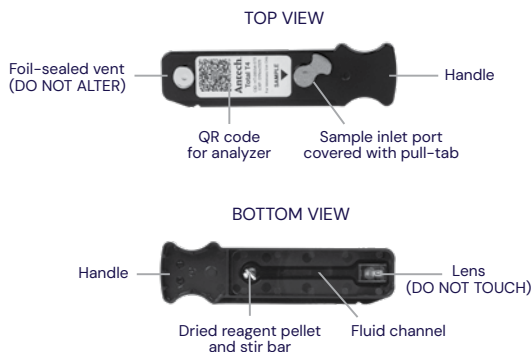


## Element i+™ Total T4 Cartridge Instructions

### 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 0.7–20.0 µg/dL (9.1–257.4 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 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
- 50 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.

### 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 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. Use supplied 50 µL fixed volume mini-pipette to aspirate 50 µL of serum or plasma sample.
    - Insert the pipette tip into the T4 cartridge sample port, and dispense the full amount into the port.
    - Insert sample on opposite side of port from the reagent pellet.
  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 the Element i+ 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: 0.7 to 20.0 µg/dL (9.1–257.4 nmol/L)

Reference method: SIEMENS IMMULITE 2000 Total T4 Immunoassay

Accuracy:

Overall bias based on the Passing–Bablok slope is less than 20% within the 95% confidence interval for samples  $\geq 1.0$  µg/dL (12.9 nmol/L) Total T4

Precision:

- Coefficient of Variation  $\leq 15\%$  for samples  $\geq 1.0$  µg/dL T4 (12.9 nmol/L)
- Standard Deviation  $\pm 0.2$  µg/dL (2.6 nmol/L) for samples  $< 1.0$  µg/dL (12.9 nmol/L) T4

## Known Interfering Substances

INTERFERENT	CONCENTRATION TESTED	RESULT
Protein	8 g/dL	No significant effect
Bilirubin	35 mg/dL	No significant effect
Cholesterol	600 mg/dL	No significant effect
Hemoglobin	1000 mg/dL	No significant effect
Triglycerides	1000 mg/dL	No significant effect

## Storage and Shelf Life

- Storage: 35.6–77°F (2–25°C)
- Expiration date: Printed on the cartridge pouch