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package insert

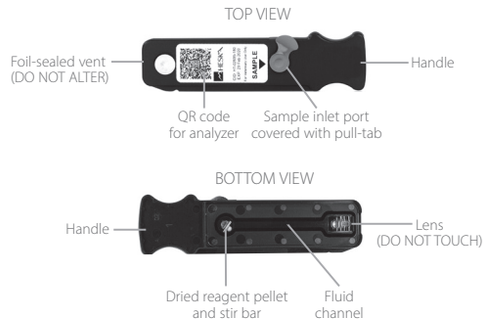
element i+
Immunodiagnostic Analyzer

Element i+ Nu.Q® Cartridge Instructions

Intended Use

The Element i+® Nu.Q® assay is an in vitro diagnostic test for the quantitative determination of nucleosomes in canine EDTA plasma. The reporting range of this assay is 15–650 ng/mL. A result that is greater than 80 ng/mL may be considered high suspicion for active neoplastic disease.

Element i+ Cartridge Description



Principle of the Measurement

The Element i+ Nu.Q test uses a one-step sandwich immunoassay to generate a quantitative H3.1 nucleosome concentration output. When a specimen is added to a cartridge inlet port, it is mixed with a dried fluorophore-labeled anti-nucleosome antibody. The mixture then reacts with an immobilized anti-H3.1 antibody on the cartridge sensor surface that recognizes an epitope on the H3.1 histone. Nucleosomes in the sample bridge between the immobilized antibody and the fluorophore-labeled antibody to form a complete sandwich pair 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 directly proportional to the H3.1 nucleosome concentration of the specimen. Fluorescence intensity is converted to a quantitative nucleosome 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 once
- ⚠ 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 (provided with analyzer and available separately)

Specimen Requirements

The test was designed to be run with fresh canine EDTA plasma samples. Other plasma sample types have yet to be tested. Samples must be spun within one hour of collection. DO NOT use serum, lithium heparin samples, or plasma with precipitates. Do not dilute the sample.

Running a Test

1. Obtain an EDTA 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 press ✓ to proceed
   - In Manual Mode, enter sample information in the required fields
   - Press ✓ 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 it to warm to room temperature for at least 15 minutes before opening the pouch
   NOTE: Cartridge must be used within one hour of removal from the pouch
5. With the cartridge flat on the bench, remove the pull-tab from the sample inlet port and discard. Use the 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 fresh tip to the 50 µL fixed volume mini pipette. Aspirate 50 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 you feel a click and hear a beep
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 the results screen
   - The screen will indicate when it is safe to remove the used cartridge

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

Reference Interval

≤50 ng/mL

Level	
≤50 ng/mL	Low Suspicion
51–80 ng/mL	Moderate Suspicion
≥81 ng/mL	High Suspicion

Performance Characteristics

Reporting Range:

15–650 ng/mL

Reference Method:

Volition Nu.Q® Vet ELISA

Accuracy:

Overall bias based on the Passing-Bablok slope is <20% within the 95% confidence interval for samples ≥23 ng/mL.

Precision:

Coefficient of Variation ≤ 15% for samples ≥ 25 ng/mL

Reproducibility:

Coefficient of Variation ≤ 20% for samples ≥ 25 ng/mL

Known Interfering Substances

Interference	Interfering Substance and Conditions Tested	Nu.Q® Sample Concentrations Tested	Result
Protein	7 g/dL	45 ng/mL and 95 ng/mL	No significant effect
Bilirubin	15 mg/dL		
Cholesterol	350 mg/dL		
Hemoglobin	Up to 3 g/dL		
Triglycerides	250 mg/dL		

Storage and Shelf Life

Storage:

35.6–77°F (2–25°C)

Expiration Date:

Printed on the cartridge pouch.

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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