Cardiac Troponin I—Cartridge Handling and Sample Analysis

cTnI Cartridge Storage

- cTnI cartridges should be stored at 2–8° C (35–46° F).
- Once removed from refrigeration, cartridges should not be returned to refrigerator, but may be stored at room temperature 18–30° C (64–86° F) for 14 days.

Sample Collection

- Collect or dispense venous blood sample into a lithium heparin (green top) collection tube. The tube must be at least half-filled with sample to properly dilute the anticoagulant.
- Invert the tube gently 10 times to mix the sample thoroughly with anticoagulant.
- Keep the sample at room temperature until analyzed.
- The sample should be analyzed within 30 minutes of collection.
- Invert tube 3–5 times again just prior to loading the cartridge.
- Non-heparinized whole blood may also be used. Sample must be drawn into a plastic syringe or evacuated tube (without additives) and tested within 1 minute of collection.
- The use of whole blood containing other anticoagulants, such as EDTA, oxalate and citrate should not be used with the cTnI cartridge as these substances will deactivate the assay substrate, resulting in decreased cTnI readings.
- Capillary tubes and direct skin punctures should not be used with the cTnI cartridge.

Filling the cTnI Cartridge

- Cartridge must warm to room temperature in the package for 5 minutes before use.
- Ensure that the cartridge has not expired.
- Remove the cartridge from the packet, holding it by the edges only (do not touch or press the center of the cartridge). **Do not tear across the bar code on the back of the packet. Do not discard the packet as you will need to scan the bar code prior to running the test.** Place the cartridge on a clean flat surface. Avoid surfaces with dust, hair or other debris.
- Fill a transfer pipette (supplied by Heska) with sample from the lithium heparin tube. Discard one drop of sample to eliminate air bubbles. (Bubbles may not be visible to the naked eye). Do not fill the cartridge using a syringe and needle. The preferred method of loading the cTnI cartridge is with the transfer pipette supplied by Heska. Using a syringe to load the cartridge will increase the possibility of suppressed results or quality check codes.
- Hang a small drop of sample from the pipette and gently touch the drop to the sample well. Capillary action will draw the sample into the cartridge. Make sure the sample has been drawn all the way to the fill line and that the sample well is full. This will take approximately 16–22 µl of sample. If the sample does not fill all the way to the fill line, add a little more sample to the sample well and gently tap the side of the cartridge until the sample pulls through to the fill line.
- Anchor the cartridge using your thumb and index finger on the side edges of the cartridge, away from the sample well. Using the thumb of your other hand, slide the plastic closure clip to the right until it locks into place over the sample well. Slide closure clip slowly to avoid spattering excess sample.
- Immediately after filling cartridge, sample well should be closed and cartridge inserted into the analyzer (see below).

Running a cTnI Analysis

- Place the i-STAT® **1** analyzer on a level surface. The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.
- Hold the cartridge by the thumb recess and gently insert it into the cartridge port on the bottom of the analyzer until it clicks into place. The analyzer screen will automatically activate upon insertion of the cartridge.

- The analyzer will prompt to scan or enter the cartridge bar code. Hold the bar code on the cartridge packet 6–8 inches behind the instrument and press the scan button at the top of the keyboard. Do not move the analyzer during the scanning process. Reposition the packet up or down and forward or backward as needed until the red laser line completely crosses the bar code. Move the packet slowly. Do not "swipe" the packet across the line. The analyzer beeps to indicate that the scan was successful.
- The analyzer will prompt to scan or enter the Operator ID. Type the Operator ID and press ENTER, or just press ENTER.
- The analyzer will prompt to scan or enter the Patient ID. Type the Patient ID and press ENTER, or just press ENTER.
- Sample analysis will begin automatically and takes approximately 10 minutes. A countdown bar and the message "Time to Results" is displayed while the test is running. Do not attempt to remove the cartridge while the test is running and/or while the "Cartridge Locked" message is on the display. The test result is displayed at the completion of the test.
- The cartridge bar code scan, Operator ID, and Patient ID steps are all required for the cTnI test to run.
- Failure to scan the package bar code within 60 seconds of cartridge insertion will result in a "Code #141, Test Cancelled by Operator" error message. If this occurs, remove the cartridge and reinsert it into the analyzer. Scan the bar code within 60 seconds and enter the Operator ID and Patient ID to initiate the test.
- If the Operator ID and Patient ID are not entered after scanning the package bar code, the test will still initiate and run to completion. At the end of the test, a "Results Ready" message will be displayed and the Operator ID and Patient ID must be entered before the results will be displayed. If the Operator ID and Patient ID are not entered within 15 minutes after the completion of the test, the analyzer will automatically turn off and the test results will not be retained.

cTnI Results Interpretation

NORMAL REFERENCE RANGES FOR cTnI‡

	Canine	Feline	Equine
Reference Range ng/mL	0.00–0.11	0.00–0.09	0.00–0.06

‡ Reference ranges were determined for venous whole blood in lithium heparin. i-STAT® 1 reference ranges and values are specific to the i-STAT® 1 analyzer; other assay methodologies may have different ranges and values. The cTnI reportable range on the i-STAT® 1 analyzer is 0.00–50.00 ng/ml.

Significance of Elevated cTnI Concentration

cTnI is a marker of cardiac myocyte injury and as such, the blood concentration of cTnI is increased in various cardiac and noncardiac conditions. Examples include, but are not limited to, dilated cardiomyopathy, degenerative mitral valve disease, subaortic stenosis, gastric dilation-volvulus complex and blunt thoracic trauma. Elevated concentrations of cTnI indicate a more thorough cardiac work-up is warranted.

cTnI Controls

- The i-STAT® **1** analyzer automatically runs a quality control check with each cartridge. If the quality control test fails, an error message and error code will be displayed on the screen (See *"Troubleshooting"* in the i-STAT® **1** User Manual for assistance). If the quality control test passes, calibration and sample analysis begin automatically.
- Three levels of cTnI controls are available. Level 1 (0.24–0.56 ng/ml), Level 2 (1.20–1.80 ng/ml), and Level 3 (21.0–49.0 ng/ml) external control solutions are available separately for purchase from Heska.

For questions or further assistance,
please call Heska's Technical Support Services at **1-800-GO HESKA, option 3.**

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