TRUFORMA®

Cortisol Test

FOR THE QUANTITATIVE DETECTION OF CORTISOL HORMONE LEVELS IN CANINE 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
Ann Arbor, MI 48108 USA
www.zomedica.com

INTENDED USE

The TRUFORMA® Cortisol Test is used for the quantitative detection of cortisol hormone levels in canine serum to assess adrenal function.

OVERVIEW

Cortisol is a steroid hormone that is produced by adrenal glands in response to stress.

This test employs a single-use cartridge containing the assay for the detection of cortisol in canine serum. The TRUFORMA Cortisol Test works as a competitive immunoassay, utilizing a cortisol-specific monoclonal antibody conjugated to a reporter enzyme and a solid phase coated with cortisol attached to a carrier protein. During the test, sample and anti-cortisol antibody-enzyme conjugate are mixed together and flow across the cortisol-coated Bulk Acoustic Wave (BAW) biosensor. Cortisol present in the sample binds to the antibody-enzyme conjugate in solution and prevents that antibody from binding to the cortisol-coated sensor surface. After several wash steps, an enzyme substrate is exposed to the BAW biosensor 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 cortisol present in the sample using the stored calibration curve. As a competitive immunoassay, a sample containing a low concentration of cortisol results in a higher amount of antibody-enzyme conjugate attached to the solid phase and a larger signal. Thus, concentrations of cortisol are inversely proportional to the anti-cortisol antibody-enzyme conjugate that is bound to the solid phase. Cortisol concentrations that fall outside of the normal reference range may be indicative of abnormal levels of cortisol as a result of an adrenal 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.
- The instrument will not display clinical guidance for results. Please refer to myZomedica for clinical interpretation of test results.
- Refer to **Table 1** to interpret ACTH stimulation and LDDST results.

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 1 hour out of the protective pouch prior to use. If not used in this time period, dispose of the cartridge.

COMPONENTS

1. Cortisol 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 Cortisol 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 the supplied bulb pipette, dispense the sample into the sample port (approximately 150µL). 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 BULB PIPETTE

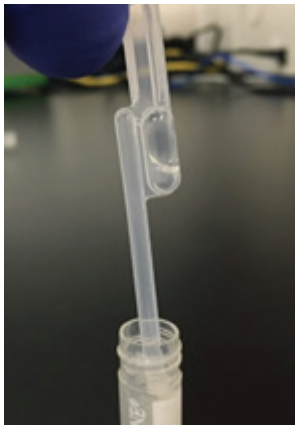


Figure 1

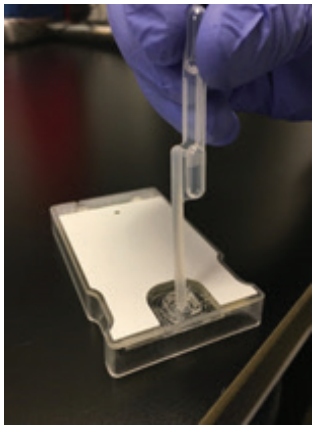


Figure 2

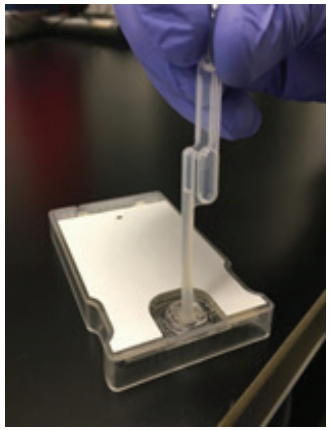


Figure 3

EXPECTED VALUES

The references ranges listed in **Table 1** are those established for the canine patient population. Test results should be interpreted in conjunction with a patient's clinical signs. For ACTH (adrenocorticotropic hormone) stimulation testing, animals were administered 5 µg/kg Cortrosyn IV and samples were collected 1 hour post injection. For LDDST (Low-Dose Dexamethasone-Suppression Test), animals were administered 0.01 mg/kg dexamethasone IV and samples were collected 4 and 8 hours post injection.

Table 1: Canine Reference Ranges

	TRUFORMA Canine
Baseline, µg/dL	0.4-5.7
1hr Post ACTH, µg/dL	7.5-22.5
4hr & 8hr LDDST, µg/dL	<1.0

Table 2: Cortisol Dynamic Range

	TRUFORMA Canine
LLOQ, µg/dL	0.35
ULOQ, µg/dL	35.0

Figure 4: Canine Cortisol Precision

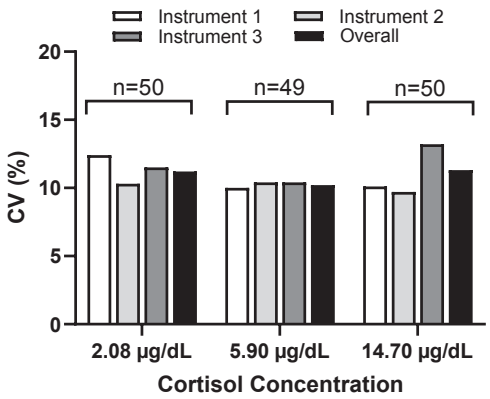
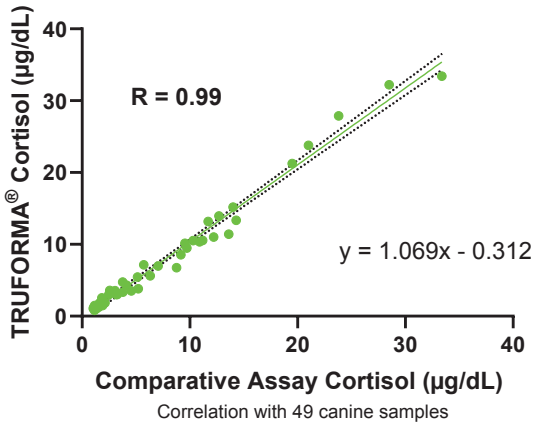


Figure 5: Correlation of Canine TRUFORMA Cortisol with Comparative Method



Correlation with 49 canine samples

PERFORMANCE DATA

See Tables and Figures for data representative of the test's performance. Results are reported in micrograms per deciliter (µg/dL). Unless otherwise noted, all data were generated on canine serum samples collected in tubes without gel barriers or other clotting performing additives. All performance data were generated on the TRUFORMA system unless otherwise noted. The reportable range for the TRUFORMA Cortisol test is found in **Table 2.**

PRECISION

Precision was evaluated by testing three canine serum samples with varying cortisol concentrations. Each sample was tested with four or five replicates on five separate days on three different instruments for a total of 149 results, see **Figure 4**.

CORRELATION

Correlation analysis evaluates the agreement and commutability of a new test method with a comparative or reference method. Cortisol levels were measured in 49 serum samples using TRUFORMA and a comparative assay. All samples were analyzed on the same freeze thaw cycle for both methods, and results were used to generate correlation statistics in **Figure 5.**

The TRUFORMA system will display the cortisol serum concentration in micrograms per deciliter (µg/dL). Please refer to myZomedica for clinical interpretation of test results. Refer to **Table 1** to interpret ACTH stimulation and LDDST results.

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