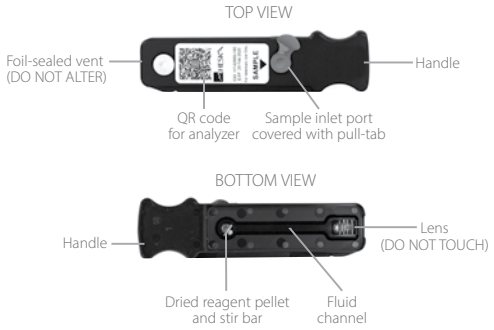
Element i+ Total T4 Cartridge Instructions

Intended Use

The Element i+® Total T4 (Thyroxine) assay is an in vitro diagnostic test for the quantitative determination of Total T4 in canine or feline serum or lithium heparin plasma. This assay is used to detect and monitor T4 hormone in canine or feline patients. The reporting range of the assay is 0.5–20.0 µg/dL (6.4–257.4 nmol/L).

Element i+ Cartridge Description



Principle of the Measurement

The Element i+ Total T4 test uses a competitive immunoassay to generate a quantitative T4 concentration output. When a specimen is added to a cartridge inlet port, it is mixed with a dried fluorophore-labeled anti-T4 antibody. The mixture then reacts with T4 immobilized on the cartridge sensor surface. T4 in the sample competes with the fluorophore-labeled anti- T4 antibody for binding to the T4 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 Total T4 concentration of the specimen. Fluorescence intensity is converted to a quantitative Total T4 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 or feline serum or lithium heparin plasma samples. Other plasma sample types have not been tested.

Avoid using plasma or serum with precipitates.

Sample requires a dilution step with the T4 Diluent Solution.

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. Dilute patient sample using supplied Heska T4 Diluent..
   a. Use supplied 100 µL fixed volume mini-pipette to aspirate 100 µL of serum or plasma sample.
   b. Gently flick or tap the Heska T4 Diluent tube to ensure no liquid is adhering to the inner surface of the cap. Visually inspect the diluent level; it should align with the lower edge of the tube label. If the tube has leaked, discard it and use a new diluent tube. The correct volume of diluent is important for test accuracy. For replacement diluent, contact Technical Support.

c. Dispense the full 100 µL patient sample into the Diluent tube. Ensure proper mixing by then aspirating and dispensing 5x using the same pipette tip.
d. Aspirate 100 µL of the diluted sample using the mini-pipette and same pipette tip, insert the pipette tip into the T4 cartridge sample inlet port hole, and dispense the full 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.

Reference Interval

Canine:

1.2–4.3 µg/dL (15.4–55.3 nmol/L)

Feline:

0.8–4.7 µg/dL (10.3–60.5 nmol/L)

Performance Characteristics

Reporting range:
0.5 to 20.0 µg/dL (6.4–257.4 nmol/L)

Reference method:
SIEMENS IMMULITE 1000 Total T4 Immunoassay

Accuracy:
Overall bias based on the Passing-Bablok slope is less than 20% within the 95% confidence interval for samples ≥1.0 µg/dL (12.9 nmol/L) Total T4.

Precision:

Coefficient of Variation ≤15% for samples ≥1.0 µg/dL T4 (12.9 nmol/L)

Standard Deviation ± 0.3 µg/dL (3.9 nmol/L) for samples <1.0 µg/dL (12.9 nmol/L) T4

Known Interfering Substances

Interference	Interfering Substance and Conditions Tested	Total T4 Sample Concentrations Tested	Result
Hemolysis	Hemoglobin up to 400 mg/dL	2 µg/dL (25.7 nmol/L)	No significant effect
Icterus	Bilirubin up to 10 mg/dL		

Storage and Shelf Life

Storage:
35.6–77 °F (2–25 °C)

Expiration date:

Printed on the cartridge pouch.

Antech™

For further assistance, please call Technical Support Services US 800 464 3752 CA 866 382 6937 AU 1300 437 522