TRUFORMA®

Equine Cortisol Test

FOR THE QUANTITATIVE DETECTION OF CORTISOL HORMONE LEVELS IN EQUINE 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® Equine Cortisol Test is used for the quantitative detection of cortisol hormone levels in equine serum to evaluate potential relative adrenal insufficiency (RAI) in foals.

OVERVIEW

Cortisol is a steroid hormone that is produced by the adrenal glands in response to physiological stress including sepsis and endotoxemia.

This test employs a single-use cartridge containing assay-specific reagents for the detection of cortisol in equine serum. The TRUFORMA Equine 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. The 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 RAI.

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 equine 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 and/or refer to **Table 1** to interpret foal baseline cortisol 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 4 hours out of the protective pouch prior to use. If not used in this time period, dispose of the cartridge.

COMPONENTS

1. Equine 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 Equine 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

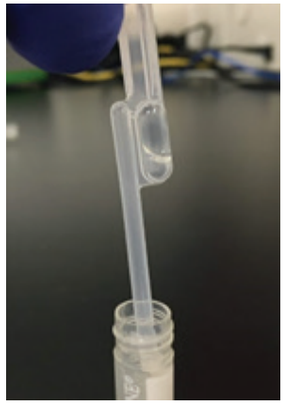


Figure 1

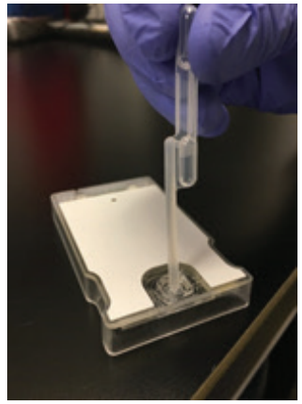


Figure 2

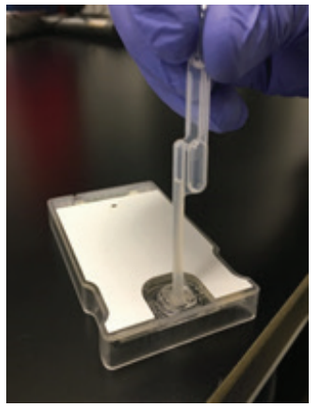


Figure 3

EXPECTED VALUES

The references ranges listed in **Table 1** are those established for foal baseline cortisol values up to a week (7 days) after birth. Test results should be interpreted in conjunction with a patient's clinical signs. For ACTH (adrenocorticotropic hormone) stimulation testing, please refer to myZomedica.com for interpretation of low- (10 µg) and high-dose (100 µg) stimulation tests.

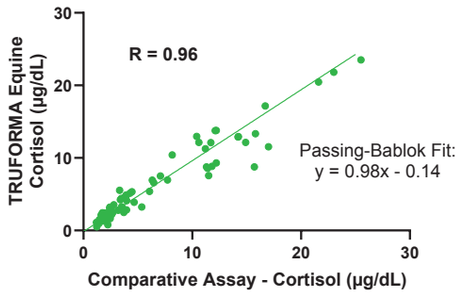
Table 1: Equine Reference Ranges

Foal Age	TRUFORMA Equine Cortisol (µg/dL)
< 4 hours	>13.5
4 – 24 hours	>6.7
24 – 48 hours	>4.4
5 – 7 days	>2.7

Table 2: Cortisol Dynamic Range

	TRUFORMA Equine
LLOQ, µg/dL	0.40
ULOQ, µg/dL	25.0

Figure 4: Correlation of TRUFORMA Equine Cortisol with Comparative Method



*Correlation with 77 Equine 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 equine 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 Equine Cortisol 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. Cortisol levels were measured in 85 equine serum samples using the TRUFORMA Equine Cortisol Test and a comparative assay. Of these 85 equine samples, 53 were from foals and the remainder were either native horse or spiked horse serum samples. All samples were analyzed on the same freeze thaw cycle for both methods and 77 samples returned quantifiable results for both assays. These 77 paired results were used to generate correlation statistics in **Figure 4.**

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

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