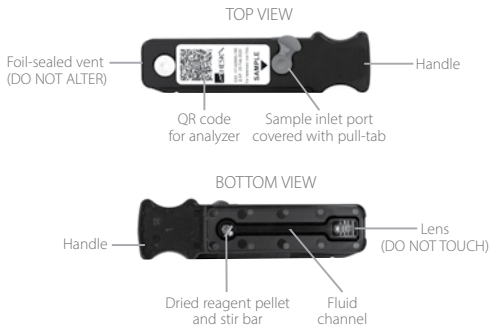
Element i+ Progesterone Cartridge Instructions

Intended Use

The Element i+® Progesterone assay is an *in vitro* diagnostic test for the quantitative determination of Progesterone in canine serum and lithium heparin plasma. This assay is used to detect progesterone and monitor ovulation cycles in canine patients. The reporting range of the assay is 0.2–40.0 ng/mL (0.6–127.2 nmol/L).

Element i+ Cartridge Description



Principle of the Measurement

The Element i+ Progesterone test uses a competitive immunoassay to generate a quantitative Progesterone concentration output. When a specimen is added to a cartridge inlet port, it is mixed with a dried fluorophore-labeled anti-Progesterone antibody. The mixture then reacts with Progesterone immobilized on the cartridge sensor surface. Progesterone in the sample competes with the fluorophore-labeled anti-Progesterone antibody for binding to the Progesterone on the surface. Fluorescence illumination is by diode laser light coupled into the lens of the proprietary planar waveguide cartridge. Fluorescence imaging is used for signal transduction. The fluorescence generated is inversely proportional to the Progesterone concentration of the specimen. Fluorescence intensity is converted to a quantitative Progesterone concentration using cartridge lot-specific calibration information.

Warnings

- ⚠ Do not touch the clear bottom of the cartridge.
- ⚠ Do not alter the silver foil seal on top of the cartridge. Do not use a cartridge with a punctured silver seal.
- ⚠ Do not use a cartridge dropped on the floor.
- ⚠ A new cartridge must be used for each measurement. The Element i+ Immunodiagnostic Analyzer will not allow a cartridge to be used more than one time.
- ⚠ Used cartridges should be disposed of as biohazard waste in accordance with local laws.

Additional Equipment

- Element i+ Immunodiagnostic Analyzer
- 100 microliter fixed volume mini-pipette (supplied with analyzer and available separately)
- Pipette tips (supplied with analyzer and available separately)

Specimen Requirements

The test has been designed to be run with fresh canine serum or lithium heparin plasma samples. Other plasma sample types have not been tested.

Avoid using plasma or serum with precipitates.

Do not dilute the sample.

Running a Test

1. Obtain a serum or lithium heparinized plasma sample.
2. On the main screen of the analyzer, touch Worklist or Manual Test.
3. In Worklist Mode, confirm that all fields have correct information and then touch ✓ to proceed.
   - In Manual Mode, enter sample information in the required fields.
   - Touch ✓ to proceed.
4. Open the pouch by tearing at the notch. Carefully remove the cartridge by the handle and place it on a flat surface.
   NOTE: Do not touch the bottom of the cartridge.
   NOTE: If the cartridge was refrigerated, allow to warm to room temperature for at least 15 minutes before opening the pouch.
   NOTE: Cartridge must be used within 1 hour of removal from pouch.
5. With the cartridge flat on the bench, remove the pull-tab from the sample inlet port and discard. Use the cartridge handle to steady the flat cartridge while removing the pull-tab.
   NOTE: Cartridge must be used within 15 minutes of removing pull-tab.
6. Affix a tip to the 100 µL fixed volume mini-pipette. Aspirate 100 µL of sample, insert the pipette tip into the inlet port hole, and dispense the full sample amount into the hole.

7. Touch on the Prepare Sample screen to open the analyzer door.
   - Insert the cartridge until a click is felt and a beep is heard.
8. The test will run automatically. A status bar and countdown timer will display on the screen and the indicator light on the front of the analyzer will blink to indicate a test is running: To cancel during the run, touch X at the upper right of the screen.
9. Upon test completion, patient results will display on the screen.
   - Touch (home button) to exit results screen.
   - The screen will provide an indication when it is safe to remove the used cartridge.

   NOTE: Do not attempt to remove cartridge before signaled by analyzer.

Performance Characteristics

Reporting range:
0.2 to 40.0 ng/mL (0.6–127.2 nmol/L)

Reference method:
SIEMENS IMMULITE 1000 Progesterone Immunoassay

Accuracy:
Overall bias based on the Passing-Bablok slope is less than 20% within the 95% confidence interval for samples ≥0.2 ng/mL (0.6 nmol/L) Progesterone.

Precision:
Coefficient of Variation ≤15% for samples ≥2.0 ng/mL (6.4 nmol/L) Progesterone
Standard Deviation ± 0.3 ng/mL (0.9 nmol/L) for samples <2.0 ng/mL (6.4 nmol/L) Progesterone

Known Interfering Substances

Interference	Interfering Substance and Conditions Tested	Progesterone Sample Concentrations Tested	Result
Hemolysis	Hemoglobin up to 800 mg/dL	9.5 ng/mL (30.2 nmol/L)	No significant effect
Icterus	Bilirubin (conjugated) up to 2.5 mg/dL		
Lipemia	Lipids/Triglycerides up to 125 mg/dL		

Storage and Shelf Life

Storage:
35.6–77°F (2–25°C)

Expiration date:
Printed on the cartridge pouch.

For further assistance, please call Heska's Technical Support Services

US 800 464 3752 www.heska.com
CA 866 382 6937 www.heskavet.ca
AU 1300 437 522 www.heska.com.au