TRUFORMA®

Progesterone Test

FOR THE QUANTITATIVE DETECTION OF PROGESTERONE 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® Progesterone Test is used for the quantitative detection of progesterone levels in canine serum to assess reproductive function.

OVERVIEW

Progesterone is a steroid sex hormone produced by preovulatory follicles and corpora lutea of the ovaries whose primary function is the maintenance of pregnancy.

This test employs a single-use cartridge containing the assay for the detection of progesterone in canine serum. The TRUFORMA Progesterone Test works as a competitive immunoassay, utilizing a progesterone-specific monoclonal antibody conjugated to a reporter enzyme and a solid phase coated with progesterone attached to a carrier protein. During the test, sample and anti-progesterone antibody-enzyme conjugate are incubated together prior to flowing across the progesterone-coated Bulk Acoustic Wave (BAW) biosensor. Progesterone present in the sample binds to the antibody-enzyme conjugate in solution and prevents that antibody from binding to the progesterone-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 progesterone present in the sample using the stored calibration curve. As a competitive immunoassay, a sample containing a low concentration of progesterone results in a higher amount of antibody-enzyme conjugate attached to the solid phase and a larger signal. Thus, concentrations of progesterone are inversely proportional to the anti-progesterone antibody-enzyme conjugate that is bound to the solid phase.

Progesterone concentrations can be used in bitches to determine optimal breeding time during estrus and to predict impending parturition.

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. Progesterone 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, immediately separate serum by centrifugation. Do not refrigerate samples prior to centrifugation. Results may vary depending on the tube used due to the presence of additives such as clot activators, gels/separators, 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 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 BULB PIPETTE

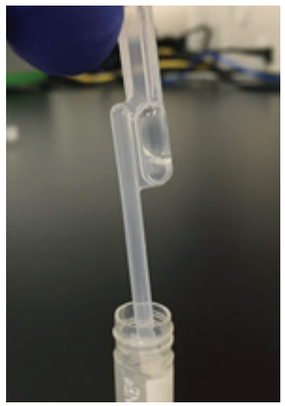


Figure 1

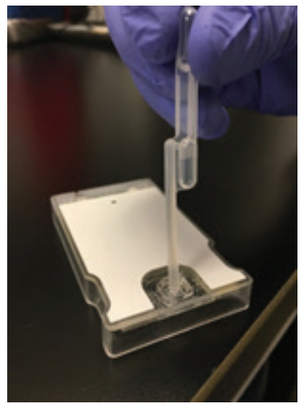


Figure 2

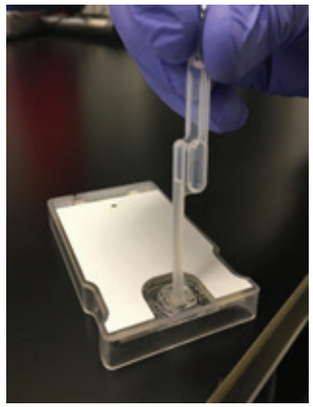


Figure 3

REFERENCE RANGES

Scan the QR code or visit myZomedica.com to see Clinical Interpretation Guidelines. Test results should be interpreted in conjunction with the patient's clinical signs.

Table 1: Progesterone Dynamic Ranges

	TRUFORMA Progesterone Dynamic Range (ng/mL)
LLOQ	0.5
ULOQ	20

Clinical Interpretation Guidelines

Figure 4: Canine Progesterone Precision

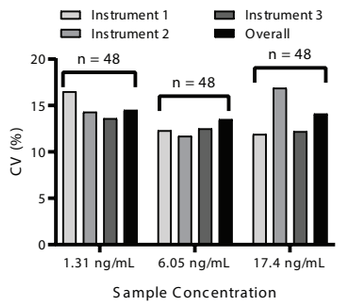
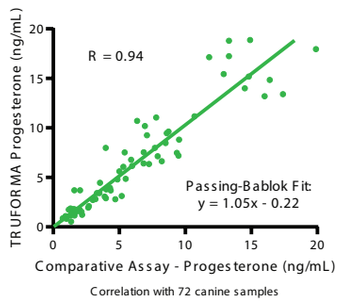


Figure 5: Correlation of TRUFORMA Canine Progesterone with Comparative Method



PERFORMANCE DATA

Test results are reported in nanograms per milliliter (ng/mL) and unless otherwise noted, all data was generated using canine serum samples collected in blood tubes without additives. The dynamic range for the TRUFORMA Progesterone Test is found in **Table 1** and additional performance metrics are detailed in the TRUFORMA Progesterone Assay White Paper available on myZomedica.com.

PRECISION

Precision was evaluated by testing three canine serum samples, each with varying progesterone concentrations. Each sample was tested in twelve replicates on four separate days using three different instruments, resulting in 48 measurements for each sample (**Figure 4**).

CORRELATION

Correlation analysis evaluates the agreement and commutability of a new test method with a comparative or reference method. Progesterone levels were measured in 72 canine serum samples using TRUFORMA and a comparative assay. All samples were analyzed on the same freeze-thaw cycle for both methods, and the results were used to generate correlation statistics in **Figure 5**.

The TRUFORMA system will display the progesterone serum concentration results and interpretation guidelines for test results are available on myZomedica.com.

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