THE QUANTITATIVE DETECTION OF THYROID-STIMULATING HORMONE (TSH) 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 by:
Zomedica
Ann Arbor, MI 48108 USA
www.zomedica.com

Manufactured by:
Qorvo Biotechnologies, LLC

INTENDED USE

The TRUFORMA® Thyroid-Stimulating Hormone Test is used for the quantitative detection of thyroid-stimulating hormone (TSH) levels in canine or feline serum in the assessment of thyroid function.

OVERVIEW

TSH stimulates the thyroid gland to produce thyroid hormones for regulation of metabolism. The concentration of TSH is inversely proportional to the concentration of thyroid hormones present in serum. The TRUFORMA TSH Test measures TSH levels exclusively and with high specificity.

This test employs a single-use cartridge containing assay-specific reagents for the detection of TSH in feline and canine serum. The TRUFORMA TSH Test works as a sandwich immunoassay, utilizing a biotin-labelled anti-TSH monoclonal detection antibody and a monoclonal capture antibody immobilized onto a bulk acoustic wave (BAW) sensor solid phase. During the test, sample is mixed with the biotin-labelled detection antibody and flows across the sensor surface. Antibodies in solution attach to TSH molecules present in the sample and this complex is captured by the immobilized antibody on the sensor surface. Next, a streptavidin-enzyme conjugate is flowed over the sensor surface, where it is immobilized to the detector antibody via the streptavidin-biotin interaction. 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 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 biosensor surface. The change in frequency is used to calculate the concentration of TSH present in the sample using the stored calibration curve. As a sandwich immunoassay, a sample containing a high concentration of TSH results in a higher amount of antibody-biotin-streptavidin-enzyme complex attached to the solid phase and a larger signal. Thus, concentrations of serum TSH are proportional to the amount of TSH that is bound to the solid phase. TSH levels which fall outside of the normal reference range may be indicative 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. TSH 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 TSH 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

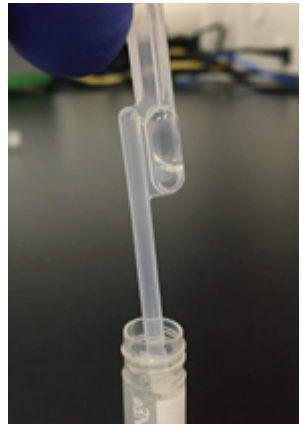


Figure 1

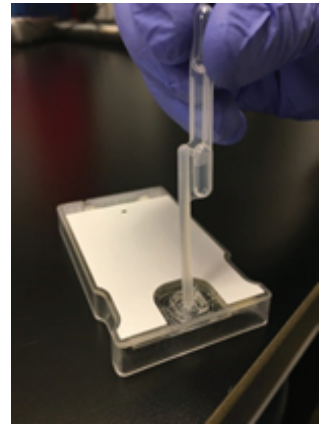


Figure 2

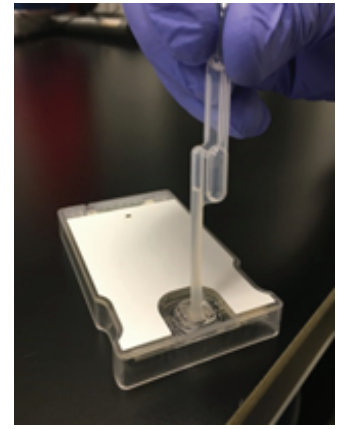


Figure 3

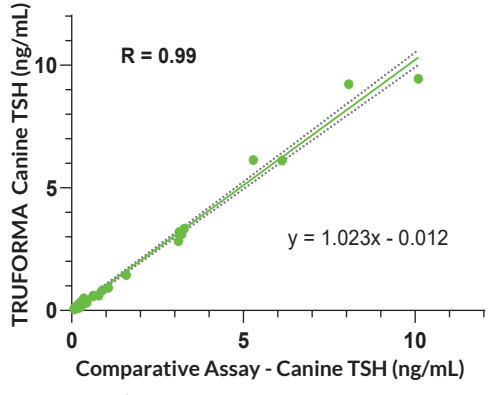
Table 1: Canine and Feline Reference Range

	TRUFORMA Canine	TRUFORMA Feline
Reference Range (ng/mL)	<0.51	0.010-0.301

Table 2: TSH Dynamic Range

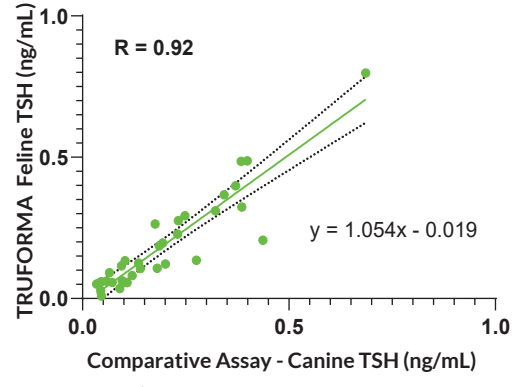
	TRUFORMA Canine	TRUFORMA Feline
Lower Limit of Quantitation (ng/mL)	0.05	0.008
Upper Limit of Quantitation (ng/mL)	10.0	1.5

Figure 4: Correlation of Canine TRUFORMA TSH with Comparative Method



*Correlation with 47 canine samples

Figure 5: Correlation of Feline TRUFORMA TSH with Comparative Method



*Correlation with 34 feline samples

Note: The comparative assay for feline samples was a canine-optimized TSH test because a feline offering isn't currently available.

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 nanograms per milliliter (ng/mL). 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 TSH 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. TSH levels were measured in 81 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 **Figures 4 and 5.**

The TRUFORMA System will display the TSH serum concentration results. Interpretation guidelines for test results are available on MyZomedica.com.

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